

ACMD

Advisory Council on the Misuse of Drugs

ACMD report on diversion and illicit supply of medicines: Index for stakeholder submissions received

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Advisory Council on the Misuse of Drugs' (ACMD) Diversion & Illicit Supply of Medicines Inquiry.

(ACMD) Diversion & Illicit Supply of Medicines Inquiry.

Association of the British Pharmaceutical Industry

The Association of the British Pharmaceutical Industry (ABPI) represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK.

Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients. Our members supply 90 per cent of all medicines used by the NHS, and are researching and developing over two-thirds of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases.

The ABPI is recognised by government as the industry body negotiating on behalf of the branded pharmaceutical industry for statutory consultation requirements including the pricing scheme for medicines in the UK.

Contact Us:

If we can provide any further information / clarification on our submission to the inquiry, please contact:

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We are happy for all information contained herein to be shared, as appropriate.

Response to Inquiry

The Association of the British Pharmaceutical Industry (ABPI) welcomes the opportunity to provide a written response to the Advisory Council on the Misuse of Drugs' (ACMD) Diversion & Illicit Supply of Medicines Inquiry.

The type of information requested for the ACMD Inquiry is not ordinarily collected or held by the ABPI, so we have had to survey our members. As a consequence of the short timelines



involved, to date, we have only received a limited number of responses which is captured below.

We would also like to take this opportunity to draw your attention to the European Falsified Medicines Directive (FMD) published July 2011 and the European Stakeholder Model (ESM) that has been designed through a collaboration of stakeholders EFPIA (manufacturers), PGEU (pharmacy), GIRP (wholesalers) and EAEPD (pharmaceutical distributors / re-packagers) to help stakeholders fulfil the requirements of the directive. The UK affiliated bodies of these organisations are also working together to enable UK alignment with the Directive, by adoption of the ESM and recognising the idiosyncrasies of the UK supply chain.

This collaboration of supply chain stakeholders has come about as a consequence of the growing global threat of counterfeit medicines and threat to public health and safety in Europe.

For example;

- Evidence involving nearly 2500 cases, allowed EU Customs to seize 27.4 million doses of falsified medicines at EU borders in 2011- an almost seven-fold increase from 2007
- In 2012 counterfeit generic omeprazole was found in Germany and counterfeit aspirin in France. Up until then it had been assumed (wrongly) by some, that counterfeiters only target high price branded medicines, not generics. Notwithstanding that not all generic products are low price, what is clear is that counterfeits are low cost to manufacture, so margin can still be made.
- Recently the MHRA seized £8.6m of counterfeit and unlicensed medicines and discovered fraudsters are infiltrating the NHS drugs supply chain and diverting medicines to street drug dealers and illegal websites. In Eire over 100,000 illegal and counterfeit prescription medications were recovered at a value of 300,000€. Both seizures were part of Operation Pangea VII, involving Interpol and other participating agencies, across over 110 countries. <http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea>

(Also please see appendix below for more detail on known counterfeit incidents as reported on the MHRA web site)

Unfortunately with the increasing sophistication of counterfeit activities it remains unknown precisely how much is escaping detection. According to a study undertaken by Deloitte, Forbes estimated the global counterfeit market at \$200 billion in 2011.

In the ongoing battle against counterfeiters, the ESM offers patients the safety that their medicines have been checked and authenticated using a unique serialisation number against the manufacturers' database, at the dispensing point. It also provides each pack with a tamper evident seal.



If you would like further information regarding the development and plans for the subsequent adoption of the ESM then please do not hesitate to contact us.

Response from ABPI member companies:

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

The UK faces an ever increasing problem relating to the illegal supply of illicit medicines via the international postal system (EMS). Based upon industry investigations, and backed by Operation Pangea, a multi-national, multi-agency exercise, the UK is a target country for criminal entities who send illicit medicines from India, Pakistan, Malaysia, and China, often in multiple parcels each containing upwards of 10,000 doses.

Based on the UK Government's recent scheduling of certain medicines and also the required update to specific products with respect to warnings around drug-driving, it appears that diversion and illicit supply of medicines is a significant problem in the UK.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

We are aware of the illicit diversion and supply of medicines, coming from India, China, Pakistan, Malaysia, this knowledge is based upon actual past and current investigations undertaken alongside our industry partners.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

We are aware, and can evidence, the illicit importation and supply of a range of medicines, however the most prevalent being those scheduled under the Misuse of Drugs Act, including Benzodiazepenes, psychotropics, and pain killers.

Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

Not assessed.

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

Increased LE action by MHRA working with industry.



It is important that any changes in status/legal availability takes into account the legitimate use of medicines by patients in conjunction with their Healthcare professional

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

Increased LE action by police, and awareness of the problem by the judiciary when handing out sentences which are currently lenient.

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

The proportions are endemic, particularly in areas of high unemployment and high illicit drug use/abuse, the North of England, South Wales, and Scotland, are particular "hot spots" with an increase of the use of illicit medicines year upon year.


This situation is similar to that found in the US, where drug users are turning to using illicit medicines which are cheaper, easier to obtain, and carry a lower penalty/risk of detection, than the traditional illicit opiates (Diamorphine)

Appendix

Falsified Medical Products discovered in the licensed UK supply chain that were recalled

Year	Product	Batch no and expiry date	Drug Alert	Location of Discovery
May 2009	Seretide 250 Evohaler 8 ml pressurised inhalers	1183R – 06/2009	EL(09)A/12	UK supply chain
July 2007	Sensodyne Original and Sensodyne Mint 50ml Tubes	PROD 07 2005 / EXP 08 / 2008	EL(07)A/13	UK supply chain UK supply chain
June 2007	Plavix 75mg	3103/1 to 3103/20 inclusive - 07/2009	EL(07)A/09	UK supply chain
	Casodex 50mg	65520 - 07/2011	EL(07)A/08	UK supply chain
May 2007	Plavix 75mg	3098 - 08/2008 6Y098 - 07/2009	EL(07)A/07	UK supply chain UK supply chain
	Zyprexa 10mg	A200127 -	EL(07)A/06	UK supply



		02/2009 A216454 - 03/2009 A229505 - 03/2009		chain
August 2006	Lipitor 20mg	067404K3 - 05/2007	EL(06)A/17	UK supply chain
July 2006	Lipitor 20mg Propecia 1mg	004405K1 - 11/2007 243828, exp 06/2007	EL(06)A/16	UK supply chain UK supply chain
February 2006	Viagra 100mg	2183401, exp 10/2008	None issued	Illicit supply chain
July 2005	Lipitor 20mg	004405K1 - 11/2007	EL(05)A/11  (40Kb)	UK supply chain
September 2004	Reductil 15mg	65542 - 01/2007	EL(04)A/08  (129Kb)	UK supply chain
August 2004	Cialis 20mg	A031410 - 06/2006 A041410 - 06/2006	EL(04)/07  (50Kb)	UK supply chain UK supply chain

Other known falsified medical products

Year	Product	Batch no and expiry date	Location of Discovery	Legitimate batch number
September 2013	Symbicort 320/9 Turbhaler	PAWT on packaging PAFA/PAUF/PAFL/P APL Exp: 04/2014 11/2014 09/2014	UK Wholesaler	Yes, PAFA/PAUF/PAFL/P APL - Turkish Market PAWL – EU market
August 2013	Gentamicin 80mg solution for injection Biviol Postinor 0.75mg	L12020299 Exp: 03/2015 920569 T13073C, T54365E, T99128L, T12104B	Guatemalan supply chain German supply chain Illicit supply chain	Yes, Central American market Yes, German Market N/K
July 2013	Postinor 2 levonorgestrel tablet, 0.75 mg	T13073C, T54365E, T99128L, T12104B	Nigerian supply chain	Yes, West African Market



	Sulfadoxine 500mg/Pyrimethamine 25mg	1833, Exp 02/2014	Illicit supply chain	Yes, Central American market
	Sutent 50mg	T737E, Exp 03/2015 U299B, Exp 10/2015	German and Romanian supply chain	Yes
June 2013	Cialis 20mg	05668	Illicit supply chain	Yes, Israeli market
	Viagra 100mg	B314 833021	Illicit supply chain	No
May 2013	Sustanon 250	3CSH550	Illicit supply chain	N/K
April 2013	Coartem	F1901, F2261, Exp: Jan-14	Cameroon supply chain	Yes, West African Market
	Remicade 100mg	2RMKA822, 2RMKA828, 2RMKA831, 2RMKA834. Expiry: 08/2015	UK supply chain, not beyond wholesale level	Yes, Romanian Market
March 2013	Omeprazole 20mg	BZ4333 E008 E018 G003	German supply chain	Yes
May 2012	Panadol Extra 500mg/65mg Panadol Cold and Flu 500mg/65mg/5mg	100055, Exp 10/2015 100231, Exp 09/2013	Illicit supply chain	Yes, Middle East market
February 2012	Altuzan 400mg/16ml	B0621, Exp 10/2012	US supply chain	Yes, Turkish market
December 2011	Viagra 100mg	PM81390, exp 01/2015	Illicit supply chain	
	Avastin Vial 100mg / 4ml	B6011B02, Exp 03/2013 B86017, Exp 03/2013 B6010, Exp 03/2012	UK supply chain, not beyond wholesale	Yes, Turkish market No Yes, North Africa and Middle East



			level	
November 2011	Truvada 200 mg/245mg	10TR064D, Expiry 03.2014	UK supply chain, not beyond wholesale level	Yes, Turkish market
	Viread 245mg	10VR057D, Exp 11/2015 11VR015D, Exp 03/2016	UK supply chain, not beyond wholesale level	Yes, Turkish market
		10VR059D, Exp 11/2015		Yes, Turkish, Australia/New Zealand, and Belgium/Luxembourg markets
September 2011	Viagra 50mg	714830241, exp 01/2013	Illicit supply chain	Yes, Hong Kong market
June 2011	Viagra 100mg	0882K07A, exp 04/2015	Illicit supply chain	No
May 2011	Viagra 100mg	314833021 exp 04/2012 314833021 exp 04/2013	Illicit supply chain	No
		7087309, exp 09/2012		Yes, Kazakhstan market
April 2011	Selsun 2.5%	10651TB21, exp 05/2012	Illicit supply chain	Yes, UK market
	Cialis 20mg	05668, exp 04/2013	Illicit supply chain	Yes, Israeli market
March 2011	Viagra 100mg	79R009A, exp 1JUN14	Illicit supply chain	Yes
	Deca-Durabolin 100mg	451766, exp 02-2014	Illicit supply chain	No
	Norditropin SimpleXx 15mg/1.5ml	XU60681, exp 11/2012	Illicit supply chain	No
February 2011	Prograf 1mg	1C6371C, exp 03/2012 1C6512A, exp 02/2012	Irish supply chain	No
		1D4434A, exp	Irish	Yes, Malaysian



	Viagra 100mg	06/2012 314833201, exp 01/2014	supply chain Illicit supply chain	market No
	Plavix 75mg	2500 exp 01/2012	Lebanese supply chain	Yes, Lebanese market
March 2007	Plavix 75mg	3051	UK supply chain, not beyond wholesale level	tbc
		3091		tbc
November 2006	Plavix 75mg	1672, exp 08/2008	Illicit supply chain	tbc
	Co-Diovan 160 12.5mg	50314, exp 06/2008	Illicit supply chain	tbc
	Hyzaar Forte	52402	Illicit supply chain	tbc
February 2006	Viagra 100mg	2183401, exp 10/2008	Illicit supply chain	No

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May 2014

Dear Professor Iversen

Thank you for giving the Welsh Government an opportunity to submit written evidence to the Diversion & Illicit Supply of Medicines Inquiry under the Chairmanship of Prof Raymond G Hill.

In Wales there is a clear national agenda for tackling and reducing the harms associated with substance misuse and it continues to remain a priority for the Welsh Government.

'*Working Together to Reduce Harm 2008 -2018*' is the Welsh Government's ten year strategy for tackling the harms associated with the misuse of alcohol, drugs and other substances in Wales. It is supported by a detailed Delivery Plan which sets out the specific actions the Welsh Government is taking, in conjunction with its partners to implement the commitments contained within the strategy.

In addition to the verbal update provided during your initial scoping meeting on the 29th April, the Welsh Government would like to provide the following response to the specific questions that you have circulated.

Yours sincerely

Alexander Chadd

This submission is not an officially endorsed Welsh Government response. Submitted by Alexandra Chadd - a Police Inspector who was on secondment to the Welsh Government at the time of submission (May 2014)

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK/Wales?

Wales appears to be typical with other areas of the UK in respect of the types of controlled drugs abused most often:

- Opioids—prescribed for pain relief
- CNS depressants—barbiturates and benzodiazepines prescribed for anxiety or sleep problems often referred to as sedatives or tranquilizers
- Stimulants—prescribed for attention-deficit hyperactivity disorder (ADHD), the sleep disorder narcolepsy, or obesity

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

Illicit Supply

Intelligence sources would tend to suggest that there are a number of illicit supply routes in a multi faceted market place. This traditional route that has always existed is through the sale of drugs by patients with legitimate prescriptions for financial gain.

Crime

The proceeds of crime can also be a source of illicit supply; Prescription fraud or Chemist Burglary has always featured in police crime statistics in Wales, but is not a significant source and is often generalised as opportunistic in nature, rather than a component in a systematic and regular supply chain. This would again be true of relatives taking medicines from each other within the family home; strictly speaking a theft; but seldom reported as such and therefore difficult to gauge its prevalence.

‘Doctor Shopping’

Doctor Shopping the term generally used to describe a patient’s journey as they visit a number of doctors in different locations with the intention of acquiring supplementary or additional prescriptions that result in a surplus medication; over and above their actual needs. This surplus is then diverted into illicit markets. The extent of this problem is unknown and at the heart of this issue would be the various and differing capabilities of NHS Information Technology systems that deal with patient records.

‘Corrupt Doctors’

There has been no evidence to suggest that any medical professional(s) in Wales are abusing their position and writing unnecessary prescriptions that create an illicit supply. The environmental scanning of global events has alerted Welsh Government to the possibility of corrupt practice leading to illicit supply of prescription only medicine and in the post ‘shipman’ world there is no room for complacency. This has led to many on going improvements to the monitoring and audit trails within the Welsh Health Service.

Doctors that ‘over prescribe’ or prescribe unnecessarily

Whilst there are numerous media headlines about Doctors being too quick to prescribe many types of medication in Wales, there is an assumption that ‘Hippocrates’ advice still holds today; *“Primum non nocere”* or *“Prescribe only where necessary, and consider benefits versus risks. Involve the patient in decisions about their care and respect patient autonomy”*.

Again there is no evidence to suggest that any medical professional in Wales is abusing their position and writing unnecessary prescriptions that create an illicit supply.

Concordance

It is known that many people with prescriptions for long-term conditions do not take their medicines as intended. Leading to significant quantities of medicines not being returned or disposed of in the correct manner.

Whilst the legitimate supply of medication has its checks and balances, audit trails and accountability, once the patient leaves the chemist, the storage and supervision of medication is almost without control. This provides the opportunity for relatives to access drugs with the potential for both unregulated treatments with patients prescribing/treating themselves and this is also a clear opportunity for ‘recreational abuse’.

Occasionally this will manifest itself in tragic events such as the death of a child who has gained access to dangerous drugs but more often; the quiet divergence of medicines into an illicit trade.

The High Street & Head Shops

At first glance high street retail outlets generally known as ‘Head-Shops’ with their overt marketing of so called ‘Lifestyle’ accessories may not be the most obvious source of illicit prescription only medicines with their focus on the grey market of pseudo ‘legal highs’ marketed as ‘plant food’ & ‘herbal incense’.

Whilst the sale of Novel Psychoactive Substances in Head Shops is not the focus of this question, what has emerged through the analysis of the products on sale is that the active ingredient of these may contain prescription only medicines.

The regulation and control of manufacturing and supply chains to these establishments are questionable and represent a very real threat of harm, with sellers and buyers alike not knowing with any degree of certainty the nature of the product they are dealing with.

In Wales a new development to identify the extent of the issue and minimize harm has been launched; the ‘WEDINOS’ Public Health Wales project, which in partnership with many other agencies is collating and testing drug samples from across Wales.

WEDINOS; an acronym for The ‘Welsh Emerging Drugs and Investigation of Novel Substances’, is a project that been designed specifically for the collection and testing of New Psychoactive Substances (NPS) and, most importantly, dissemination via the

website of pragmatic evidence based health advice.

Whilst the target drugs are NPS orientated the results are showing that prescription only medicines are being sold or marketed as other products both illicit and so called 'legal highs' a moniker discouraged for obvious reasons.

A comprehensive list of the drugs being found in the results pages at www.wedinos.org

The 'Dark Internet'

The Internet is a source of diverted drugs; more recently, several anonymous online market places that operate via Tor hidden services (distributed traffic software enabling online anonymity) or using other identity-masking techniques. One such marketplace is *Silk Road*, where controlled substances can be purchased with a reasonable expectation of anonymity for both the purchaser and seller. Prospective buyers access Silk Road through a distributed network, which provides anonymity to the IP addresses of both the buyer's Web client and the Silk Road server. The Silk Road web site is taken down by the authorities at regular intervals, however it appears to have great resilience and quickly re appears with a variation on the address or name. It was recently exposed in May 2014 by the Sunday Mirror newspaper exposé that detailed its trading practices.

Whilst a legitimate on-line market place such as 'e-bay' is fully searchable by key words, sites such as Silk Road are not. You are required to enter a specific address (URL) to arrive where you want to go which is generally a practice referred to as 'stealth listing' and clearly intended to make enforcement activity difficult.

The 'dark internet' sites in common with the legitimate on-line market places need to use an electronic form of payment and not surprisingly legitimate service providers such as 'PayPal' are unsuitable for buyers wishing to hide their identity. Silk Road like many other types of site where anonymity is preferred or required uses Bitcoin (BTC), an international peer-to-peer digital currency, for payments. Bitcoin prices are generally converted to US dollars for global sales, although any currency is possible.

An unregulated banking system is likely to be out of the scope of this enquiry, nevertheless it is without doubt facilitating an international trade in illicit materials.

Gyms & Sporting Establishments

There is much empirical evidence of a more comprehensive approach to the types of drug being imported into Wales from abroad, for example in a recent South Wales drugs warrant executed by the Police and Customs 17 different types of drug were recovered having been posted into the UK from India. Although recreational drug use was clearly an intended outcome for many of the pills, the recovery of Viagra, hair loss remedies, weight loss or gain and body enhancing products all demonstrate a varied demand for controlled drugs and the supply is often driven by the simple economics of

what can be sold for the most financial gain.

Steroid and Image Enhancing Drugs (SIED) are very much part of this market and put Gyms and Sporting establishments into the spotlight for potential market places for the supply of prescription only medicines.

Public Health Wales provide a comprehensive overview of the issue at www.siedsinfo.co.uk

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

Methadone: Present and generally used to “tie users over”. Relatively small market, thought to be due to the general ease at which Heroin can be sourced;

Subutex: Also present but to a limited extent. Suggestion that there may be a market within Prisons (relatively cheap to obtain “on the outside”/high profit margins as tablets can be repeatedly split/easy to conceal/leaves the system quickly so negates testing);

Diazepam: By far the most prevalent illicit prescription drug in circulation, with some dealers said to have access to thousands of tablets at a time. Both good quality, high strength and poor quality, weaker tablets in circulation;

Temazepam, Pregablin, Fentanyl, Oramorph, Dihydrocodiene, Phenazepam, Quetiapine & Tramadol all appear to have been present in the past but to a very limited extent.

Tramadol – Tramadol, the synthetic opioid similar to codeine, and used in the treatment of moderate to severe pain, is available online and easily obtainable without a prescription; popular in Welsh prisons.

Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

In respect of the extent of the ‘problem’ or impact of illicit POM there is little clarity to be found as the issue of New and Emerging drugs, or the New Psychoactive Substances (NPS) market can not be discounted with its impact upon consumption habits and personal preferences. Unfortunately ‘poly drug’ use and combinations with legal substances such as alcohol only serve to further confuse the picture; for example experiences in some parts of Wales have seen that Opiate use fell as Mephedrone (MCAT) substitution became a popular alternative.

The following points reflect practitioners’ opinions;

- The effects/harm of diversion not only impact upon the illicit user, but also the legitimate patient who may be getting shorted on treatments.
- The connection to poor mental health has not been established, but is potentially a rich source of speculation and research.
- There can be ‘professional failures’ because of diversions that take place during their supervision, typically uncovered through a coroner’s inquest and Police investigation in to a sudden or unexplained death.

- Emergency Service Practitioners do not know what they are treating or how they should be treating it. Generic treatments are at best broad and non specific.

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

Writing prescriptions

There is already an abundance of guidelines on how a health practitioner should draft a prescription; such as avoiding unnecessary use of decimal points, avoiding abbreviations of drug names, along with many more sensible and pragmatic principles to follow. Yet some of these points are considered good practice rather than mandatory and as an example in the case of stating a patient's age this could well reduce the opportunity for prescription fraud through deception type offences.

It is suggested that the list of General Prescribing Guidance is reviewed with a view to strengthening the tone or mandate of the notes.

Hand Written or Computer Generated prescriptions

Many prescriptions are now computer-produced; a welcome development. However hand-written prescriptions and the stationary pads they use remain common and provide a greater opportunity for misuse through fraud or theft.

It suggested the use of handwritten prescriptions is reviewed.

Repeat prescriptions

It is not unusual for other health care professionals to write on behalf of the Doctor or for computers to generate repeat prescriptions. This can be an efficient time-saving measure, however if the patient is not being reviewed at appropriate intervals with regard to the need for ongoing medication, this may provide opportunities for the diversion of medicines into illicit markets.

It is suggested that the guidance on review periods is reconsidered and the guidance considered.

Prevention Messages in the Workplace

Workplace substance misuse policies can provide a framework for managing all substance misuse related issues and should be seen as being central to the Principles of a responsible, supportive and caring organisation. It is important; however, that the substance misuse policies link in with other relevant human resources and health and safety policies.

It is suggested that workplace substance misuse policies are considered.

Reducing Drug Related Deaths (DRD).

On the 28th August 2013 the Office of National Statistics (ONS) published the 2012 data for drug related deaths in England and Wales. The Welsh figure of 131 deaths was a reduction of 6 (4.4%) deaths from the 137 recorded in 2011. Whilst this reduction is welcomed we must not be complacent and Welsh Government is conducting a systematic review processes to establish more 'real time' reviews to help ensure any lessons learnt can be implemented as soon as is practically possible.

It is suggested that drug related death procedures are considered on a national basis.

Prescription Only Medicine; Harm Reduction Compendium

Welsh Government working with Public Health Wales have developed guidance designed to inform and assist service planners, commissioners, substance misuse and wider health and social care providers working with those with problematic substance use, including those not currently accessing services. The guidance includes recommendations for action in key aspects of health care including safer injecting and other routes of ingestion, reducing fatal and 'near fatal' poisoning and targeting vulnerable groups.

It is suggested that a similar initiative is considered on a national basis.

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

The initial steps in resolving the issue would need to ascertain the extent of the illicit supply. Traditional Survey work or enforcement activity such as seizures may not provide the full picture and here we can learn from the lessons other territories around the globe. In the USA where the illicit supply of prescription only medicine is causing almost as many fatalities as road traffic collisions the study of market forces such as cost appears to have been particularly informative.

It is suggested that a baseline is established that reflects the national and regional position through appropriate survey work.

Establish Cost

Data about the street price of diverted prescription medications can be useful to policymakers and public health officials, but timely and accurate data is rarely available publicly. Research in the USA suggests that the prices for different opioid active ingredients on the illicit market reflect their clinically established potency.

It can be assumed that street prices of diverted prescription opioids can be used to provide an approximate indicator of drug availability, demand, and abuse potential.

The advent of web based survey opportunities such as 'Crowdsourcing' can be used to contribute by providing a collaborating source of data. Crowdsourcing is a method for harnessing distributed 'human intelligence'. Here small pieces of independently derived information are systematically collected. In much the same way as a site such as 'Tripadvisor' facilitates peer reviews of holidays and hotels. A 'crowd-sourced' survey could in the case of prescription only medicine provides an insight into price, availability and quality. These results can then be compared with a survey of UK law enforcement officers such as the National Crime Agency and Regional Task Forces.

It is suggested that Costs are established and monitored to reflect the national and regional position through appropriate survey work.

Develop accurate testing equipment

The Review of Drink and Drug Driving Law by Sir Peter North, published in June 2010, concluded that there was "a significant drug driving problem" with an estimated 200 drug driving-related deaths a year in Great Britain.

However in 2011 around 41 % of the prosecutions in magistrates courts for 'driving whilst impaired through drugs' were withdrawn or dismissed. The comparable figure for exceeding the drink drive limit is just 3%.

These statistics relates to all classifications of drug illicit or legitimate and highlight the practical problems faced by front line staff- the paucity of accurate testing undermines efforts any efforts at enforcement of the law.

It is suggested that accurate testing equipment is developed to aide practioners in the detection of Prescription Only Medicines

Public Awareness

The dangers of Prescription only Medicine are not well known by the wider community and can be characterised by the thinking that if a Doctor has prescribed the drug and a chemist has dispensed it then it can.t be abused – a complacency that fails to take in to account the addictive nature of the drugs, the high value and the demand by those 'in the know' who intend to misuse or trade them. In Wales there has been a steady expansion of the use of the Drug and Alcohol Helpline (DAN 24/7) which supplements a number of other publicity campaigns

It is suggested that a public awareness campaign is used along side any measures taken to improve the divergence of Prescription only Medicine.

Head shops

- The legislation around selling drug paraphernalia is ineffective and requires a review.
- The presence of Head Shops on our high streets sends the wrong message about drugs.
- Product labelling; 'Not for Human Consumption', 'Plant Food' , 'Herbal Incense' and other similar disclaimer type loopholes require review.

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

See question 1, 2 & 3 for response.

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Advisory Council on the Misuse of Drugs (ACDM)
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12th August 2014

Dear Mr. Ali,

Ref: ACMD Diversion & Illicit Supply of Medicines Inquiry – call for evidence letter – RCP(2)

Please find my response to the Council's questions below:

Q.1 *In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?*

R.1 The numbers of individuals who use medicines illicitly in the UK are not known with any degree of certainty. The number of individuals who come to harm through illicit medicines use can be estimated from mortality and morbidity data attributed to drugs misuse. These sources do not specifically record the misuse of medicines obtained illicitly, however a crude order of magnitude can be inferred in terms of mortality and morbidity. The Office of National Statistics registered 2,597 deaths as occurring through drug-related poisoning, of which 1,496 were attributed to drug misuse¹. Morbidity can be estimated from data supplied by the UK National Poisons Information Service, which received 32,785 telephone enquiries regarding suspected poisoning with pharmaceutical products during 2012/13².

Evidence of the extent of the problem documented in the peer-reviewed medical literature is limited with respect to the UK situation. The international literature does provide evidence of harm, at least with respect to opioid misuse, although the magnitude of the problem appears to vary between states. An Australian study of methadone-associated deaths reported to the Victoria Coroner between 2001 and

¹ Office for National Statistics. *Statistical bulletin: Deaths Related to Drug Poisoning in England and Wales, 2012*. 2013. Available at: <http://www.ons.gov.uk/ons/rel/subnational-health3/deaths-related-to-drug-poisoning/2012/stb---deaths-related-to-drug-poisoning-2012.html>. Accessed Sep 2013.

² National Poisons Information Service. *National Poisons Information Service Annual Report 2012/13*. 2013. Available at: http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317139808601. Accessed Aug 2014.

2005 that identified 36 cases (14%) in which methadone had been obtained through diversion³. A Swedish study of deaths attributed to methadone noted that 69% of deaths occurred in individuals not on a methadone treatment programme, suggesting that the drug had been obtained illicitly⁴. This observation was confirmed in a larger Swedish study of opioid deaths, which observed that in approximately 80% of deaths attributed to methadone the patient had not been prescribed the drug⁵. Prescription drug diversion has been recognised as a problem in the US since the 1960's⁶. Post-market surveillance of opioids suggests that a high rate of methadone diversion also occurs in the US⁷.

The extent to which the problem of methadone diversion occurs within the UK is not clear. A study on the availability of heroin and methadone in England and Wales between 1993 and 2004 concluded that deaths attributed to methadone correlated closely with drug seizures by law enforcement officers than with prescriptions, suggesting that the drugs were obtained by means other than diversion⁸.

Anecdotally, I encounter individual patients on the poisons ward of my hospital on a daily to weekly basis who claim to abuse medicines obtained illicitly. The poisons unit admits approximately 1400 to 1800 patients annually. I have not made a formal study of the proportion that obtain medicines illicitly but would be willing to undertake such research if resources were made available. The frequent presence of such individuals on a poisons ward does, however, suggest that the problem is relatively common and is associated with at least a degree of morbidity.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

R.2 The majority claim to obtain pharmaceuticals from their social networks. I am also aware of a minority who claim to have obtained medicines over the internet. In particular, I am aware of several patients who claim to misuse veterinary benzodiazepines obtained either over the internet or purchased at street level. I am not aware of any research that has specifically addressed this issue within the UK. A recent study from the US would seem to support this observation that pharmaceutical opioids are most frequently obtained for non-medical use through immediate social networks⁹.

³ Pilgrim JL, McDonough M, Drummer OH. *A review of methadone deaths between 2001 and 2005 in Victoria, Australia*. *Forensic Sci Int*. 2013;226(1-3):216-22.

⁴ Vormfelde SV, Poser W. *Death attributed to methadone*. *Pharmacopsychiatry*. 2001;34(6):217-22.

⁵ Wikner BN, Ohman I, Seldén T, Druid H, Brandt L, Kieler H. *Opioid-related mortality and filled prescriptions for buprenorphine and methadone*. *Drug Alcohol Rev*. 2014 Apr 16. doi: 10.1111/dar.12143. [Epub ahead of print] PubMed PMID:24735085.

⁶ Inciardi JA, Surratt HL, Kurtz SP, Cicero TJ. *Mechanisms of prescription drug diversion among drug-involved club- and street-based populations*. *Pain Med*. 2007;8(2):171-83.

⁷ Dasgupta N, Bailey EJ, Cicero T, Inciardi J, Parrino M, Rosenblum A, Dart RC. *Post-marketing surveillance of methadone and buprenorphine in the United States*. *Pain Med*. 2010;11(7):1078-91.

⁸ Morgan O, Griffiths C, Hickman M. *Association between availability of heroin and methadone and fatal poisoning in England and Wales 1993-2004*. *Int J Epidemiol*. 2006;35(6):1579-85.

⁹ Daniulaityte R, Falck R, Carlson RG. *Sources of Pharmaceutical Opioids for Non-Medical Use among Young Adults*. *J Psychoactive Drugs*. 2014;46(3):198-207.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

R.3 The European Monitoring Centre for Drugs and Drug Addiction recently noted that pregabalin, tropicamide, and carfentanil have been diverted for illicit use¹⁰. From personal encounters with patients who claim to misuse medicines obtained through diversion or by illicit means the main classes of drugs would appear to be the benzodiazepines and the opioid analgesics. These drug classes also feature in the list of pharmaceutical agents that the UK National Poisons Information Service most frequently receives telephone and internet enquiries about, although data is often lacking on how the medicine was obtained by the patient¹¹.

Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

R.4 The patients I have encountered who claim to misuse medicines obtained through diversion or by illicit means have been admitted to hospital with acute toxicity, often involving the ingestion of several chemicals. These individuals often also exhibit features of dependency.

There may be a potential risk to children exposed to diverted medicine. A post-marketing surveillance in the US identified eight deaths and 257 cases of major or moderate toxicity following opioid ingestion in children exposed to a prescription opioid¹².

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

R.5 Understanding is indispensable to informed decision-making¹³. The first stage should be to develop awareness of the extent and causes of the problem. Part of the solution may include limitation of the prescription of drugs of misuse in primary care and a greater role for therapeutic drug monitoring to determine compliance.

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

R.6 Understanding is indispensable to informed decision-making¹⁴. The first stage should be to develop awareness of the extent and causes of the problem. Any action should however be comprehensive, rather than targeted against one specific drug class, to limit the risk of substitution.

¹⁰ European Monitoring Centre for Drugs and Drug Addiction. European Drug report: trends and developments 2014. Lisbon. May, 2014. Available at http://www.emcdda.europa.eu/attachements.cfm/att_228272_EN_TDAT14001ENN.pdf. Accessed on Aug 2014.

¹¹ National Poisons Information Service. *National Poisons Information Service Annual Report 2012/13*. 2013. Available at: http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317139808601. Accessed Aug 2014.

¹² Bailey JE, Campagna E, Dart RC; RADARS System Poison Center Investigators. *The underrecognized toll of prescription opioid abuse on young children*. *Ann Emerg Med*. 2009;53(4):419-24.

¹³ Developments, Concepts and Doctrine Centre. *Joint Doctrine Publication 04: Understanding*. Ministry of Defence Publication. December 2010.

¹⁴ Developments, Concepts and Doctrine Centre. *Joint Doctrine Publication 04: Understanding*. Ministry of Defence Publication. December 2010.

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

R.1 The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) stated this year that a “*growing number of new drugs that are detected on the drug market have legitimate use as medicines*”¹⁵. A study of illicit drug use in Sweden suggests that adolescents and young adults are more likely to misuse diverted benzodiazepines and tramadol than the more potent opioids¹⁶. This reflects my personal encounters with patients. The young adults tend to misuse diverted benzodiazepines, whilst the 30 to 50 year olds tend to also abuse opioids in addition to benzodiazepines.

Thank you for giving me the opportunity to respond to the Council’s questions on behalf of the Royal College of Physicians of London. I would be willing to provide any further details that the Committee may require.

Yours sincerely,

Dr. James Coulson BSc(Hons), MD, MRCP(UK), ERT

Clinical Senior Lecturer/Honorary Consultant Physician, Clinical Pharmacologist & Toxicologist
Cardiff University/Cardiff & Vale University Health Board

¹⁵ European Monitoring Centre for Drugs and Drug Addiction. *European Drug report: trends and developments 2014*. Lisbon. May, 2014. Available at http://www.emcdda.europa.eu/attachements.cfm/att_228272_EN_TDAT14001ENN.pdf. Accessed on Aug 2014.

¹⁶ Richert T, Johnson B. *Illicit use of methadone and buprenorphine among adolescents and young adults in Sweden*. Harm Reduct J. 2013;10:27. doi:10.1186/1477-7517-10-27.



British Association for Psychopharmacology

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Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

Almost all non-opioid drugs are now easily available on the internet including stimulants such as Adderall. As it is so easy to get these drugs via the internet there is little diversion of prescribed drugs.

Opioid substitution treatment such as buprenorphine and methadone can be diverted to obtain money (eg to buy heroin) but the treatment providers are generally well aware of this issue and monitor it so it is not a big problem.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

We have come across rare examples of diversion mainly of benzodiazepines when prescribed for anxiety and some analgesics but this is relatively rare.

Rarely patients whose children are prescribed stimulants for ADHD “try them out” because they recognize the ADHD symptoms in themselves and want to see if they might also be helped – and then come to seek treatment if they are.

Beyond this there is little diversion of stimulants for ADHD as they act too slowly to give a “high” and the stuff on the street is much better. Moreover modern slow-release preparations e.g. Concerta can’t be extracted and injected.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

V few – see answers to 2 above. The availability of drugs on the internet and the street has made diversion of marginal importance.

Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

There have been some reports of GPs being asked for benzodiazepines for insomnia and anxiety and these being sold but this is rare.

There are potential risks to public health and safety but no good data- these is needed to guide any response.

Moreover diversion is of minor importance to public and patients given the wide availability of drugs and other substances on the internet and the even wider

availability of other psychotropic substances (eg alcohol) with much greater health and safety impacts.

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

We recommend funding independent research to determine the extent of diversion, health impacts and the impact of existing controls on limiting the availability of effective treatments for patients

Before acquiring evidence, educating doctors to be alert to this is all that is required.

Any action that is being considered should be proportionate and avoid unwanted and perverse effects such as insufficient control of pain particularly in the terminally ill. There is already the strong sense that the fear of diversion is leading to under-prescribing eg of opioid analgesics to patients detriment.

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

Incentivise the use of non-abusable forms of medicines. For instance slow release variants of methylphenidate such as Concerta XL, and the pro-drug of amphetamine lis-dexamfetamine, should be removed from Class B of MDAAct1971 to encourage their use. Neither of these has significant abuse liability and, unlike with methylphenidate, cannot be injected to give significantly greater effects.

Combination therapy for heroin dependence using agonists with antagonists to prevent iv injecting partic buprenorphine/naloxone [suboxone] should be encouraged as it has lower diversion propensity than buprenorphine alone [subutex]

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

There are no good recent data. These are needed- see above.



FACULTY OF PAIN MEDICINE
of the Royal College of Anaesthetists



THE BRITISH PAIN SOCIETY

ACMD Diversion & Illicit Supply of Medicines Inquiry

Thank you very much for inviting the British Pain Society to provide evidence for your Inquiry on the diversion and illicit supply of medicines. The response below is from both the British Pain Society and the Faculty of Pain Medicine of The Royal College of Anaesthetists, and so relates specifically to analgesic medicines.

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?
Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?
Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?
Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?
Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?
Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?
Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

Specialists in pain management acknowledge that diversion and illicit supply of analgesic medicines does occur in the UK, however it is extremely difficult to quantify the extent of this. There are no data that tell us what happens to a prescription after it has been dispensed by a pharmacist. In part this is due to lack of identifying cases, inadequate appropriate recording and a under-reporting cases to the National Drug Treatment Monitoring System. In addition, it is extremely difficult to examine the trends in diversion and illicit use of medicines as there is no centralised data resource.

The increasing number of deaths associated with tramadol is a concern and its availability over the internet has been identified as a source by which individuals may obtain excessive supplies. The recent change in legislation and its classification as a Schedule 3 controlled drug should bring this route of supply to an end. In addition, there needs to be much greater discussion and collaboration with other EU countries since tramadol is readily available over the counter in some European countries notably Spain.

It would be unhelpful if concern regarding illicit use or diversion of prescription drugs resulted in reticence to prescribe the drugs to those who genuinely need and derive benefit from them. Other countries, namely the United States of America and Australia, have developed prescription monitoring schemes for controlled drugs. Such schemes allow greater sharing prescribing and dispensing information between healthcare professionals, including community pharmacists.

Experience from the United States points up a clear relationship between quantity of controlled drugs prescribed and their misuse and associated morbidity and mortality. We do not know

whether such a relationship pertains in the UK. Healthcare professionals play an important role in ensuring that prescription of controlled drugs is considered only when informed by knowledge of the risks of misuse for an individual. Controlled drugs for pain relief are not, on the whole, effective for the majority of people with pain in the long term. Sensible prescribing restricted for only those patients who demonstrate clear benefit from the drugs and adherence to dosing regimens for which safety data are available should mitigate the upward trend in prescribing which might be expected to limit the availability of these drugs for misuse.

The British Pain Society and Faculty of Pain Medicine, in collaboration with RCGP and the Faculty of Addictions Royal College of Psychiatrists, have previously published guidance on the appropriate use of opioids for pain and also on pain management in substance misuse. ~~Both of these documents are scheduled for revision.~~ We are aware that guidelines in the UK and elsewhere have had little if any impact on opioid prescribing trends and may have the unwanted effect of falsely reassuring prescribers and eroding sound patient-centred clinical decision making.

Rather than updating existing guidance the British Pain Society, the Faculty of Pain Medicine and other clinical and policy stakeholder groups ~~propose to develop~~ a central opioid prescribing resource. ~~This will be~~ based on the best available evidence regarding the benefits and harms of opioids which prescribers can then draw on to make a good clinical decision for an individual patient, influenced of course by the individual's clinical presentation, comorbidities and circumstances. This key resource can be drawn on to produce a suite of documents and educational materials in different formats for a variety of audiences including patients, which in turn should promote sensible prescribing to minimise risk.

The careful selection of stakeholder groups ~~will ensure~~ that advice on opioid prescribing is consistent, regardless of the information source. The document ~~will be~~ co-sponsored and published by PHE/NHS England who will support the administrative team at the Faculty of Pain Medicine, Royal College of Anaesthetists. Stakeholder partners in this project include RCGP, Faculty of Addiction RCPsych, The British Pain Society, RPS, CQC, Chronic Pain Policy Coalition, NICE, MHRA, ~~ACPO and the Department for Transport.~~

Professor Roger Knaggs
Associate Professor in Clinical Pharmacy Practice
On behalf of the British Pain Society

Dr Cathy Stannard
Consultant in Pain Medicine
Chair opioid prescribing resource project
On behalf of the Faculty of Pain Medicine

Call For Evidence – ACMD Diversion & Illicit Supply of Medicines Inquiry

Cathryn Kemp Former OPD Patient

I am in recovery from a profound and terrifying addiction to prescription painkillers. I would like to add my voice to the evidence being submitted to this inquiry, knowing that it is not directly relevant regarding illicit supply, but as an holistic overview of addictive process and eventual recovery.

In 2004, I was struck by a severe, life-threatening illness, acute-on-chronic pancreatitis. I was put onto a morphine drip for four years, and sent home with prescriptions for OxyContin. In 2007 I was referred to a London hospital that saved my life with two bouts of surgery. I suffered a massive attack of pancreatitis as a result, a condition so severe it can lead to death and permanent disability, alongside excruciating pain.

My medication was switched to Fentanyl, as it was considered a more appropriate opiate drug for the specific disease. I was on an IV drip for six months and sent home with a repeat prescription for fentanyl lozenges and fentanyl patches. It took just three short months or my use of the lozenges to increase over and above the maximum of eight lozenges a day.

After three months I had upped my dose to 11 to get the same pain-killing effect, then after six months it became 20, then 25, then 40, until I was eventually cut off by my GP at 60 lozenges a day. A fatal dose – all of it on prescription from my GP.

I used to collect my prescriptions for 240 lozenges in a large black binliner, there were so many boxes of them. Every day was a cycle of using the lozenges, rationing them out then waiting till the earliest point at which I could go back to my GP to get a prescription before the whole process started again.

It was a living hell.

My GP realized I was heavily dependent on the drugs and tried many ways to make me stop, including Provocative Therapy, electro-acupuncture and creating charts for me to cut down by myself. I resisted every attempt to free me from my addiction. I would reach a point and be overwhelmed by withdrawal symptoms, and then my use would go back to its original high dose.

Towards the end of my addiction I would hide lozenges in nooks and crannies around my cottage, fearful that I would run out and be left to cope with the withdrawal symptoms on my own.

In January 2010, my GP finally cut me off, saying he would not prescribe fentanyl lozenges for me again. That week I put my cottage on the market and borrowed £30,000 to put myself into a residential rehab. I had been refused NHS rehab three times. If it was not for my parents' money, and the fact I had a property to sell, I would be dead. Killed by the drugs that saved my life in hospital.

I have now been in recovery from my addiction to prescription painkillers for four years. I have written a book 'Painkiller Addict: From Wreckage To Redemption' to illustrate how easy it is for anyone, from any background, to fall prey to the potent drugs routinely used by doctors and surgeons. I am setting up the first UK charity to raise awareness of addiction to medicines, the Painkiller Addiction Information Service (PAIN) and I speak publically about the need to create sustainable recovery pathways for the 1.5million people in the UK believed to be dependent on their medications.

I would be happy to speak, from a patient's point of view, to add my voice to the discussion on the misuse of medicines in the UK.

In response to the questions put forward in the brief:

What should healthcare professionals do? And what should the government do?

There needs to be a programme of education for healthcare professionals in primary care services; recognising addiction to medicines and its symptoms. There also need to be recognised strategies for dealing with patients who are dependent. There needs to be a clear pathway for dealing with patients who are dependent, whilst recognising they may have pain issue. There are interesting services in Scotland where pain and addiction clinics are combined to provide the best possible use of expertise and resources. Government must recognize it must fund detox beds and rehab places for patients who may have been left long-term on potent drugs.

GPs should be actively trained to spot prescription drug-dependent patients, and have the services to offer them once patients are identified with the problem.

What would you want changed in the services from your experience? What needs to change to ensure others like yourself can be better helped with a dependency?

I was given little help to recover from my addiction. I was referred to the Substance Misuse Service and told my only choice of treatment was Methadone replacement therapy. While I recognize, Methadone has a part to play in harm reduction, it was absolutely the wrong path for me as by that time I wanted to be free of opiates. I applied for NHS rehab three times and was refused as I was not homeless nor offending. In the end I sold my house to pay for private treatment. There are many people who don't have this fall-back. There needs to be a recognized recovery pathway available for all those who need it, whether that is through an outpatient clinic or through detox and rehabilitation.

I felt I was discriminated against when asking for help because my addiction was not to illegal or 'street' drugs. I was not offered in-patient services as a result, though it was an inpatient service that helped me to come off fentanyl completely.

It is essential that people who are addicted to their medicines feel they are not stigmatised in the way addiction patients usually are. There might be a separate entrance to the same facility that treats all addictions, a simple way of making patients feel they are not looked at in the same way. Essentially anyone suffering from addiction needs to be treated with dignity, and this is no different for patients.

Cathryn Kemp 2014

Cathryn Kemp

College of Paramedics

Written Evidence in response to the **ACMD Diversion & Illicit Supply of Medicines Inquiry**

Dear Professors Iverson and Hill,

Thank you for your letter of the 12th of May 2014 regarding ACMD Diversion & Illicit Supply of Medicines Inquiry. Please accept my apologies for the very late return of responses.

I have completed the written evidence section below. The College of Paramedics is limited in the amount of information collected from members on issues such as this, and accordingly our evidence is not exhaustive, and based on the experiences noted in common practice.

I am not available to attend the evidence gathering meeting on the 12th June due to other commitments. The College of Paramedics strongly supports the enquiry and extends any future assistance with this matter.

Yours sincerely,



On behalf of the College of Paramedics

Andy Collen
DipHE MSc MCPara
Medicines and Prescribing Project Lead
College of Paramedics
andy.collen@collegeofparamedics.co.uk

Question	Response
Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?	<p>Paramedics in the UK are on the frontline, and see examples of illicit drug use. The problem is endemic, and has risen greatly over the last 20 years, in line with growing 999 demand.</p> <p>The range of drugs in use for illicit purposes has grown, but it is hard to pin down exactly the impact of medicines used illicitly in comparison to street-drugs (drugs which are home-grown, smuggled into the country, or manufactured in the UK).</p>
Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?	<p>The media reports almost weekly on incidences of medicines being stolen; either for personal habitual use by health professionals, or for organised criminal purposes. The College of Paramedics is not aware of any specific examples where a consistent supply of illicit medicines has been diverted from practice facilities which employ paramedics. We are aware of localised incidents of theft of POMs and CDs for personal use, and these result in appropriate action when discovered. We are not aware of these thefts relating to illicit supply.</p>
Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?	<p>Paramedics regularly deal with incidents relating to;</p> <ul style="list-style-type: none"> • Benzodiazepines • Diamorphine • Amphetamines <p>These medicines are often found to be packaged or presented as prescription only medicines, suggesting the supply has been diverted for illicit use.</p>
Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?	<p>The College of Paramedics has not received any direct concerns relating to the illicit supply or diversion of drugs. We are aware of individual cases of theft for personal use, and this of course can result in lack of or limited supply for patients by paramedics in the course of clinical care.</p>
Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?	<p>In all areas of healthcare there are opportunities to divert supplies of medicines. The College of Paramedics feels that all medicines supply should be electronic and work based on auditable actions via technology such as bar-coding and RFID tagging.</p>

Question	Response
	<p>The transfer of patients between facilities is an issue which affects paramedics, and the method by which CDs are prescribed and dispensed to patients being transported needs to be more robust to ensure losses do not occur without being immediately noticed.</p> <p>Patients who receive POMs and CDs on a regular basis should be subject to regular medicines reviews to ensure that the medicines are being taken as prescribed and are efficacious.</p>
<p>Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?</p>	<p>The College of Paramedics feel that there should be the facility to raise a concern relating to prescribed and dispensed CDs in the community in such a way as to preserve the confidentiality of the patient, but which prevents diversion of their medicines.</p> <p>For instance, if it was suspected that the son of a patient receiving opiate pain relief was in fact stealing the patient's medication for illicit supply, health professionals should have better ways of raising this concern. Safeguarding systems have a role to play and the Police must also facilitate the investigation of reports made in confidence.</p>
<p>Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?</p>	<p>In the experience of practicing paramedics the range of drugs available for illicit use is growing and the age group of drug users is expanding to include younger users. The College of Paramedics however has no evidence available relating to the trends relating to individual products and drug types.</p>

RESPONSE TO DIVERSION & ILLICIT SUPPLY OF MEDICINES
INQUIRY CALL FOR EVIDENCE.

Dr Fiona Wilcox

**HM Senior Coroner Inner West London,
Medico-legal Secretary to the Coroners' Society of England and Wales,
The Coroner's Court,
65, Horseferry Road,
London.
SW1P 2ED.**

There has been no time nor any resources available to undertake a systemic review, I have therefore answered the questions posed on a generic basis based upon my experience as a coroner investigating unnatural deaths and with input from other members of the Medico-legal Committee of the Coroners' Society of England and Wales and review of a small number of recent Prevent Future Death Reports written by coroners after hearing evidence in inquests where such medicines may have been implicated.

<p>Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?</p> <p><i>This appears to be an increasing problem over the last few years.</i></p>
<p>Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?</p> <p><i>The experience from evidence heard at inquests appears to be either via internet purchasing from the US, Europe and the Far East including China, or via hoarding of prescribed medicines.</i></p>
<p>Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?</p> <p><i>Opeates via both routes, barbiturates including those usually only used in veterinary practice via the internet from the US, newer designer drugs of mis-use often via the internet from the Far East including China, designer appetite suppressants via the internet from Spain.</i></p> <p><i>The illicit drugs are often advertised as fertiliser or other gardening related products.</i></p>
<p>Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?</p> <p><i>Both accidental and deliberate overdoses resulting in death.</i></p>

Exacerbation of psychiatric conditions.

Difficulties in diagnosis, unexpected and unanticipated problems with drug interactions.

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

Ensure that questions are asked about such drugs, consider drug screening and monitor prescribing.

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

Work with other countries to try and negotiate control and supply of such drugs and medicines.

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

Presumably most people who use such drugs do not end up before the coroner, so it must be reasonable prevalent.

Subjectively tending to be more male and younger age group.

Subjectively the trend is rising reasonably fast.

Mohammed Ali
Home Office
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2 Marsham Street
London
SW1P 4DF

Email: [REDACTED]

6 June 2014

Dear Mr Ali

**GPhC Response to the Call for Evidence ACMD Diversion & Illicit Supply of Medicines
Inquiry**

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacies in Great Britain. It is our job to protect, promote and maintain the health, safety and wellbeing of patients and the public who use pharmaceutical services in England, Scotland and Wales.

The GPhC sets the standards for education and training, conduct, ethics and performance and continuing professional development for the pharmacy professions. We have also developed standards for registered pharmacies. Our standards are intended to provide a workable framework for pharmacy professionals to practise safely and effectively. Our standards can be found at www.pharmacyregulation.org/standards.

Among healthcare professional regulators the GPhC is unique because it also regulates registered pharmacies as well as individual pharmacy professionals. The GPhC also has its own long-standing Inspectorate. In addition to our responsibilities in relation to pharmacy professionals, our inspectors visit all registered pharmacies in Great Britain to ensure that they comply with all legal requirements and regulatory standards. The inspector will examine how the pharmacy operates with the aim of securing and promoting the safe and effective practice of pharmacy at the registered pharmacy.

As part of our ongoing routine inspection of registered pharmacies, on a day to day basis, our Inspectors monitor and secure compliance with relevant legal requirement that include requirements for the sale and supply of medicines in general, and controlled drugs in particular. Much of the following feedback we have provided has been gathered from discussions with our inspection and investigation teams.

Some of this is data from cases and some of it includes anecdotal information, as we do not

routinely collect this type of information in this way about the medicines involved in cases.

We welcome the opportunity to respond to the ACMD's call for evidence on the diversion and illicit supply of medicines, predominantly controlled drugs. Thank you for the invitation to take part in the Evidence Gathering Meeting / Inquiry on 12th June, however given our limited role in this area we believe that this written submission constitutes the bulk of our evidence and beyond this we would have little to elaborate on in a public setting.

We have limited our responses and evidence to where we feel our work is relevant to the particular questions posed and are happy to clarify any areas as necessary.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

In the course of our work we have become aware, and have investigated, a number (less than 10 cases) of concerns raised about allegations of unlawful sales and supplies through registered pharmacies. We have recently established a number of memoranda of understanding (MOU) with other regulatory bodies and authorities, to share information about concerns, and we continue to develop further arrangements with other bodies. Where we have found areas of concern that fall outside our remit we have shared this information, and have worked, with the other relevant regulators and bodies such as the Home Office, the Medicines and Healthcare products Regulatory Agency (MHRA), the Care Quality Commission (CQC), Healthcare Improvement Scotland (HIS) and Healthcare Inspectorate Wales (HIW).

Evidence from the cases we have investigated, and have previously discussed with bodies such as the MHRA, indicate the areas in which illicit supplies may be coming from include:

- internet sites both domestic and international;
- illicit imports;
- stocks obtained by theft from pharmacies, hospital wards and departments; and
- inappropriate prescribing, prescription fraud and prescription theft.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

Although we do not capture this information routinely, in the course of our investigations, we are aware that the following types of medicines have been diverted or supplied illicitly:

- Antibiotics and antivirals
- Lifestyle drugs (drugs for slimming, or to treat erectile dysfunction)
- Hypnotics (diazepam, flunitrazepam)

- Analgesics (codeine, dihydrocodeine, tramadol)
- Anti-epileptics (gabapentin, pregabalin)
- Antihistamines
- Controlled drugs (methadone)
- Abortifacients (mifepristone, misoprostol)
- Chemicals / cutting agents (vitamin C powder)

Some medicines are being diverted and exported due to their high cost and high demand (or unavailability) in other countries.

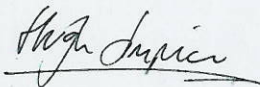
- Antineoplastics (Glivec, Tyverb, Votrient)
- Antivirals and antiretrovirals (Valcyte, valganciclovir, Copegus, Invirase, Atripla, Truvada)
- Antibiotics (tobramycin)
- Antidepressants (Cymbalta)
- Osteoporosis treatments (Bondronat, Aclasta)
- Others (peginterferon alpha, dornase alpha, Sandostatin and Exjade)

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

Whilst it would not be for us to direct you on how this should be done, we are committed to joint working with the appropriate bodies, through our MOUs, for clarity on regulating legal and illegal supplies.

Through our existing joint working arrangements and positive working relationships we will continue to work with other regulatory bodies and authorities to assist where we can in minimising illicit supplies and diversion. If you would like further information on any of the points raised in this response, or any other aspects of the GPhC's work please do not hesitate to contact us on the details provided below.

Yours sincerely



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**Home Office Advisory Council on the Misuse of Drugs (ACMD)
Diversion and Illicit Supply of Medicines Inquiry**

Evidence submission from the General Medical Council

13 August 2014

The role of the GMC

1 The GMC is the statutory regulator for the medical profession in the UK. Our legal purpose is to protect, promote and maintain the health and safety of the public by making sure that doctors meet our standards for good medical practice.

2 We do this by:

- controlling entry to the medical register, keeping the register up-to-date and making it publicly available so all who need to can check the status of anyone claiming to be a doctor.
- establishing the ethical principles and values that underpin professional practice and publishing a range of guidance and materials to promote those principles and values
- regulating medical education and training by setting standards and requirements that must be met by education providers, and checking that those standards are met, through quality assurance activity
- dealing firmly but fairly with doctors whose fitness to practise is in doubt - investigating any concerns and, if necessary, taking action to protect the public and maintain confidence in the medical profession.

3 Section 35 of the *Medical Act 1983* gives the GMC powers to provide 'in such manner as the Council think fit, advice for members of the medical profession on standards of professional conduct, professional performance or medical ethics'. Since 1995 we have exercised this power by publishing [Good medical practice](#), (GMP), our core guidance which is applicable to all doctors, whatever their careers stage or area of practice. As GMP necessarily sets out high level principles of good practice, we also publish a range of explanatory guidance which gives more detail on how the principles apply to particular situations, groups of patients, or aspects of practice such as prescribing.

4 Our guidance [Good practice in prescribing and managing medicines and devices \(2013\)](#) covers a range of topics including:

- Keeping up to date and prescribing safely, including when delegating responsibility for dispensing or administering medicines
- Need and objectivity (including self-prescribing and prescribing for friends and family)
- Getting consent; helping patients to understand their medicines and comply with instructions about their administration
- Sharing information with colleagues and good practice in shared care arrangements
- Reporting adverse drug reactions, medical device adverse incidents and raising concerns about patient safety incidents
- Repeat prescribing, prescribing with repeats (repeat dispensing) and keeping medicines under review
- Prescribing remotely via telephone, video-link or online
- Prescribing unlicensed medicines

The nature, purpose and status of GMC guidance

5 GMC guidance is commonly thought of as a professional code that is binding on doctors. In fact, as our statutory power is to provide 'advice', the guidance is not strictly binding. It is not a statutory code, or a set of rules, and there is no automatic link between breaching the guidance and action against a doctor's registration.

6 That said, the guidance is not merely advisory. It sets out the standards of competence, care and conduct that the GMC expects of all doctors. Serious or persistent departure from the guidance will raise a question about a doctor's fitness to practise medicine, or practise unrestricted.

7 Doctors are therefore expected to be familiar with and follow the guidance, and to use their professional judgement about how to apply the principles to the particular situations they face in practice. We indicate in the guidance, through [the use of 'must' and 'should'](#), the degree of flexibility that doctors may have to take a different approach. They must be prepared to justify their decisions and actions against the standards set out in the guidance.

8 We do not have a role to publish clinical guidance. Detailed information on the provision of particular treatments or medicines is available from a wide range of sources including NICE and the medical Royal Colleges. We rarely address specific issues of clinical practice in our guidance unless there is compelling evidence of poor practice in a particular area. The prescribing guidance is one of the few publications that does so (see paragraph 9 below).

Why we provide this guidance

9 In GMP we set out the principles of good care and make some general statements around good practice in prescribing. *Good practice in prescribing and managing medicines and devices* provides more detailed advice on how to comply with these principles. The guidance was also intended:

- to assist doctors with prescribing situations that they find challenging (such as pressure to prescribe medicines for the convenience of other social and healthcare professionals, for example those caring for patients with dementia)
- to explain how the standards of good practice apply in areas where change is fast paced and new issues are emerging (such as remote prescribing via the internet or video-link)
- in response to evidence of poor practice that might place patients at risk (for example, the remote prescribing of injectable cosmetics without a face to face consultation with the patient)
- to clarify the legal and parameters within which doctors can exercise their professional judgement (for example, when considering whether to prescribe an unlicensed medicine)

10 The prescribing guidance is consistently one of the pieces of guidance most frequently downloaded from our website. The latest version, published in 2013 was accessed around 9,000 times in the first quarter of 2014.

11 The guidance does not say anything specific about the diversion or illicit supply of medicines, emphasising instead the principles of safe and appropriate prescribing. However, the issue of drug misuse is touched upon in:

- [paragraphs 17-18](#), which caution doctors against prescribing for themselves or those close to them and note the particular dangers associated with prescribing controlled drugs in this way.
- [paragraph 53c](#), where we emphasise the importance of reviewing patients' medicines, particularly where a patient is prescribed a controlled or other medicine that is commonly abused or misused.

12 We also say at [paragraph 65](#) that doctors should not collude in the unlawful advertising of prescription only or unlicensed medicines by prescribing through websites that breach advertising regulations.

Developing the guidance

13 We have regularly revised and updated the prescribing guidance over the past decade as issues have emerged or been resolved. Remote prescribing has in particular been an evolving area as rapidly developing technology has brought new opportunities and challenges.

- *Frequently Asked Questions* (2004) brought together and superseded existing statements on repeat prescribing, providing advice and medical services on-line or by telephone, and the use of drugs in the treatment of obesity.
- *Good practice in prescribing medicines* (2006) included new or revised advice on: doctors prescribing for themselves or those close to them (with a focus on the particular dangers of controlled drugs); doctors' financial or commercial interests in pharmacies and dispensing practices; remote prescribing for overseas patients; and striving for concordance with patients and the provision of information about their medicines' use and side effects.
- *Good practice in prescribing medicines* included minor additions concerning the remote prescribing of Botox and other cosmetic injectables.

All of these documents are available in our [guidance archive](#).

14 The current prescribing guidance was the subject of a public consultation on the draft text, which ran from April to June 2011. We received 189 responses, including from organisations representing patients and the public and from organisations and individuals from medical, pharmaceutical and other health care professions.

15 The consultation process provides assurance that the guidance is accurate, realistic and represents a consensus between the public and the profession about what good practice should look like.

The GMC's role in supporting doctors and promoting the guidance

16 We know that doctors face a challenge keeping up with the volume of professional and clinical guidance that is issued by a range of bodies, including the GMC. Information overload with limited reading time can prevent awareness and assimilation of published guidelines. We therefore undertake a range of activities to help doctors understand and apply the principles of our guidance in their daily practice:

- *GMP* and the core explanatory guidance booklets are sent to all doctors when they join the register and when new editions are published. All of our ethical guidance, including the explanatory guidance on prescribing, is published on our website.
- From time to time we publish reminders on specific issues in our *GMC News* e-bulletin. We also regularly promote our guidance through our social media channels. We will shortly be publishing a piece on our blog to promote awareness of our guidance on doctors prescribing for themselves or their families.
- We develop and publish a growing range of learning materials to help bring key issues in our guidance to life for doctors. These include the interactive case studies [GMP in Action](#) and [Medical students: professional values in action](#). *GMP in Action* includes four scenarios specifically dealing with good prescribing practice.

- We have recently introduced a Regional Liaison Service (RLS) in England which gives talks and workshops for medical students, junior doctors, doctors on CPD programmes, multi-disciplinary teams and patient organisations, to help raise awareness and understanding of our guidance. Our offices in Scotland, Wales and Northern Ireland provide a similar outreach service. We prioritise a number of topical or key themes each year - for example reporting patient safety concerns in 2014.

Evidence of issues around diversion or illicit supply of medicine

Fitness to practise cases - threshold for action

17 As with all our guidance, our prescribing guidance includes a statement advising doctors that 'serious or persistent failure to follow this guidance will put your registration at risk.'

18 However, it is important to be clear that not all failures to follow the guidance will lead to action on the doctor's registration. Our role is to ensure that doctors are fit to practise medicine now and in the future. Our fitness to practise processes consider whether some form of action to restrict or remove a doctor's registration is needed in the public interest, taking into account the current risk that the doctor poses and our role in maintaining confidence in the medical profession. Our processes are not intended to be punitive, although actions such as suspending or removing a doctor's registration can of course have a punitive impact.

Types of allegation

19 For the period 2009–2013, we reviewed the allegations investigated under our Fitness to Practise procedures in two areas where there is potential for diversion and illicit supply of medicines – prescribing of controlled drugs (specifically opiates) and remote prescribing via the internet. The allegations are recorded on receipt of the concern but, as a result of our investigation, concerns may not be substantiated or can turn out to be less serious than previously thought.

20 By far the most common opiate-related allegations concerned a doctor's opiate dependency, often associated with self-prescribing or fraudulent prescribing (under the name of a relative or patient). Some doctors' registration is presently subject to restrictions (conditions and/or undertakings) relating to opiates.

21 The handful of matters recorded as internet or other remote prescribing largely presented as irresponsible practice – eg prescribing without adequate discussion or with no appropriate supervision and review arrangements in place. Following investigation, all these matters were either concluded with no further action, or with a letter of advice.

22 We found no allegations that related solely to illicit supply or diversion of drugs.

Consultation records and correspondence

23 We have reviewed our consultation records, inquiries to the Standards and Ethics team, and records of our face to face engagements with doctors around the country, to try to identify any evidence that would assist the ACMD in assessing the scale of the problem of diversion or illicit supplies of medicine.

24 The main issues attracting interest during the consultation on our current prescribing guidance included: prescribing on the basis of patient need not convenience; prescribing of medicines for unlicensed indications (and whether it was lawful to do so on grounds of cost); and whether doctors should prescribe for themselves or those close to them. One respondent raised the issue of patients 'registering at several practices to obtain medicines which might be abused e.g. benzodiazepines and codeine', and suggested that remote prescribing services could facilitate such activity, especially if patient objection to GP liaison is respected. This was presented as a hypothetical risk, and no evidence was given of a problem in practice.

25 No specific concerns about diversion or illicit supply of medicines have emerged in correspondence or through our engagements with doctors. We receive enquiries from time to time about the processes for stocking emergency bags (particularly with controlled drugs) and for returning emergency stocks once a GP moves to a different area. We direct those enquirers to the National Prescribing Centre guidance. We also receive enquiries about the rules governing private prescriptions and dispensing of medicines for patients who are not in the UK. These are often family members, and we respond with advice on good practice about treating friends and family. Where there is uncertainty about export rules, we direct doctors to the MHRA for guidance on these questions.

26 We therefore have no strong evidence to help assess the scale of the problem, but we are not complacent. If this inquiry finds that there is a significant issue, we will of course consider what role the GMC can in addressing it, for example by using our various channels of communication with the medical profession.

Issues raised by the Inquiry Chair

Information from regulators outside the UK

27 There are three ways in which we might obtain information about a finding against a doctor outside the UK.

- When a doctor who has been practising in another jurisdiction applies for registration with the GMC, they have to complete a declaration of fitness to practise. If any findings have been made against them in another country, they would be expected to declare it at this stage.
- We also request a certificate of good standing from any country where the applicant has been registered during the last five years. This provides

another opportunity to establish whether a doctor had been investigated, or action taken against them.

- If an overseas regulator notifies us that they have taken action against a particular doctor, we place an alert on the doctor's record, so that it can be reviewed if the doctor applies for registration. If the doctor is already registered, we consider what if any action would be appropriate.

28 If we find out (in whatever manner) that an applicant for registration has had a finding made against them in another jurisdiction, or they are currently being investigated, we would take a formal decision on whether the applicant's fitness to practise is impaired.

29 Only a few regulators regularly notify us of action they have taken against doctors, and there are only a few European states that regularly send notifications to us. The modernised Professional Qualifications Directive adopted in November 2013 has introduced a legal duty on member states to share fitness to practise info but this will not come into force until 2016.

Movement within the EU – temporary and occasional registration

30 The Recognition of Professional Qualifications Directive includes provisions for doctors to practice in the UK on a temporary and occasional basis. These were included in the recognition Directive in 2005 and the most recent revisions clarify some aspects of the provisions.

31 Doctors practising in the UK under the temporary provisions still need to be on the GMC register (it would be a criminal offence if they practised without a licence) but we have to apply a lighter touch registration procedure (for example, they do not have to pay a registration fee, and revalidation does not apply to them).

32 They do however have to provide a certificate from the competent authority of their Home State declaring that they are lawfully established in practice in that State and are not prohibited (whether on a permanent or temporary basis) from practising as a medical practitioner there. This is renewed annually. Their entitlement to provide medical services in the UK will cease if they cease to be registered/recognised as a medical practitioner in the Home State or they are prohibited from practice on a temporary or permanent basis

33 These doctors are also subject to fitness to practise procedures in the UK. The number of doctors registered under these arrangements is very small (less than 10).

Newly qualified doctors' entitlement to prescribe

34 The purpose of provisional registration is to enable newly qualified doctors to participate in and complete an acceptable training programme for provisionally registered doctors. The only programme for provisionally registered doctors that we recognise is the first year of the Foundation Programme (Foundation year one, or F1), a 12 month programme which must meet the requirements set out in our guidance, The Trainee Doctor.

35 Provisionally registered doctors are considered to be fully registered medical practitioners so far as is necessary to enable them to participate in an acceptable programme for provisionally registered doctors, but no further. The effect of this is that they may issue prescriptions for prescription-only medicines or controlled drugs only as required by participation in the programme. They may not order for private patients or for their own use.

36 Provisionally registered doctors also have an obligation under GMP to keep up to date with and adhere to the laws and codes of practice relevant to their work.

'Doctor swapping'

37 To the extent that this is a potential issue with the healthcare system – for example what safeguards there might be to prevent patients from registering with more than one GP, or registering with multiple identities – this is not an issue the GMC can comment on.

38 From the perspective of professional regulation, we would expect a doctor to be satisfied that the medication is for the use of the patient in front of them, and serves their interests based on what the doctor knows about the patient's medical history. As part of that, expect the doctor to refer to the local record to review the prescribing history and to discuss with the patient the proposed treatment and how the patient will adhere to it.

39 Of course there is no obligation to provide a treatment if the doctor does not believe it serves the interests of the patient. So if a doctor did doubt the legitimacy of a request for a medicine, it would be open to the doctor to refuse to prescribe it.

ACMD

Advisory Council on the Misuse of Drugs

Diversion and Illicit Supply of Medicines

Submission by Dr Iain Brew

General Practitioner - HMP Leeds

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

Patients coming into prison report abusing drugs purchased over the internet, but also those bought/extorted from patients exiting pharmacies. Patients describe “GP shopping” and acquiring prescriptions from agreeable doctors often using excuses like theft, loss of script and accidental disposal of the drugs themselves.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

Occasional reports from patients of community pharmacy staff selling pregabalin and benzodiazepines illicitly and without prescription. However the majority of cases are covered in Q1 in my experience.

In the prison setting, diversion of drugs is extremely common despite close supervision with pregabalin, mirtazapine and buprenorphine being the main products.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

- 1) Pregabalin
- 2) Tramadol
- 3) Benzodiazepines
- 4) Morphine and other strong opioids
- 5) Quetiapine and other sedating psychotropics

Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

Genuine patients not receiving their prescribed medication: especially when extorted from them by drug users

Difficulty in assessing drug use: patients presenting often do not volunteer their use of diverted drugs

Combinations of multiple sedating drug has undoubtedly led to drug related deaths, both in

community and prison settings

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

Improved guidance on the assessment of patients before prescribing the drugs listed above. I have patients, who have been prescribed pregabalin on the flimsiest of evidence and often for unlicensed applications such as musculoskeletal back pain and knee cartilage injuries. Clinicians should be aware of the learned behaviour: patients describe “shooting pains” in the knowledge that this may lead to an erroneous diagnosis of neuropathic pain. Clinicians should be aware that when patients request drugs by name, prescription abuse may be a possibility.

There is already a great deal of work ongoing to increase national awareness of the problems associated with neuromodulators: led by Dr Cathy Stannard et al

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

A clear statement badged by the DH, NHS England and Public Health England indicating that addiction to prescription medicine: both iatrogenic and illicit is a major public health problem. This should be underpinned by clear advice to control prescribing of these drugs: both to save costs associated with inappropriate prescribing and to reduce the potential for addiction and adverse outcomes such as drug related death.

Consideration should be given in particular to the rescheduling of pregabalin, which has become the foremost recreational prescription drug among the drug-using population.

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

I have no information on the prevalence of diversion, but patients wanting pregabalin have told me on arrival in prison:

“I got them from an old woman and she doesn’t even need them because her leg’s been amputated!

“If you get the dose right, you only have to be conscious a few hours a day”

“My specialist prescribed them so you can’t stop them: my solicitor says it’s against the law!”

“I’m not having amitriptyline: that’s for psychotics, not pain!

“Pregabalin is better than crack!”

Submission to the Advisory Council on the Misuse of Drug's Inquiry on Diversion & Illicit Supply of Medicines

by Her Majesty's Inspectorate of Prisons

Introduction

1. We welcome the opportunity to submit information to the Advisory Council on the Misuse of Drug's Inquiry on Diversion and Illicit Supply of Medicines.
2. Her Majesty's Inspectorate of Prisons (HMI Prisons) is an independent inspectorate whose duties are primarily set out in section 5A of the Prison Act 1952. HMI Prisons has a statutory duty to report on conditions for and treatment of those in prisons, young offender institutions (YOIs) and immigration detention facilities. HMI Prisons also inspects court custody, police custody and customs custody (jointly with HM Inspectorate of Constabulary), and secure training centres (with Ofsted).
3. HMI Prisons coordinates, and is a member of, the UK's National Preventive Mechanism (NPM), the body established in compliance with the UK government's obligations arising from its status as a party to the UN Optional Protocol to the Convention Against Torture (OPCAT). The NPM's primary focus is the prevention of torture and ill treatment in all places of detention. Article 19 (c) of the Protocol sets out the NPM's powers to submit proposals concerning existing or draft legislation.
4. HMI Prisons inspect adult male prisons at least once every five years and immigration removal centres (IRCs) at least once every three years. All inspections are full and almost all are unannounced. The inspection of the treatment of, and conditions for prisoners and other detainees necessarily involves examining health care provision. To maximise the available expertise, the majority of our inspections are carried out with the assistance of partner organisations including the Care Quality Commission, Ofsted and the General Pharmaceutical Council. This coordinated approach to inspection reduces the burden on inspected organisations and allows us to develop a full picture of the custodial environment in which health is an integral part.
5. All inspections are carried out against our *Expectations* - independent criteria based on relevant international human rights standards and norms. Expectations are brigaded under four healthy prison tests: safety, respect, purposeful activity and resettlement. All our expectations are supported by a series of 'Indicators' which we would expect to see in place if the expectation is met although these do preclude an establishment demonstrating to us that the expectation is met in other ways.
6. On each inspection we carry out a survey of a randomly selected sample of prisoners to obtain their views and perceptions on all aspects of their life in the prison. These surveys have now been undertaken for many years and provide an opportunity for us to compare prisoners' views in each establishment with both the previous inspection and comparable establishments.
7. Our answers are based on our inspection evidence and relevant research from the medical field.

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

Current situation in the UK

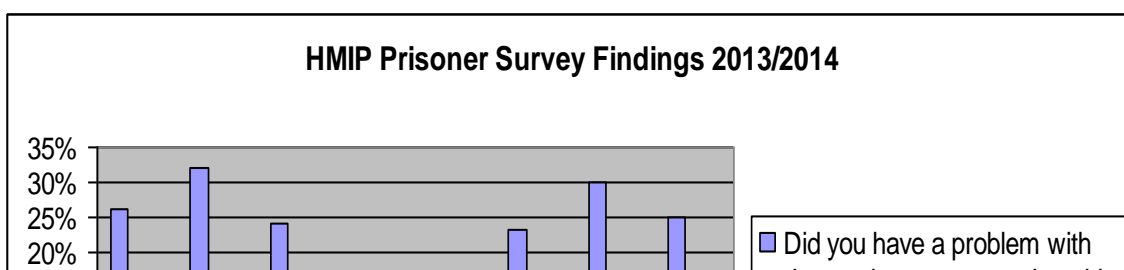
8. While there are no definitive figures on the number of prisoners who misuse drugs while detained, the fact that 70% of offenders report drug misuse prior to entering prison and 51% report a drug dependency gives some indication about the scale of the problem (Home Affairs Committee, 2012).
9. In 2009–10 2% (3,735) of those in drug treatment services reported their primary problem to be prescription-only or over-the-counter medication while a further 14% (28,775), whose primary dependency was illegal drugs, reported additional problems with prescribed or over-the-counter medication (NTA, 2011). Furthermore, 2% (1,297) of people newly presenting to alcohol treatment in 2009–10 cited additional problems with prescribed and over-the-counter medicines (NTA 2011). However, because most people who have issues with prescribed or over-the-counter medication are managed by their GP, with only the most complex cases presenting to specialist services, this makes it difficult to accurately assess prevalence (NTA, 2011 and Reay, 2009).

Her Majesty's Inspectorate of Prisons evidence

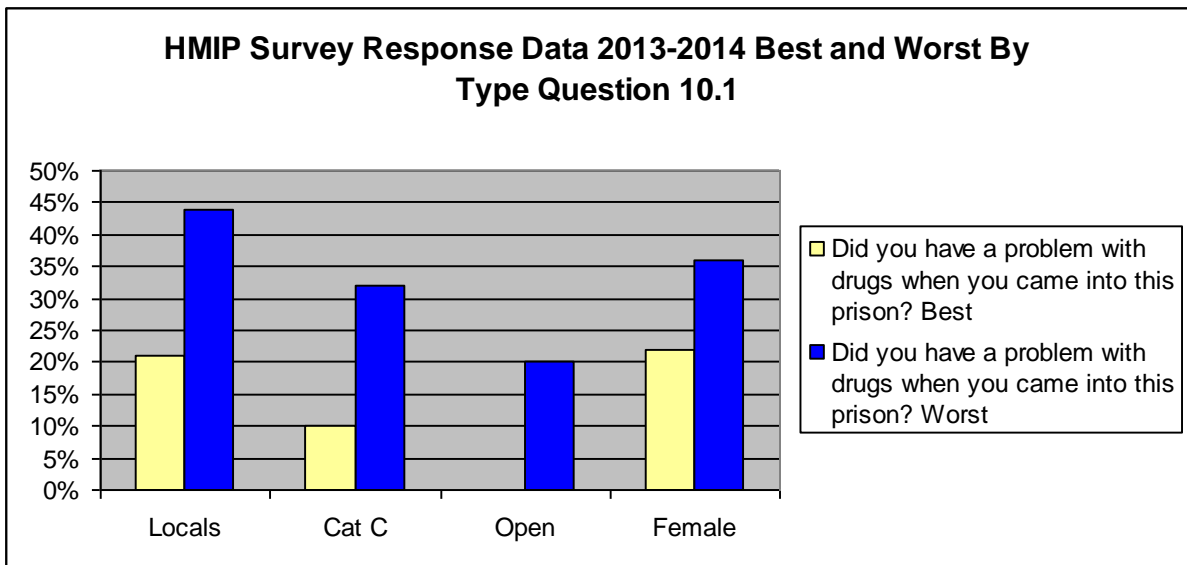
10. Her Majesty's Inspectorate of Prisons (HMI Prisons) has reported (HMI Prisons Annual Report 2010-11) that while the integrated drug treatment system (IDTS) improved treatment for opiate-dependent prisoners, it also resulted in some inadequately managed high-dose and long-term methadone prescribing. The government's 2010 drug strategy placed a focus on recovery and abstinence as the ultimate goal of drug treatment and some establishments responded by enforcing inflexible reduction regimes despite compelling evidence that effective opiate substitution treatment supports recovery (NTA 2011). Inflexible prescribing can contribute to relapse and illicit use (Patel, 2010).
11. Since the introduction of IDTS, there has been a significant reduction in the illicit use of heroin in prisons. There has also been a shift in reported patterns of substance misuse in the community with a general decline in the use of opiates and crack cocaine and more reported use of new psychoactive substances (NPS) and abuse of prescription-only and over-the-counter medicines (NTA, 2013b and NTA, 2011). It is thought that this also impacts on prison patterns of substance misuse.
12. HMI Prisons has also highlighted a growing problem with diverted medication (HMI Prisons Annual Report 2011-12 and 2012-13). The primary medicines of abuse have been opiate-based painkillers, sedatives and psychiatric medication. In 2010-2011 the problem appeared to be primarily among high secure and vulnerable populations, however from 2011-2012 onwards it was a more mainstream problem. Because of this, since 2012, our prisoner survey has included a question asking adult prisoners if they have developed a problem with diverted medication in their current prison.

HMI Prisoner survey

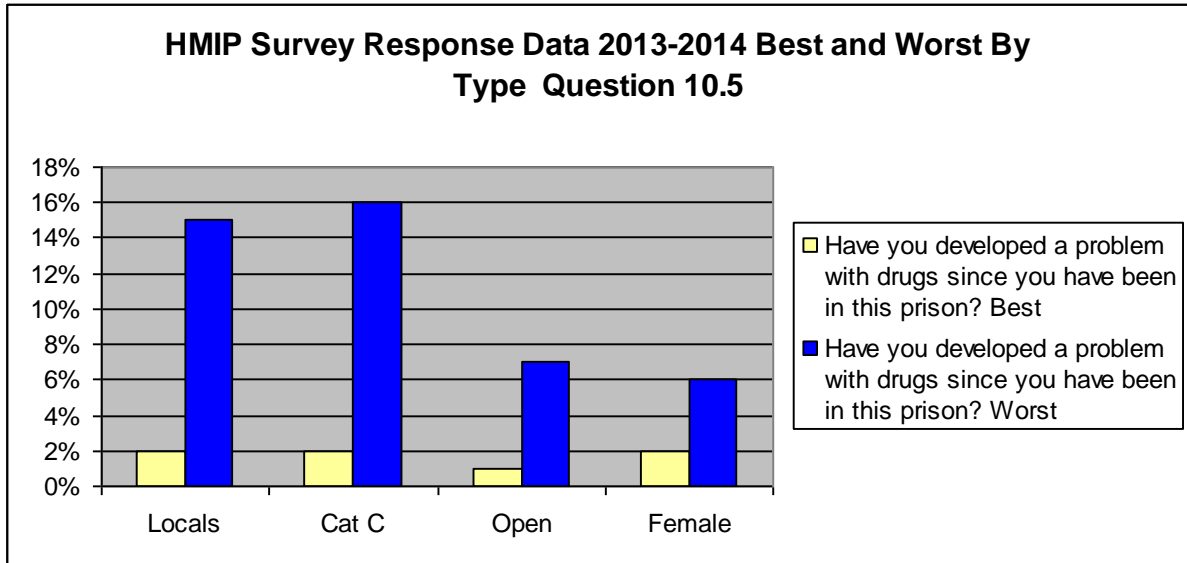
13. In 2013-2014, HMI Prisons conducted a survey of prisoners in 45 adult establishments. The following tables illustrate a range of findings.
14. The table below shows the percentage of prisoners surveyed who reported developing a problem with illegal drugs and medications, comparing the different functional types of prison. It should be noted that these results are specific to the individual establishments and cannot be generalised across the estate.



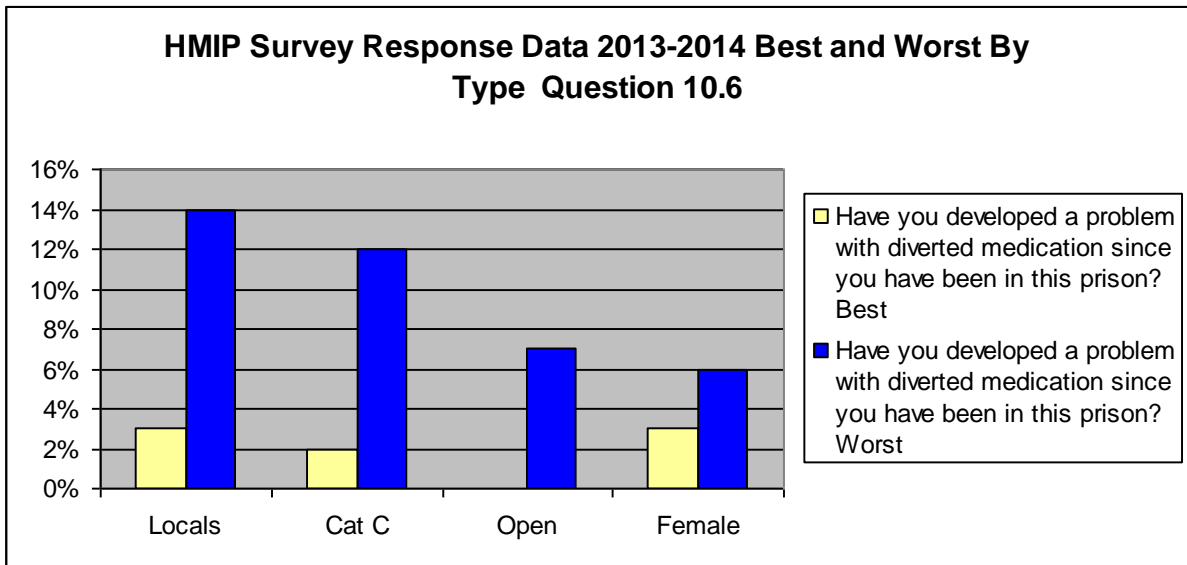
15. The table below indicates the lowest (best) and highest (worst) rate of positive answers to the question “did you have a problem with drugs when you came into this prison” among the prisoners surveyed in 2013-2014 in four different types of establishments:



16. The table below indicates the lowest (best) and highest (worst) rate of positive answers to the question “have you developed a problem with drugs since you have been in this prison” among prisoners surveyed in 2013-2014 in four different types of establishments:



17. The table below indicates the lowest (best) and highest (worst) rate of positive answers to the question “have you developed a problem with diverted medication since you have been in this prison?” among prisoners surveyed in 2013-2014 in four different types of establishments.



**Please note that these figures provide a snapshot of specific prisons at a specific time and cannot be generalised across all prisons.*

Fatal incidents

18. The Prisons and Probation Ombudsman (PPO) reported in 2011–2012 that 6% of all fatal incidents investigated were due to drug toxicity. Recurring factors in these deaths included:

- trading in prescribed or smuggled drugs;
- the hoarding of drugs for later use; and
- the combined effects of prescribed medication and illicit drug use (PPO, 2012a).

19. The PPO recommendations to reduce prison drug fatalities included:

- reviewing the medications prescribed to prisoners with known drug habits;
 - improving the information sharing between prison prescribers to ensure that prisoners are not prescribed medications which can be fatal when taken together; and
 - reducing the supply and use of illicit drugs within prisons.
20. The PPO has also highlighted recent increases in drug-related deaths among newly released prisoners – most of whom were found to be using diverted prescription medicines (PPO, 2012b). It recommended that staff at approved premises are made aware of the dangers of both mixed drug and methadone toxicity and to ensure medication is not kept in possession in contravention of the risk assessment. This would reduce the opportunity for the trade of prescription drugs.
21. It is extremely difficult to report accurately on actual prevalence of certain drugs as most prisoners do not self report and many of these drugs cannot be detected in Mandatory Drug Testing (MDT). Although some of these drugs can be detected in urine, MDT can only be used to test for illegal drugs. The National Offender Management Service has advised that Tramadol will be tested for under MDT once it becomes a Schedule 3 drug in June 2014. Compact-based drug testing (CBDT) can be used to test for a wider range of substances and was a useful indicator to inform supply reduction strategies, but funding cuts have resulted in CBDT rarely being available.

Identification of illicit drug use

22. HMI Prisons has warned that there have been potential missed opportunities to identify some illicit drug use due to slippage on suspicion and risk mandatory drug testing. In 2013-2014 the problem of suspicion testing either not occurring or being completed outside the time frame was an issue in 71% of male prisons and 50% of female prisons we inspected. Additionally 21% of adult male establishments inspected were not monitoring the non-completion of tests.
23. In our 2012-2013 annual report HMI Prisons highlighted that MDT positive results pointed to Buprenorphine (licensed opiate substitute) and cannabis rather than heroin as the primary drugs used. Some prisons have attempted to prevent the diversion of Buprenorphine (an effective licensed substitute) by not offering it as an option for opiate-dependent prisoners. However, this unacceptably inhibits recovery for some prisoners. Additionally, finds of Buprenorphine tend to be whole tablets, even in establishments where it is crushed, and even when not prescribed it is still found in MDT, indicating it is being smuggled in (Holme House).
24. HMI Prisons, Her Majesty's Inspectorate of Probation, Her Majesty's Inspectorate of Constabulary, the Care Quality Commission and Health Inspectorate Wales are currently undertaking a review of these issues to enable recommendations to be made in relation to both health care and security. We anticipate publishing our findings in 2015.

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Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

25. Diverted medications have gained popularity because of their low cost, availability, perceived undetectability and guaranteed effect (Penfold et al., 2005; Plugge et al., 2009). The main source of these medications is believed to be through the diversion of medication that is supplied and administered in prison, although some medications are also being smuggled in various ways including visits, "over the wall", in the post, brought in by prisoners and corrupt staff (Blakey, 2008). Different prisons have different challenges due to factors including design, type of prison (open prisons have greater opportunities) and type of prisoner held. As part of Phase 2 of our thematic report into current patterns of substance misuse in prisons we are conducting interviews and a prisoner survey which looks at supply in more depth.
26. HMI Prisons has identified several factors contributing to medication diversion including:
 - high levels of prescribing of medications liable to abuse;
 - divertible medication inappropriately given to prisoners in possession; poor supervision of medication queues; and
 - a lack of secure in-cell storage for medications and an inadequate strategic approach to the problem.

27. HMI Prisons has also identified ongoing issues with prisoners arriving in prison who have been inappropriately prescribed medication. There has also been some inappropriate prescribing of medication in prisons. National guidance including the Royal College of General Practitioners guidance on Safer Prescribing in Prisons (2011) and NHS England joint guidance on pain management (2013) have improved practice in some areas. HMI Prisons has observed examples of good medicines management reducing diversion opportunities (Full Sutton) and effective joint working between security and health providers reducing diversion (Ryehill). Despite this, however, we continue to encounter issues surrounding the diversion of medication from within and outside the establishment in a significant number of the prisons that we inspect.

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Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

28. Finds, drug tests and reports from prisoners and staff suggest the most commonly misused medicines are:

- Tramadol
- Gabapentin
- Pregabalin
- Opiate-based analgesia
- Quetiapine and other antipsychotics
- Benzodiazepines
- Mirtazepine
- Amitriptyline
- Night sedation
- Buprenorphine

29. Prisoners rarely report wanting to get 'high' as a motivating factor for using drugs in prison (Turnbull, 2000). Depressants result in decreased awareness of surroundings, decreased alertness, a narcotic effect and blunted emotions, which prisoners reported to be preferable within a prison environment (Bullock, 2003).

30. Although this enquiry is focused on illicit supply of medicines it is important to note increasing reports of NPS use in prisons. In 2013/2014, NPS, specifically 'Spice' and 'Black Mamba' were cited as causes for concern at 14 (29%) of the adult male establishments HMI Prisons inspected, particularly local and Category D jails. Whilst many prisons had taken steps to promote awareness we highlighted the necessity for some establishments to provide prisoners and staff with accurate and up-to-date information on the acute health dangers associated with NPS.

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Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

31. The problems associated with diverted and illicit medicines for prisoners include bullying, violence, drug debts, unexpected drug interactions and overdose. In our 2012–13 surveys of prisoners 4% of prisoners, across all functional types of prison, reported that they had been victimised by other prisoners because of their medication, and 3% stated that had been victimised because of drugs. In addition to potentially being bullied for their medication, prisoners can also end up in debt through purchasing medications and drugs from other prisoners which can lead to violence, self harming behaviour or recalcitrant behaviour intended to generate a prison transfer to escape the debt. There is also a risk of prisoners leaving prison with an untreated and unmanaged drug addiction which may generate increased risk of withdrawals, drug seeking behaviour or overdose upon release.
32. Clinicians have reported threats and in some instances actual violence related to prescribing. As stated above, some prisoners also arrive into prison having inappropriately been prescribed medication and the process for investigation, specialist advice and interventions and reviews can incur significant costs.

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

- Drug testing that can respond promptly to changing patterns of use and detect the primary drugs reported. The fact that these drugs cannot be detected on MDT has been cited as a significant factor for some diverted medication and for NPS.
- Adequate resources to undertake Mandatory Drug Testing and Compact Based Drug Testing.
- Effective supply reduction strategies and accompanying action plans that adequately consider diverted medication.
- Effective communication and integration between prison departments including those responsible for security, health, substance misuse and residential.
- Regular spot checks of prisoners in possession of medication to ensure the amount they have in possession matches the quantity expected if it was taken as prescribed.
- 'In-possession' risk assessments which consider the drug type, the prisoner and the environment. These should be regularly reviewed.
- Strict medicine management guidelines to prevent diversion.
- Appropriate evidence-based prescribing and reviews in the community and prisons, including partnership working with substance misuse services where required.
- Access to pain specialists that understand the wider context and can give consistent appropriate timely support to prisoners with chronic pain.
- Effective medicine management committees that receive aggregated prescribing data and discuss prescribing trends.
- Auditing of prescribing.
- Reliable information for prisoners about the effects, risks and potential consequences of using diverted medication.
- Training staff about the signs, risks and potential consequences of medicines.
- Facilities for private drug administration in prisons – many prisons have facilities that lack privacy meaning prescribing cannot be kept confidential.
- Discipline staff adequately supervising medication administration.

- Secure in-cell storage for prisoner medication.
- Targeted psychosocial support for prisoners who have developed a dependence on these substances.
- Appropriate management of other issues. Reports from prisoners and some speculation in the literature indicates that some misuse of diverted medication may be due to self medication of mental distress or physical symptoms such as pain or insomnia. Access to timely support to identify and address these issues is important.
- Adequate purposeful activity - boredom has been cited as a significant factor in some establishments.

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

- Adequate resources to undertake Mandatory Drug Testing and Compact Based Drug Testing.
- Adequate resources for purposeful activity - boredom has been cited as a significant factor in some.
- A change in legislation to allow Mandatory Drug Testing to be used to test for medications/drugs that are reported as being used locally.
- Raising awareness of the risks of misusing medications.

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

33. Please refer to the HMI Prisoner Survey graphs in question 1.

Majella Pearce
Healthcare Inspector

2nd June 2014



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██████████
Advisory Council on the Misuse of Drugs (ACMD)
Secretary to the Diversion & Illicit Supply of Medicines
Inquiry
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Reference: HQSG/Ph/RFI/2

1 Sep 14

ACMD Diversion and Illicit Supply of Medicines – MOD Response

Dear ██████████

On behalf of the MOD, I would like to thank you for the opportunity to provide evidence for your inquiry on the diversion and supply of medicines. I am not sure that our presence at the Working Group meeting on 5 Sep 14 would be of any great benefit but please accept this written submission as our evidence.

Q.1 Can you confirm if medicine diversion and illicit supply is a major problem within military settings, and if so, where are these medicines coming from? What do you see as being the causes?

Whilst the MOD accepts that diversion and illicit supply of medicines does occur, there is a significant deterrent in the military environment with compulsory drug testing (CDT). The aim of this is to improve operational effectiveness by ensuring that the Army understands that drug misuse is contrary to its Values and Standards ensuring that individuals are sufficiently confident to identify and report incidents of drug misuse, and for those with rank, exercise the leadership to prevent it. Data we do have on Service Personnel tested under CDT shows a very small number found to be positive. It should be noted that some of these medicines have been prescribed for friends or family members and passed onto other users, often ignorant of the legal and clinical implications. The remainder are likely to be from internet or illegal sales but we are unable to connect the user to a source, or even to identify the source.

It is difficult to quantify the level of diversion or illicit supply but there is currently no evidence to suggest that this is a major problem in the military. There are tight controls on all medicines and the MOD has a further additional category of accountable drugs which includes those Controlled Drugs in Schedules 3 to 5 and other drugs deemed attractive to misuse or abuse eg Oramorph, zopiclone, and cyclizine. Also, the majority of the prescribing and dispensing is integral to our medical centres which provides us with better control over the process. Once a prescription has left our medical centre dispensaries there is no way of knowing whether the patient uses them appropriately or not. It is therefore believed that the majority of diversion and supply is outwith the military context.

Q.2 Which medicines/drugs do you consider are being diverted and supplied illicitly?

Without investigating individual cases there is no way of knowing all the medicines that are being misused. However, benzodiazepines appear more frequently in the low number of cases we have seen in our CDT programme. With the tight controls over our medicines, there have not been any trends identified within the MOD to suggest recurring diversion or illicit supply. Because of potential illicit supply or diversion we have tighter controls on some of the more commonly misused drugs eg hypnotics, analgesics and drugs for impotence.

Q.3 What actions should healthcare and other relevant sectors taken to resolve the issue of diversion and illicit supply of medicines?

From a clinical perspective it is essential that healthcare organisations use appropriate resources and research to provide prescribers with the best information to make informed and evidence based decisions for each patient. It is also vital that organisations and regulatory bodies share information and make better use of Local Intelligence Networks. At a practical level, it is vital that prescribers and pharmacy personnel remind all patients on the dangers of misusing medicines and that once dispensed, they are patient specific - It is an offence to share with other personnel.

Q.4 What actions could the UK Government take to resolve the issue of diversion and illicit supply of medicines?

This is not for the MOD to direct but supporting better communication between healthcare organisations and regulatory bodies would improve the use of those medicines that are routinely diverted. Introducing the use of smart labelling and bar-coding on medicines would not only help with tracking diverted medicines but also prevent the misuse of counterfeit medicines.

Q.5 How prevalent is diversion and illicit supply of medicines within military settings, what are the demographics of users and is the trend rising or falling

I have covered this in question 1 and current evidence suggests that this is not prevalent, particularly compared to the civilian sector and other drug misuse. There have been no trends identified in either the type of drugs, demographics or numbers but Service Personnel that are more likely to use diverted medicines are young, single soldiers. Note that failing CDT remains consistently low. Trends with such a small sample are not statistically reliable.

If you require any more information on any of the points raised then please do not hesitate to contact me at the address above.

[signed on original]



For Surgeon General



Freedom of Information Publication Scheme		
Protective Marking: Not Protectively Marked	Publication (Y/N): Y	
Title: ACMD Diversion Illicit Supply of Medicines Inquiry- ACPO response to call for evidence		
Summary: Report outlining the National Policing lead officers response to the ACMD call for evidence for inquiry hearing on 12 June 2014		
Branch / OCU: SCO3 Drugs Directorate		
Date created: 6 June 2014	Review date: 6 June 2015	Version: 1
Author: Ian Goldsborough A/DCI		

Background.

This report outlines the National Policing lead for Controlled Drug Liaison activity, (Commander Simon Bray MPS), response to the Advisory Council on the Misuse of Drugs (ACMD) inquiry into the illicit diversion and supply of medicines.

The response is based on questionnaire returns from law enforcement officers engaged in this role. This was enhanced by contact with a number of close partners/stakeholders.

Limitations of response.

The short time frame available to respond to specific questions, posed by the review, meant that only a proportion of ACPO police forces have examined their disparate information and intelligence systems and provide a response. Competing demands may have made this impracticable in any case.

The questionnaire was therefore circulated to Police Officers and staff who are engaged throughout the United Kingdom in providing a policing response to the safe custody, use or illicit diversion of medicines that are controlled drugs.

The law enforcement response is, therefore, limited in the definitive data that can be provided to the council and relies heavily on professional perception and anecdotal support.

Law enforcement in this arena.

Figure 1 shows the Policing areas where there are law enforcement personnel who have some duties in relation to medicines within healthcare provision. The majority of these personnel share these duties with other roles (i.e. chemical liaison officer, drug expert witness, etc).

It should be noted that for the last few years re-organisation of individual Police Forces has often meant that the CDLO role has been dissolved, or personnel have retired and not been replaced. It is clear that a review of the issues and risks has meant that a number of forces are now employing staff to conduct these duties.



Figure 1.

Responses to questions asked

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

The responses accepted that no research had been conducted to properly assess the problem. It was noted that diversion and illicit supply did occur. Anecdotally it occurs throughout the UK and it is an apparently growing issue. Factors that contributed to this were seen as:

- General Practitioners over-prescribing or prescribing without thorough investigation to fraudulent or problematic users.
 - This results in excess medicine to be sold or passed on as those obtaining medicines in such a manner are more likely to divert substances onwards.
- Use of fraud or deception to obtain medicines in order to further use or dependence
- Use of internet to purchase medicines. These may then be sold on by the purchaser Benzodiazepams were noted.

The onward supply of prescribed medicines such as medicines to fund a Heroin habit is perceived as a significant issue and this is again an issue supported anecdotally.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

There was considerable consensus between respondents as to where the medicines were coming from. The small number of sources provided were:

- Users of illicit drugs, who are service users, obtaining prescribed medication and selling onwards to others in order that the service user may be able to purchase of the illicit drug responsible for treatment.

- Healthcare employees obtaining patient returns, patient's medicine or non controlled drugs available from stores. Using for themselves or divert to others.
- Patients sharing prescription only medicines
 - with family or close associates to provide pain relief, or
 - when large amounts prescribed - own use and sell or supply of remainder.
 - Patients being unsupervised at point of medication - allowing removal and diversion
- The internet facilitates purchase, especially from laboratories, or providers in other known countries.
- To a lesser extent the theft and fraudulent presentation of prescriptions.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

It is clear that although there will always be opportunist diversion of medicines and controlled drugs; and that from time to time new trends or popular commodities will become prevalent there are a number of medicines that are sought after, or diverted throughout the United Kingdom. The most commonly identified include:

Methadone - widely diverted.

Fentanyl patches,

Subutex

Pregablin and **gabapentin**- widely diverted.

All the Benzodiazapines (especially Diazepam) - widely diverted. In the South east of England there was an occasion of six individuals, who were not prescribed Diazepam, overdosing on it.

Zolpidem, Zopiclone- widely diverted.

Tramadol - widely diverted.

Temazepam- widely diverted.

Pregabalin- widely diverted.

Oxycodone - widely diverted.

Buprenorphine and strong analgesics.

Tramadol- widely diverted.

Methylphenidate- widely diverted.

Tamoxifen, Clomid and other aromatase inhibitors

Viagra,

Also Steroids and stimulants in the gym/bodybuilding are a longstanding area of concern with a growth in the use of Liothyronine (T3),Cytomel, Tamoxifen , other cytotoxins and hormones.

Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

In response to this question there was some discussion linking deaths and serious harms on individuals to the issue of diversion and illicit supply. The first example of two cases came from an east Midlands Police force, where there were two deaths in a house fire. The deceased had taken what they thought were Diazepam tablets but was, in fact, Phenazepam. Their children were unable to wake them.

The second example, from a North Western English force was an example of diversion of prescribed Fentanyl where the deceased swallowed a whole Fentanyl patch and died rapidly. The deceased had obtained it from an associate who, in turn, had stolen it from a relative's medication. The main area of concern was the ability of the patient to obtain extra supplies

of the patches by convincing both the pharmacist and practitioner that the patches were not adhering in the shower and not enough oversight was given to the additional supply by health professionals. This example shows a clearly significant risk to the public who obtain such medicines; it also places the Healthcare practitioners at professional risk and criticism by HM Coroner.

Where there is a dependency or problematic need for any commodity there is likely to be minimal negative impact on the public until such time when those with using the commodity either cannot fund the use within their means, or control is lost due to use of the substances. On these occasions the public may become victims of anti-social behaviour, acquisitive crime, or violence at the hand of the individual. Law enforcement partners and criminal justice stakeholders are engaged in dealing with high-harm offences, but we would not suggest, in any way that this is a diverted medicine issue.

There are a number of problems in relation to practitioners. Firstly, there is a body of law which means that practitioners who act outside it could be liable to prosecution. Additionally as registered professionals there is a risk of suspension, or lost livelihood, should their actions fall below what is acceptable in their role.

The diversion and onward supply of medicines, whether it is by fraudulent or continued over-prescription, or by theft or removal of returned CDs has a considerable cost implication to the Healthcare services, (and by extension the tax-payer). An additional real cost to be considered is the cost of future treatment to those who may become dependant or problematic users as a result of ingesting these commodities provided by diversion.

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

It is suggested that there needs to be more communication in relation to the issues discussed in this response.

- It is perceived that there is a need to inform patients of the addictive tendencies of these Prescription only medicines prior to prescribing. To allow a real, informed choice. Prescribers to regularly enquire into repeat prescriptions as opposed to continually handing out without consultation.
- Improved information sharing systems and communication between healthcare and law enforcement, to combat dual and over-prescribing. The sharing of information where GPS receive constant reports of patient lost prescriptions - where requests are made for duplicates. There should be support to clinicians to feedback any breaches regarding supply.
- Perhaps more preventative education is required in relation to medicines, the public are fully aware of the law and health implications concerning illicit street drugs, not much is said about medicines purchased over the internet, or sold/shared/diverted from genuine prescriptions.

Stricter supervision of those service users who are provided with controlled drugs when they attend to consume the drugs. There is a cost implication attached to this enhanced activity for the dispenser, however, if service users are supervised correctly there would be no opportunity for diversion. Consideration may be given for an alternative where the supervised issue of such drugs takes place at the drug treatment centres where the service conducts business rather than at community pharmacy.

A review into enhancing and improving record keeping and security into patient returns, especially controlled drugs. CDs used in end of life scenarios need far more monitoring and security in the way they are kept, returned and destroyed. This includes those at patient's

home addresses (One East Anglian Force is in the process of having sealed bags in the patient's home where certain drugs are administered by healthcare. This is recorded and monitored to reduce the risk of removal and diversion).

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

There is an amount of legislation that goes towards combating these issues but greater education more preventive education for patients & all healthcare professionals concerning addiction is needed.

This may include;

- Better guidance to all healthcare practitioners with regard to irresponsible and inappropriate prescribing. This would reduce the ability of individuals to visit GP practice and temporarily register and obtain drugs which then themselves become available to the market.
- Better measures to monitor and record private prescribing.

As stated above, legislation already exists that makes it an offence to supply medicines without proper authority. It was the opinion of the law enforcement personnel that a review and amendment, empowering police enforcement of breaches in the law where non-controlled diverted drugs are involved.

Alternatively the publication of policy or guidance for non-controlled drugs that are diverted where agencies have a duty to share information with regards all drug Diversion or illicit supply. This legally bound information sharing could include repeat requests for lost/stolen prescriptions

It has been suggested throughout this response that, anecdotally, the intranet plays a significant role in the illicit supply of medicines to users. It is appreciated that it is problematic to legislate or guide behaviour of this. However, there should be consideration to prohibit the advertisement or search facilities for controlled or licenced medicines on the open web. There is precedent for this when the United States Government took action against Google for allowing medicines on their sites. Again preventative or educational programmes using the very sites people visit may reduce demand or illicit supply.

Additional control could be considered with regards to -

- Improved monitoring of small scale pharmaceutical wholesalers and suppliers where records are often lacking. This provides additional opportunities for diversion and poor records reduce the opportunities of law enforcement to trace back supplies.
- The Methadone programme should also be reviewed and other methods considered. This includes sites of medication, record keeping and responsibilities under current regulations.

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

Respondents to the request for information all indicated that, in their opinion, such activity was either extremely prevalent or prevalent in their areas and that the trend for diversion was increasing.

It was suggested that this was not only amongst those receiving alternative medicines as treatment, but within the general public. There were reports of people travelling to multiple locations and also utilising private Doctors to obtain large quantities of medicine.

This understanding of prevalence is further supported in the eyes of some law enforcement personnel by localised numbers of personal harms or deaths (not thought to be supported Nationally by statistics) In examples of drug service users deaths in North West England, it was stated that there have frequently been large quantities of unused medication retrieved from the home or returned to healthcare premises and it was felt that this illustrated evidence of hoarding. (MB)

Further support of this suggestion is provided by the number of easily identifiable suppliers of such medicines. It is suggested that if there wasn't a demand for the drugs there would be so many sources of supply. A Google search, conducted by a Drug Expert Witness in an East Midlands Police Force showed that for "buy Diazepam" gives 2,800,000 hits, "buy Phenazepam;" 87,700 hits, "buy Zopiclone;" 1,430,000 hits, "buy "Tramadol;" 21,900,000 hits and buy "Methylphenidate;" 818,000 hits. While it is accepted that some of the sites identified will be forums discussing each drug and others will be duplicates this does show the scale of online supply.

Summary

Diversion and illicit supply is seen as a live and increasing trend within England, Wales and Northern Ireland by Law enforcement personnel. It will be difficult to quantify this from Police data as competing policing demands and objectives means that police activity and enforcement in relation to the illicit supply of medicines is limited. Whilst some of the substances subject to this enquiry may be controlled as Class A, B or C of the Misuse of Drugs Act 1971, police efforts will concentrate on those offenders and offences that cause the most harm to the communities and individuals they police. The Criminal Justice process and partners are unlikely to prioritise actions and prosecution, in general, at this stage and preventative education along with strengthening the law in relation to over-prescribing, record monitoring and sales of medicines over the internet are seen as in need of consideration.

MHRA

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Date 11 June 2014

Dear Professor Les Iversen

Call For Evidence - ACMD Diversion & Illicit Supply of Medicines Inquiry

Thank you for your letter dated 12 May 2014 concerning the Advisory Council on the Misuse of Drugs' (ACMD) Inquiry into the Diversion & Illicit Supply of Medicines, inviting MHRA to give written or oral evidence or both at the Inquiry to be held on the 12 June in London.

As previously confirmed to the Home Office ACMD secretary, MHRA is to provide written evidence for the Inquiry members to consider. This written evidence is provided in Annex A to this letter.

The Inquiry is asked to note that from a MHRA stand point diversion is the term used for the fraudulent activity where human medicines destined for non-EU markets re-enter the EU and are placed back on to the European market at a higher price.

The diversion of human medicines involves medicinal products being offered at preferential prices and exported to specific markets (normally third countries) outside the EU. Diversion occurs when unscrupulous traders, on receipt of the medicines, re-export the products back to the EU – with the consequence that patients for whom these preferentially-priced medicines were intended, are denied access to them. Such products appearing on the EU market are then known as “diverted” from their intended market. This represents not only a corrupt diversion for profit, but such activity also poses the risk of inappropriate or unlicensed use, and the risk that the product may also be compromised due to poor storage and transportation.

As a consequence the focus of MHRA evidence in Annex A is at a general level on the work of the Agency, illegal supply of medicines through unregulated supply and measures in relation to the Falsified Medicines Directive intended to prevent counterfeit medicines entering the supply chain. It is not specific to the supply of controlled drugs.

I am happy to address any questions once the ACMD has had opportunity to consider the evidence.

Yours sincerely,



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MHRA Background

The Medicines and Healthcare products Regulatory Agency (MHRA), is the UK government body responsible for regulating all human medicines by ensuring that they work and are acceptably safe.

MHRA is a Centre of the Medicines and Healthcare Products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC), and the Clinical Practice Research Datalink (CPRD). MHRA is an executive agency of the Department of Health.

Human medicines are subject to an extensive European regulatory regime that includes controls on the quality of materials used in their manufacture, the quality of manufacture and the way they are distributed within the European Community. It also sets out rules and standards to apply to the import of human medicines and substances used in the manufacture of human medicines from countries outside the European Community. (*Directive 2001/83/EC*)

The UK has legislation in place, for human medicines, for the protection of patients. Human medicines are controlled through the Human Medicines Regulations 2012 [SI 2012.1916] (*Prior to this the 1968 Medicines Act, the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, and its supporting regulations*). Amongst other things, the Human Medicines Regulations 2012 provide that it is unlawful for human medicines to be marketed, manufactured, imported from a third country, distributed and sold or supplied in the UK except in accordance with the appropriate licences or exemptions.

MHRA has powers to enforce the Human Medicines Regulations 2012 and will take regulatory action where breaches are identified. This may take the form of revoking licences or the instigation of criminal proceedings.

ACMD Inquiry questions

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

There is evidence to suggest that human medicines (and medical devices) are increasingly subject to illicit trading. The Internet has facilitated the supply of human medicines from websites and spawned a growth in illegal online trading.

Facts and figures can be provided from Operation Pangea – this is an international initiative to target illegal Internet trade in human medicines and was instigated by MHRA in April 2006. It started as the UK Internet Day of Action (IDA) and has grown annually into an International Week of Action. It is the largest internet based enforcement action of its kind to date. It is coordinated by INTERPOL and carried out with the assistance of police, the World Customs Organisation (WCO), and law enforcement agencies / drug regulatory agencies across the world.

The latest Operation Pangea (Pangea VII) ran between 11 May and 21 May 2013 where MHRA seized £8.6 million of counterfeit and unlicensed medicines in the UK, including huge hauls of potentially harmful slimming pills and controlled drugs such as diazepam and anabolic steroids.

This week-long international crackdown on the illegal Internet trade of human medicines resulted in seizures totaling approximately £18.6 million globally and resulted in 237 people being arrested worldwide. (More than 543,531 packages were inspected by regulators and customs officials resulting in the seizure of over 8,376,726 doses of unlicensed and counterfeit medicines worth approximately £18.6 million.)

This operation also targeted 10,603 websites that were illegally selling counterfeit and unlicensed medicines and led to them being closed down or suspended through having their domain name or payment facility removed.

In the UK, MHRA, with assistance from Home Office Border Force and local police, raided addresses in connection with the illegal internet supply of potentially harmful medicines.

This UK activity resulted in the seizure of 3.6 million doses of counterfeit and unlicensed medicines, five arrests and the shutdown of 1,891 websites.

A breakdown of the UK seizures highlights the trend towards lifestyle medications that are unlicensed, adulterated or controlled under the Misuse of Drugs Act 1971. The most commonly seized drugs were: erectile dysfunction medicines (1.2 million doses), slimming products (383,000 doses) and powerful and often misused drugs like sleeping pills, tranquilisers and antidepressants (330,996 doses). The majority of packages seized that contained human medicines supplied illegally originated from India and China, with 72% and 11% of seizures originating from these countries respectively.

For the first time MHRA targeted YouTube accounts and videos as criminals seek to exploit new channels to profit from the illegal sale of medicines. MHRA removed 18,671 videos since last year's operation and has seen an increase in the use of social media as the UK domain tree becomes a more hostile environment for criminals to operate in, due to a concerted effort cracking down on illegal activity on UK based websites.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

Intelligence suggests that a range of medicines/drugs are available for purchase in the UK, via the internet from bespoke websites – see details from Operation Pangea above.

Mainly the medicines involved are generic versions of licensed human medicines – for example versions manufactured in India. These are not licensed for the European market and any unlicensed sale and supply would be in breach of human medicines legislation. Some of the medicines supplied have been found to be counterfeit – China is a known source country.

A range of human medicines have also been discovered on digital platforms such as Amazon, E-bay and Gumtree. These include steroids, human growth hormones, Zopiclone and Tramadol.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

Intelligence suggests that the Internet trade mostly concerns “lifestyle” medicines rather than life-saving medicines. “Lifestyle” products include erectile dysfunction products, slimming tablets, baldness cures and smoking cessation products.

The reasons behind this are likely to include an embarrassment factor – buying online negates the need to consult face-to-face with a doctor.

Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

Unlicensed human medicines cannot be guaranteed to meet set standards of quality, safety and efficacy. They may contain too much or too little active ingredient – or none at all. Some have been found to contain adulterants – some dangerous and this poses unquestionable risks to public health

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

See response to Q6 below.

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

At a European level the Falsified Medicines Directive 2011/62/EU amends the principal Directive 2001/83/EC which lays down the rules for the marketing, manufacture and wholesale distribution of human medicinal products in the European Union. The objective of the Falsified Medicines Directive is

to introduce measures designed to strengthen the human medicines supply chain from the threat of falsified human medicines.

The Falsified Medicines Directive came into force in Europe in January 2013. To ensure the reliability of the supply chain the Directive substantially changes the European framework around the supply of human medicines and covers businesses that have traditionally not been directly regulated through human medicines regulation. It extends human medicines legislation to the entire supply chain, including brokers of human medicines, manufacturers, importers or distributor of active substances and persons that sell human medicines at a distance, all of which were previously unregulated. The Falsified Medicines Directive also introduces the requirement for a tamperproof evident seal and a unique identifier that will be used to track the human medicine to the point of dispensing.

The Falsified Medicines Directive is transposed through The Human Medicines (Amendment) Regulations 2013 [SI 2013/1855] which came into force on 20 August 2013.

Whilst the Falsified Medicines Directive introduces measures designed to strengthen the human medicines supply chain from the threat of falsified medicines it will impact on human medicines sold electronically at a distance to the public and will reduce the potential for diverted medicines.

Electronic distance selling.

The illegal sale of human medicinal products to the public via the internet is an important threat to public health. At a European Union (EU) level specific conditions for retail supply of medicinal products to the public have not been harmonised. Therefore Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty on the Functioning of the European Union (TFEU). The Falsified Medicines Directive amends the Community code relating to medicinal products for human use (Directive 2001/83/EC) to take account of internet sales.

Supplying medicines at a distance means that the service is provided without the parties buying and selling the medicines being simultaneously present. Sales of certain human medicines at a distance are permitted in the UK and are governed by regulations that require the supplier to be a person authorised or entitled to supply human medicines to the public.

The General Pharmaceutical Council holds a register of pharmacies, including those that supply human medicines via the internet, and a voluntary logo scheme provides some assurance to the public that the service provided is authentic as it is linked to 'bricks and mortar' premises and meets current regulatory requirements.

At present there is no common EU approach to encourage use of legitimate sources of sales of medicines at a distance, nor advice to discourage use of illegitimate sites.

Registration of suppliers of medicines at a distance

Under the provisions of the Falsified Medicines Directive the person offering to sell human medicinal products at a distance must provide the contact details of the body with which the service is registered.

Every page of a person's website that relates to the sale of human medicines at a distance must display a common EU logo that is to be adopted for such sites, together with a hyperlink to the national website of the Member State in which that person and their business is established.

Each national website must provide information on the national legislation relevant to the sale of human medicines at a distance, the purpose of the national logo, a list of suppliers of human medicines at a distance in that country, information on the risks of purchasing human medicines illegally from the internet and a link to the website to be established by the European Medicines Agency.

Any person offering to sell human medicinal products at a distance will be restricted to only selling a medicinal product that is authorised in the destination Member State. To accord with UK legislation where that sale is made to a member of the public that sale must comply with specific provision for prescription only medicines and those not on a general sale list and those that are.

These measures will affect those professions that are entitled to supply human medicinal products to the public if they sell at a distance:

- pharmacies offering their dispensing services and licensed human medicines over the internet
- retailers of human medicinal products (not POMs) that they sell on line. This will include large supermarket chains that provide internet shopping.
- doctors that offer online consulting with a dispensing service though generally they are affiliated to an online pharmacy for the latter part.
- dentists offering a similar service. However we not found any evidence of dentists offering medicines over the internet unless they have some kind of on line repeat prescription services).
- retailers of authorised homoeopathic and herbal remedies.

Common European logo

The logo to be used, and the means by which its authenticity is protected, will be determined by the European Commission and specified in separate implementing Acts regarding:

- a. the technical, electronic and cryptographic requirements for verification of the authenticity of the common logo.
- b. the design of the common logo.

These Acts have to be implemented by a year after the date of their publication.

The UK's transposing provisions of the Falsified Medicines Directive will come into force one year after a common logo has been agreed.

Safety features

The Falsified Medicines Directive introduces the requirements for the outer packaging of certain human medicines to include unspecified safety features which allow wholesale distributors and others who supply medicines to the public to verify the authenticity of the medicine by looking at an independently resourced and populated repository of information. The Falsified Medicines Directive provides for safety features comprising of a seal on the outer packaging (to indicate whether the pack has been tampered with) and a unique identifier to be applied to certain categories of human medicines. The safety features will enable individual packs to be identified.

The Falsified Medicines Directive states that these features must be applied – in principle – to all prescription-only medicines and to non-prescription medicines if they are at risk of counterfeiting. The exact nature of the safety features and the characteristics and the technical specifications of the unique identifier of the safety features will be decided by the European Commission in separate legislation (a delegated act).

The scheme, operated by the Commission, will put in place a transparent list of human medicines affected by these provisions, along with the exact nature of the safety features which meet the requirements in relation to authentication and identification.

The delegated act is expected to be in place by the end of 2014. Member States will have three years after adoption of the delegated act to ensure the requirements are put in place.

The unique identifier will be added to the packaging during its manufacture and checked into a community data base. The unique identifier will also allow for a single scanning of the medicinal product at the final supply point (Dispensing) or the "check-out" and will include transfer between territories and export to a non-EEA country.

The unique identifier will deter diversion because if a diverted product is returned to the supply chain the checking out procedure will identify its previous audit trail.

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

See response to Q1 to Q4 above.



Dear Sir/Madam,

Thank you for the opportunity to contribute to the 'call for evidence-ACMD Diversion & Illicit Supply of Medicines Enquiry'.

Napp Pharmaceuticals is a UK healthcare company, with a large base in Cambridge, and has been a leader in the field of pain management for over thirty years. The company is mainly involved with the manufacture and distribution of opioids, highly effective analgesics often used in the treatment of moderate to severe chronic pain, including cancer related pain.

Question 1.

In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

We can contribute to this enquiry with regard to the management of Napp's own supply chain. However, the company is not able to estimate the extent of diversion and illicit supply of medicines across the UK as a whole.

Mitigating risk and ensuring patient safety regarding its narcotic products are the highest priorities for Napp. The company has shipped narcotics worldwide for over 25 years. The Security Operations Group oversees the manufacture, storage and distribution of our products worldwide. This is a multi-layered approach and includes tamper-evident packaging, security auditing, documented processes and tracking technologies to protect our goods throughout the supply chain. The Napp security model is an industry benchmark and has used its processes to inform the pharmaceutical industry of best practice in complying with the Misuse of Drugs regulations.¹ The rigorous approach to security has enabled the company to transport raw oxycodone material from the USA since 2008 without incident. **There have been no instances of diversion from the Napp UK supply chain in the last 20 years.**

It is widely acknowledged there are important differences between the US and UK healthcare systems; GP prescribing is more closely monitored in the UK and individual patients are generally registered with a single GP. Consequently the prescription of opioids is more tightly controlled and wide scale addiction to prescription medicines is much less prevalent in this environment.

In addition to our own tight security arrangements, several significant enhancements to UK-USA customs relations have also further increased supply chain security in the UK. These include:

- Customs Cooperation Agreement (1997) - enabling closer cooperation, collaborative working and sharing of information.²
- Expansion of the 1997 Agreement in 2004 to include transport security cooperation, and container screening measures, with USA officials permanently stationed at UK ports.

At the EU level, the focus has been on coordination of national efforts to safeguard the drugs trade, providing a framework to combat the illicit trade in drugs and drug precursors (including minimising the risk of diversion in precursors) whilst leaving the licit trade in controlled narcotics to the Member States' national agencies to monitor.³

For further information, please contact Andrew Roberts on andrew.roberts@napp.co.uk

Question 2.

Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

There have been no instances of diversion of opioids from the Napp UK supply chain in the last 20 years. However, from our data systems, we can contribute the following information relating to instances of diversion that have occurred outside our supply chain that have been reported to the Napp Group.

Cumulatively to the 12th of May 2014, 34 drug diversion cases have been reported potentially involving at least one Napp product in the United Kingdom:

- Ten (29.4%) of these cases were confirmed by a healthcare provider
- Seventeen (50%) of these cases were received via media articles. **N.B. care must be taken when analysing data from media reports due to the unconfirmed nature and intent of these reports.**
- Oxycodone hydrochloride was mentioned in 18 out of the 34 reports.
- Morphine sulphate and buprenorphine were each reported as suspect in nine reports.
- Dihydrocodeine bitartrate was reported in six instances.
- Tramadol hydrochloride was reported in four cases.

Among the 34 cases, only one case referred to diversion using the internet. This case, sourced from a report received via the Public Health Agency in Northern Ireland, concerns a small group aged 17 to 20 years from the Derry area in Northern Ireland. This group had been abusing oxycodone, which was considered to have been obtained over the internet.

The remaining cases refer to medicines sourced from friends or diverted from healthcare services such as care homes, pharmacies or hospitals by healthcare professionals or criminals. Considering the relatively small volume of drugs diverted in these reports, it is expected that these medicines were sourced for personal use only.

In addition to the post-marketing data provided above, Mundipharma Research Limited has commissioned a data report on the results from the Global Drug Survey (GDS)⁴ conducted at the end of 2011 (GDS2012) and at the end of 2012 (GDS2013).

GDS⁴ conducts annual on-line surveys in the UK and Europe asking questions about the drug use habits of participants, including questions around their motivations for drug use, and where they had sourced their products from. Participation is advertised through a limited number of popular publications and social media outlets (e.g. Guardian, Mixmag, Gay Times, Reddit, Facebook, or Twitter).

The UK data presented in this document are based on participation in GDS2012 and GDS2013 only (8,184 in GDS2012 and 7,360 in GDS2013). In the UK samples surveyed, 24.7% and 35.8% reported use of at least one prescription opioid in the past 12 months, in GDS2012 and GDS2013 respectively.

Only a small minority of the population surveyed reported obtaining prescription opioids from the internet or from a dealer; the majority obtained from a doctor or a friend. This may suggest that in the UK there is no sizeable black market for prescription opioid painkillers.

Although these data provide some insight into the problematic use of prescription opioids in the UK, the limitations of these surveys should be considered. These include the fact that GDS utilises non-random, opportunistic, purposive sampling methods to recruit very large numbers of people who use drugs, over a very short time period. A more extensive review of GDS methodology and limitations can be found on their website⁴.

Question 3.

Which medicines/drugs do you consider are being diverted and supplied illicitly?

Napp does not feel that it is best placed to address this question. We suggest contacting relevant specialist healthcare professionals in pain medicine via the British Pain Society (www.britishpainsociety.org).

Question 4.

What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

Napp does not feel that it is best placed to address this question. Again we suggest contacting relevant specialist healthcare professionals in pain medicine via the British Pain Society (www.britishpainsociety.org).

Question 5

What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

Healthcare professionals should continue to work closely with the pharmaceutical industry to monitor patient safety and prescribing of opioid medicines to ensure that incidences of diversion and illicit supply of prescription medicines are appropriately reported. Prescribing decisions concerning opioid medications must be informed by a comprehensive pain assessment of the patient, and treatment must be tailored to the individual and monitored regularly. For some, opioids will be an appropriate and beneficial means of managing their pain, but this is not the case for everyone. When prescribed appropriately, opioids can reduce the negative impact that poorly controlled pain has on patients' quality of life. Napp supports the 2010 recommendations of the British Pain Society *opioids for persistent pain: good practice*⁵, especially Section 7 page 25 on 'opioids and problem drug use'.

Question 6.

What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

The European Council developed a comprehensive drug strategy, the EU Drugs Strategy 2005-2012 and two Action Plans.³ The strategy aims to provide a framework, objectives and priorities for Member States when implementing their national policies. The Home Office should consider options at a national level in line with these action plans. The Government should continue to work with customs authorities in the UK, EU and USA to build on the advances made as a result of the current regulations and collaborative work that is ongoing.²

Question 7.

How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

NAPP cannot comment on the prevalence of diversion and illicit supply of all the medicines available in the UK's market.

We can comment on the post-marketing safety data that was reported to the Napp group of companies and discussed in question 2. Demographic details of the subjects were reported to 24 out of the 34 cases of drug diversion reported. Among these, thirteen were male and nine were female; with regards to the age group of the subjects, eleven were between 22 to 44 year-old and two were elderly.

The UK samples surveyed in GDS2012 and GDS2013, also presented in question 2, are representative of a younger (average age 29 years) drug taking population, comprising of more males (70% for GDS2012 and 66% for GDS2013) than females. As stated above, these results have to be analysed carefully due to the study limitations. The demographic of users surveyed may represent an artefact of the media channels used and the access to the internet of the users. It is also relevant to highlight that this is the sample surveyed and not the population that reported diverting medicines.

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Dear Ali,

29th April 2016

ACMD Diversion & Illicit Supply of Medicines Inquiry: Health and Justice Evidence for final report

The evidence is submitted on behalf of **NHS England's Health and Justice Clinical Reference Group (H&J CRG)** and can be used in the publication of the ACMD report. The CRG supports NHS England in commissioning healthcare to: HM Prisons, Immigration Removal Centres; Secure Training Centres and Secure Children's Homes.

In Health and Justice secure environments illicit supply and diversion of opiate medication and also pregabalin and gabapentin occurs mainly in HM Prisons with less evidence of this in other residential settings and temporary custodial settings. The evidence overleaf is therefore based on the issues known within HM Prisons coupled with information gathered from primary care/community prescribing and information sharing as part of the wider offender healthcare pathway.

Since the submission of our evidence to the ACMD in June 2014, the H&J CRG have been leading and collaborating with partners on a number of programmes to improve the safe use of these medicines:

- Advice on prescribing of gabapentin and pregabalin Dec 14 (<https://www.gov.uk/government/publications/pregabalin-and-gabapentin-advice-for-prescribers-on-the-risk-of-misuse>)
- HMIP Thematic Review on changing patterns of substance misuse Dec 15 (<http://www.justiceinspectorates.gov.uk/hmiprison/inspections/changing-patterns-of-substance-misuse-in-adult-prisons-and-service-responses/>)
- The prison pain management formulary publications Dec 15 <https://www.england.nhs.uk/commissioning/health-just/pain-formulary/>
- Opioids Aware resource (Dec 15) <https://www.fpm.ac.uk/faculty-of-pain-medicine/opioids-aware>
- Formal training is now available from the Royal College of Anaesthetists, Faculty of Pain Management: [Pain in secure environments](#).

Signed: 

Mrs Denise Farmer MRPharmS
NHS England, Pharmaceutical Adviser Health and Justice Commissioning,

Copy:

Kate Davies OBE, NHS England Head of Armed Forces and their Families, Health & Justice and Sexual Assault Services Commissioning

Dr Linda Harris, Chair of Health and Justice Clinical Reference Group

Chris Kelly, NHS England Assistant Head Health and Justice commissioning

Evidence Requested:

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

Based on dialogue with clinicians, prescribers, commissioners and drug treatment service users and by looking at the significant increase in prescribing of over the counter medications there is widespread diversion, misuse and illicit supply. It has been reported in a number of forums by prescribers in primary care, prescribers in the custody setting and commissioners and providers of drug treatment services that people are seeking to gain prescriptions for medications to misuse (in particular gabapentin and pregabalin) by themselves or in order to sell on. It has been reported to and evidenced that Internet forums and blogs give advice about what medication to ask a GP for and a list of symptoms to describe to the GP in order to illicit the prescriptions. In the prison setting medications such as tramadol, gabapentin and pregabalin have continued to be involved in medication safety incidents related to abuse and diversion. These medicine safety incidents are reported by individual providers as part of quality assurance reporting

There are some worrying prescribing trends in some prisons from analysis of 2012 and 2013 data. For example in one prison holding approximately 1000 prisoners the prescribing of tramadol in a 3 month period increased from 39 patients in 2012 to 130 patients in the same 3 month period in 2013. Gabapentin saw a similar pattern - 2012 there were 16 patients on a prescription in the 3 month period but in 2013 this went up to 50, pregabalin prescribing followed the same trend there were 10 patients in the 3 months counted in 2012 but this increased to 48 in 2013. There was a similar prescribing trend in the other prisons - all saw an increase in the number of patients being prescribed these medications although not as marked as the prison described.

In primary care the trend is similar to that in the custodial setting, there has been a marked increase particularly in gabapentin and pregabalin. It is acknowledged that this increase in the prescribing of these medications doesn't necessarily constitute an increase in diversion or misuse but when all of this information is put together then it is clear that these medications may be over-prescribed and misused and this is across most areas of healthcare.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

The medications are coming from people who are genuinely having them prescribed but don't use them and pass them on to people they know. The medicines are also being prescribed for people who don't need them but persuade their GP to prescribe for them: These people may be involved in illicit drug use already and are engaged in drug seeking behaviour in order to supplement their own drug misuse or to sell on to other people. An abstinence based recovery centre offering support for people who have been through a treatment programme for either drugs or alcohol and attended an 'honesty group' reported that a number of the clients admitted that they were buying pregabalin (street name Budwiezer because it makes you feel drunk when you take enough of it) and using this instead of heroin. This isn't viewed in the same way as illicit drugs and there appears to be an acceptance amongst the client group that this can be used as it's not illegal, despite being obtained illicitly.

A pharmacist heading up medicines management in a CCG reported that people are going round NHS walk in centres in order to obtain prescriptions especially tramadol, generally a weeks worth of medication will be issued to a 'patient' so if they manage to get a few prescriptions in a day or a week they can then sell these on. It has also been reported that medication is being purchased off the internet.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

In the prison setting the medicines that are being reported as being misused and diverted are medicines that cannot easily be tested for and are outside the mandatory drug testing schedule. It therefore appears that gabapentin and pregabalin are especially sought after and being misused. It also appears that tramadol continues to be widely misused and traded. Other medications that are sought after are opioid analgesics (i.e. co-codamol). It is reported that buprenorphine (subutex) is still being traded in prison. This is brought into prisons by drug mules rather than being prescribed and diverted because very small numbers of prisoners are given this form of medication and if they are it is crushed before being administered under supervision.

Within the community there is wide scale diversion and misuse of prescribed medications including opiate substitution treatment, opiate based analgesics, benzodiazepines but the biggest increase in medications that are being misused and diverted seems to be gabapentin and pregabalin.

Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

In the custodial setting there are some real concerns about the numbers of prisoners who are being bullied and intimidated for medications that are legitimately prescribed for them but there are also prisoners who are clearly playing the system in order to get certain medication prescribed to them, either for personal use or to sell on. The other very real risk is the increased chance of overdose for people who misuse potentially dangerous medications such as tramadol, gabapentin and pregabalin. In one of the coroner's reports shared nationally it was suggested that the risks of misusing pregabalin and gabapentin should be highlighted. A suggestion has been made in local cases and regionally that gabapentin and

pregabalin should be included in the toxicology reports for all suspected drug related deaths.

A review of unclassified deaths in custody published in May 2012 also highlighted the issue of abuse and polypharmacy associated with opiate medication and pregabalin and gabapentin.

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

There are already policies and guidance in place ([PSI IDTS 2010/45](#) ; [PSO3550 Clinical Services for Substance misusers](#); [NHS England Guidance on the handling of Tramadol in Health and Justice Residential sites](#) June 2014) that healthcare providers can use to minimise the risk of diversion of opioid medicines (especially Schedule 2-4 CDs). These recommend that these medicines should not be held in the possession of prisoners but administered under supervision by a healthcare professional. There is also a plan for a recommended prison pain management formulary as part of the NOMS, PHE and NHS England Prison Healthcare Board partnership agreement.

There should be tighter controls relating to the dangers that some medications hold if they are abused. There should be more awareness raising for GPs in primary care and other prescribers about the fact that so many medicines are open to misuse and that if taken with other prescribed medications such as methadone or strong opiate based medicines that there is a real risk of overdose.

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

There needs to be much stronger controls around prescribing medications that are subject to misuse coupled with training of healthcare professionals (both at pre-registration and post-registration) that provides them with the skills and tools to identify patients that are potentially misusing or are unintentionally dependent on these medicines. It will be interesting to see if there is an increase in prescribing of strong opioid analgesics and or gabapentin or pregabalin once tramadol is rescheduled to a controlled drug. Medications with the potential for misuse should not be as widely prescribed, while it is of course right to acknowledge that there is a place for these medications and they do genuinely help people who genuinely need and benefit from them.

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

Below is a breakdown of the prescriptions generated and the cost of prescription is for medications that are reported to be widely misused. It is only for the Yorkshire & Humber PCTs and latterly the CCGs and covers the same three month period in 2012 and 2013. It does not cover prescribing in the acute trust settings or prisons. This information is used locally to compare rises in HM prison prescribing to establish whether similar trends are occurring.

Tramadol	2012 March/April/May	2013 March/April/May
Prescriptions	229436	241985
Cost	£1,576,799.93	£1,613,011.46
Gabapentin		
Prescriptions	95472	110754
Cost	£765,433.74	£555,743.26
Pregabalin		
Prescriptions	82058	99038
Cost	£5,428,200.65	£6,183,213.72

Based upon data collected from prisons and the community it appears that there is a very significant increase in the prescribing of gabapentin and pregabalin. National ePACT data shows that there is a wide regional variation in prescribing of these medicines (see Appendix 1 Figure 1).

An audit in prisons ([link](#)) showed that a) prescribing rates were double that in the community (see Appendix 1 Fig 2) and b) over 50% of prisoners prescribed these medicines have a history of substance misuse. These medicines are likely to be sought after by released prisoners (especially if this has been stopped during custody) and their abuse potential communicated into the wider community. A recent publication by Public Health England ([Management of Persistent Pain in Secure Environments 2013](#)) recommends that amitriptyline or nortriptyline are used as first line agents for neuropathic pain in this patient group. There has also been helpful publications to support clinicians in all care settings consider the place of gabapentin and pregabalin ([link](#))

Local initiatives have evolved to address this issue: In the Addiction to Medications Task Group in Yorkshire and & Humber there has been communication with a number of prescribing colleagues about the misuse of medications, including consultant psychiatrists, GPswSI, pharmacists and non medical prescribers. The group are focusing on the prescribing of pregabalin and gabapentin initially as this is where it was felt the most benefit could be done in terms of raising awareness about the potential misuse of these drugs and to educate other colleagues about the dangers of unregulated prescribing. The group even asked if it was possible to take pregabalin off formulary. This was discussed but as it was still identified as first line treatment in the recently revised NICE guidance it would be difficult to implement as there are some patients who benefit from the medications mentioned but it is clear that there should be much stronger awareness about the prescribing, more rigorous assessment for patients who present to primary care settings asking for these medications by name, and there should be much more done to review patients on medications open to misuse and diversion so that they are not able to divert medicines as easily.

Appendix 1: Primary care prescribing of Gabapentin and Pregabalin 2011-2013

Fig 1: Volume of prescribing (i.e. number of prescriptions)

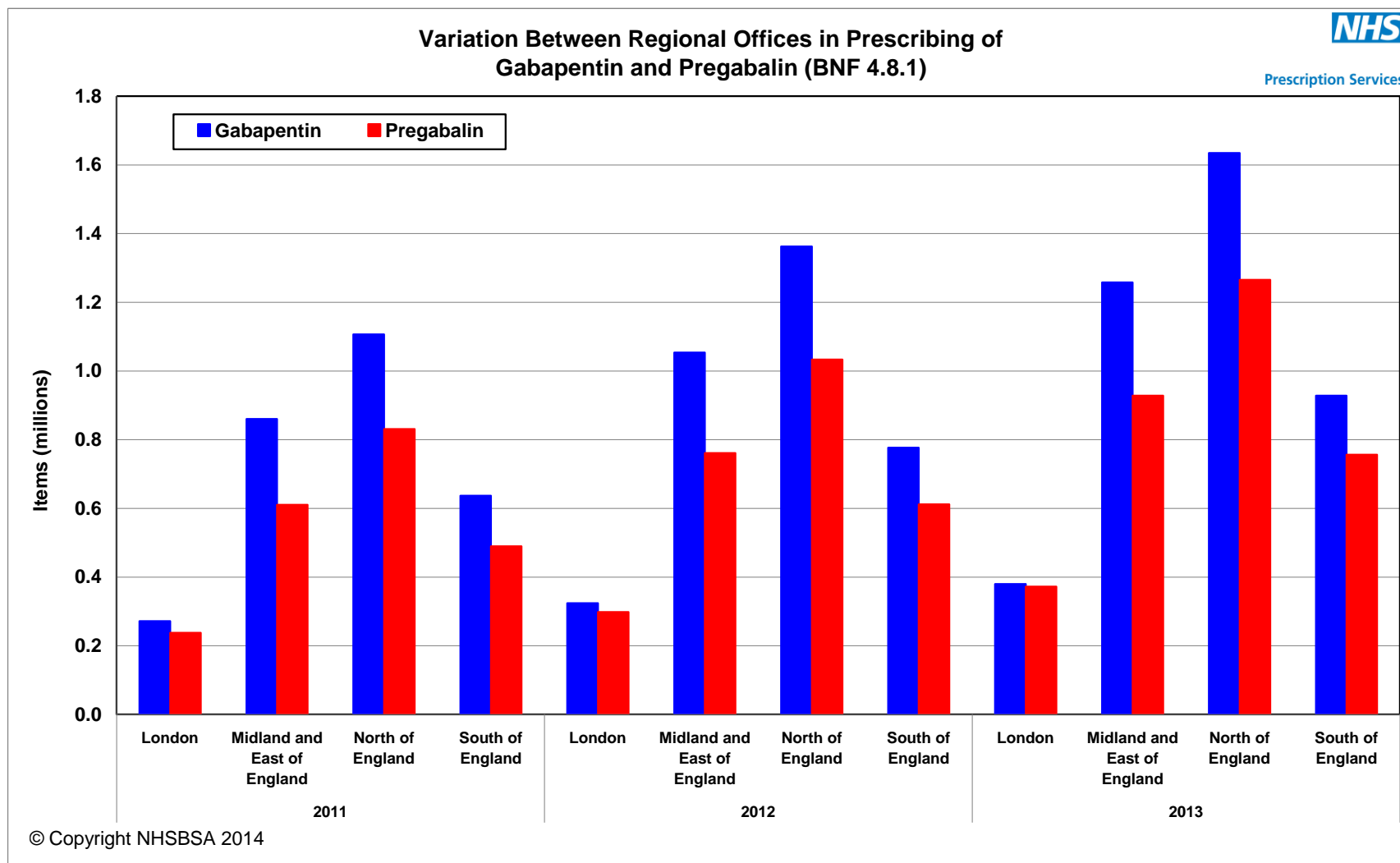
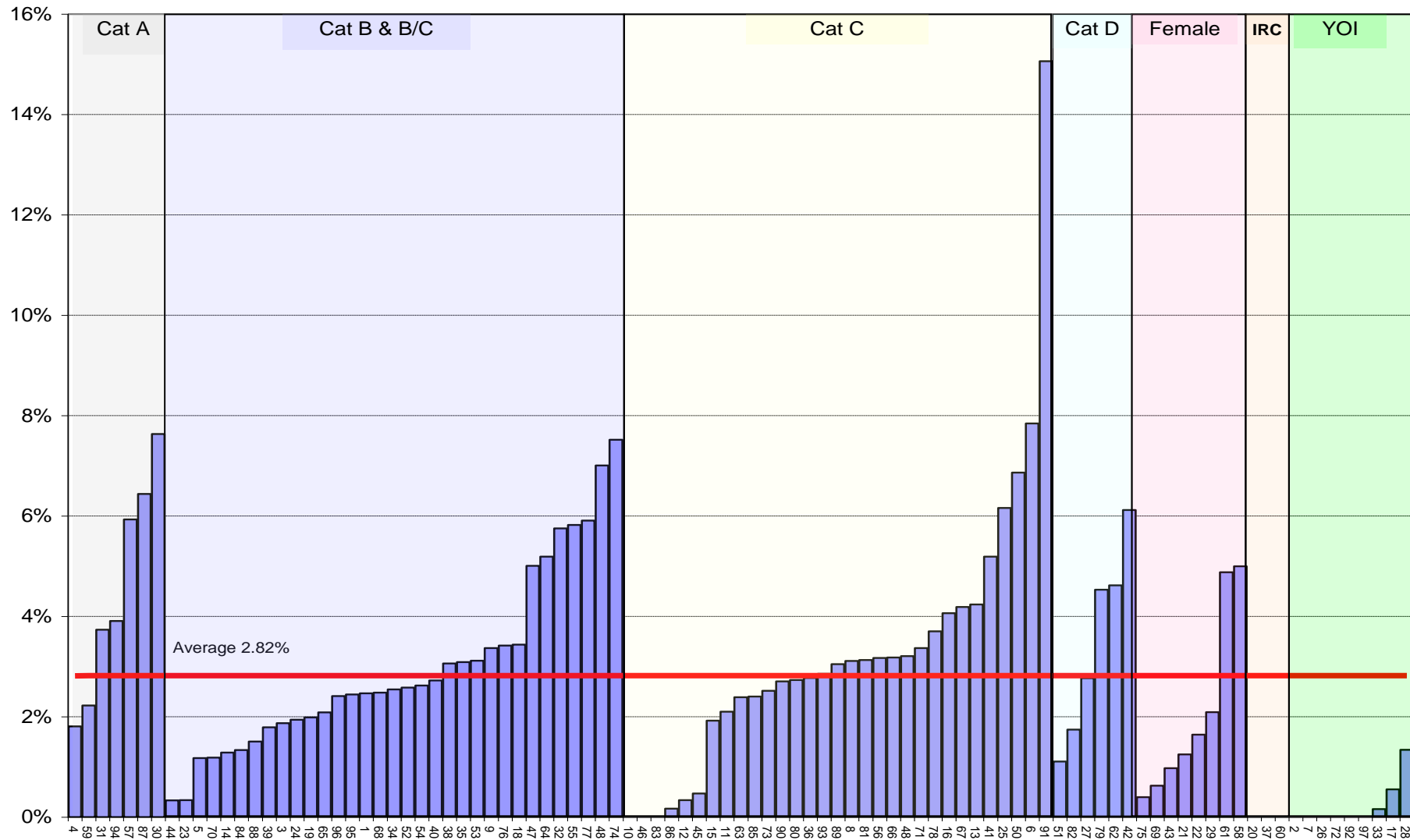


Fig. 2: Prescribing rates for pregabalin and gabapentin in HMP Prisons (by prison category) and Immigration Removal Centres (2012) n= 97



Published in "The prescribing and management of Gabapentin and Pregabalin in HM Prisons and Immigration Removal Centres in England audit report 2013"

4 June 2014

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ACMD Diversion & Illicit Supply of Medicines Inquiry

Reply to call for evidence from NHS Protect.

Dear Sirs,

Thank you for your letter to NHS Protect dated 12 May 2014 in relation to your call for evidence. Where we are able to respond to your questions, these are listed below. Limited background information is also attached for your information.

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

It is considered likely that the vast majority of NHS drug diversion does not come to the attention of NHS Protect. The true nature and scale of NHS drug diversion is not known or possible to estimate at this time.

In this context, NHS drugs means drugs that have been purchased by the NHS/Department of Health for the benefit of NHS patients, or made available via an NHS prescription.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

Intelligence indicates that the majority of drug diversion takes place at community pharmacies by patients/third parties.

The majority of known attempts to divert drugs by patients and third parties relate to alterations and additions to genuine prescription stationery.

It is possible that those attempts to divert NHS drugs that are less easily detected are not coming to the attention of NHS Protect.

Other principal areas of patient diversion known to occur include:

- multiple-scripting
- obtaining repeat prescriptions where there is no longer a clinical need, and
- theft of prescription stationary.

Formal reports to NHS Protect on the theft of NHS drugs from hospitals, pharmacies, surgeries and drug treatment clinics are rare.

While these matters are likely to be reported at a local level, it also considered likely that there is significant under-reporting to NHS Protect. A request for information to all police constabularies in England for the period 1 April 2012 to 31 March identified 147 crimes involving controlled drugs where the NHS was the victim. Twenty three of the 39 police constabularies contacted replied to our request.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

Intelligence indicates that the vast majority of reported drug diversion coming to the attention of NHS Protect is likely to be related to achieving or managing recreational highs.

A review of 120 suspected drugs diversions occurring between 1 January 2013 and 31 January 2014 identified the following prevalence of drug types:

	Number of reports	As a percentage
Diazepam	51	42.5
Codeine (including codeine phosphate)	16	13.3
Dihydrocodeine	15	12.5
Zopiclone	13	10.8
Clonazepam	6	5
Temazepam	6	5
Tramadol	4	3.3
Methadone	2	1.7
Other	7	5.8
Total	120	100

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

It is recommended that those NHS bodies with a responsibility for the management of controlled drugs follow guidance issued by NHS Protect. These include:

- Medicine security self-assessment tool
- Security of prescriptions forms guidance
- Security standards and guidance for the management and control of controlled drugs in the ambulance sector

Regards,

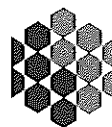


Chris Cockell
Intelligence and Research Development Manager

Background

1. NHS Protect is the operating name of the NHS Counter Fraud and Security Management Service.
2. NHS Protect is a named responsible body under the Controlled Drugs (Supervision of Management and Use) Regulations 2006.
3. The medicine security self-assessment tool is designed for use by providers of hospital based pharmacy services in the acute, mental health and community settings. The tool focuses on the security and governance arrangements of all medicines within the organisation. It has been designed to support chief pharmacists in their evaluation of organisational policies and procedures against guidance and legislative requirements for the secure management and storage of medicines. The self-assessment tool can also be used to demonstrate on-going progress against identified actions. Instructions for completion are in the main document.
4. The guidance on security of prescriptions forms aims to assist those responsible for the security of prescription forms to develop and implement local procedures and systems in this area. It is an updated version of NHS Protect's guidance on the subject, following the changes introduced by the Health and Social Care Act 2012. The guidance applies to both NHS and non-NHS settings.
5. The security standards and guidance for the management and control of controlled drugs in the ambulance sector sets out security standards to improve the safe and secure management of controlled drugs in ambulance trusts in England. The guidance establishes minimum security standards for ambulance trusts and their contracted providers and makes recommendations for best practice. First published in June 2012, the document has been revised to take account of recent changes and new secondary legislation, particularly the Controlled Drugs (Supervision of Management and Use) Regulations 2013. Ambulance trusts should use it as a starting point to review and improve security standards for the management and control of controlled drugs in their trusts.
6. NHS Protect manages the Pharmacy Reward Scheme. The pharmacy reward scheme pays pharmacists a reward of £70 if they identify a fraudulent prescription (i.e. a form which is not a genuine order for the person named on it, e.g. stolen, counterfeited or illegitimately altered). During the period 1 April 2012 to 31 March 2013 only 1.4% of all pharmacies submitted one or more claims under the scheme.

FROM THE MINISTER FOR HEALTH,
SOCIAL SERVICES AND PUBLIC SAFETY
Edwin Poots MLA



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Our Ref: SUB/477/2014

Date: 10 June 2014

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Dear Professor Iversen & Hill

Call for Evidence – ACMD Diversion & Illicit Supply of Medicines Inquiry

Thank you for the opportunity to input to the Advisory Council on the Misuse of Drugs' (ACMD) Diversion & Illicit Supply of Medicines Inquiry.

The written response from Northern Ireland (attached) incorporates input from the Department of Health, Social Services and Public Safety, the Department of Justice, the Health and Social Care Board, the Police Service of Northern Ireland, and the Organised Crime Taskforce Substance Misuse Subgroup. At this stage we do not propose to give an oral presentation, however officials in my Department are happy to discuss this response further with the ACMD as required.

This is an important issue, and one that is of increasing concern in Northern Ireland. I therefore look forward to seeing the outcomes of this work and this in turn informing practice right across the UK.

Edwin Poots MLA
Minister for Health Social Services and Public Safety

NORTHERN IRELAND – input to ACMD Diversion & Illicit Supply of Medicines Inquiry

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK/Northern Ireland?

The misuse of prescription drugs has been recognised as a growing issue of concern in Northern Ireland. It was therefore identified as an emerging issue in the Northern Ireland Strategy to prevent and address the harm related to alcohol and drug misuse, known as the New Strategic Direction for Alcohol and Drugs Phase 2 (http://www.dhsspsni.gov.uk/new_strategic_direction_for_alcohol_and_drugs_phase_2_2011-2016, pp 24).

In light of this a task and finish group was established to scope the issue and develop an action plan for consideration and implementation by key stakeholders. This was finalised in summer 2013 (attached), and work is now underway to develop an appropriate response.

This work includes measures to improve our information base in relation to the misuse of prescription and over-the-counter medicines; raise awareness and workforce development; reduce inappropriate prescribing; tackle diversion, displacement, illicit markets, and internet purchases; and provide appropriate treatment and support.

Given the nature of the issue, it is very difficult to get a clear picture of its size and scale. Experience and anecdotal evidence suggests that diversion and illicit supply of medicine is a direct cause of prescription drug misuse.

The following statistics may help to set the overall context:

Prevalence

- Prevalence rates on the use of (though not misuse of) sedatives and tranquilisers and anti-depressants in Northern Ireland were published in the 2010/11 Drug Prevalence Survey (http://www.dhsspsni.gov.uk/bulletin_1-ni_prevalence_rates.pdf and http://www.dhsspsni.gov.uk/bulletin_6-

[sedatives or tranquillisers and anti-depressants.pdf](#)).

- This survey showed that 21 % of adults (aged 15-64 years) had used sedatives and tranquillisers and 22% anti-depressants (22%) at some point in their lifetime.
- 11% had used sedatives and tranquillisers and 12% anti-depressants in the last year.
- In the last month 8% of respondents had used sedative and tranquillisers and 10% had used anti-depressants.
- Since the last survey in 2006/07 there has been an increase in the last year and last month use of anti-depressants; last year use has increased from 9% in 2006/07 to 12% in 2010/11 and last month use has increased from 8% in 2006/07 to 10% in 2010/11.
- Comparative figures for the Republic of Ireland are as follows: lifetime prevalence of 14% for sedatives and tranquillisers and 10% for anti-depressants; last year prevalence of 7% and 5% respectively; and last month prevalence 3% and 4% respectively.
- The survey shows that the majority of respondents reported obtaining the drugs on prescription on the last time they had taken them. 95% of respondents that had used sedatives and tranquillisers in the last month, 99% of respondents that had used anti-depressants in the last month and 69% of respondents that had used other opiates in the last month, obtained the drugs on prescription the last time they had used them.

Treatment

- Treatment figures are reported in the Drug Misuse Database (http://www.dhsspsni.gov.uk/dmd_report_2012-13.pdf). According to the most recent figures benzodiazepines were the second most commonly reported main drug of misuse reported by 14% of individuals, and codeine & paracetamol were reported as the main drug of misuse by 2%.

Deaths

- Provisional figures show there were 110 drug-related deaths in Northern Ireland in 2012 (<http://www.nisra.gov.uk/demography/default.asp30.htm>):
 - 46 had a benzodiazepine mentioned on the death certificate

- 28 mentioned an antidepressant
- 4 mentioned paracetamol
- 22 mentioned Codeine (not from compound formulation)
- 8 mentioned Dihydrocodeine (not from compound formulation)
- 31 mentioned Tramadol

Further information on statistics in Northern Ireland can be found at:
http://www.dhsspsni.gov.uk/index/stats_research/stats-public-health/stats-drug-alcohol.htm.

The reasons for the misuse of prescription drugs in Northern Ireland are varied but may include:

- Legacy of prescribing (some related to Northern Ireland's history - see: http://jech.bmj.com/content/65/Suppl_2/A14.2.abstract)
- Reductions in levels of prescribing in recent years
- Internet sales
- View of prescription drugs as a "safe and acceptable" alternative of illegal drugs
- The quality (perceived or real) of prescription meds vs. illegal drugs

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

The PSNI have stated that the majority of illicitly supplied prescription drugs enter the Northern Ireland market via the postal system, usually from Asia (and Pakistan in particular), however other identified countries of origin have included African countries and Malaysia. In addition, the Operation Pangea report (2013) identified as the primary region of origin of shipment to receiving countries (including UK and Ireland): India (28 per cent), China (including Hong Kong – 14 per cent), and Singapore (6 per cent) were the most frequently mentioned countries.

Individuals can order prescription drugs easily over the internet and information held by PSNI suggests this is done both by individuals for personal use and also by organised crime groups for onward supply. Organised crime groups involved in the supply of prescription drugs appear to usually provide these as an additional 'service'

alongside the supply of other drugs.

Medicine diversion from legitimate prescription sources may also be a factor in individual cases. It is difficult to gauge how large a problem this is; it is often only discovered by chance intervention from GPs or pharmacists. Whilst this may not be on the scale of the entry of drugs via the postal system it is still of concern and poses a real danger to life, particularly where potent drugs such as fentanyl, morphine and oxycodone are concerned.

There are anecdotal reports that some drug misuse relates to using prescription medicines to manage the “come down” from other illicit/illegal substances. These are often said to be purchased via “friend” and may be diverted from legitimate prescriptions.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

In the 2013/14 financial year PSNI seized a total of 148,366 benzodiazepine tablets as a result of 475 seizure incidents. This was an increase on the previous year when 95,542 tablets were seized in 444 seizure incidents. (Please note: additional tablets may have been seized by UK Border Agency and not included in these figures).

There have also been seizures, and reports of wide spread availability from drug services and service users, of:

- The Z drugs
- Tramadol
- Opioids (Fentanyl in particular)
- Pregabalin/Gabapentin
- Viagra / performance enhancing drugs.

Northern Ireland is recognised as having significantly higher than UK average prescribing rates for benzodiazepines. In 2012 a total of 28,787,582 diazepam tablets (2mg, 5mg and 10mg) and temazepam tablets (10mg and 20mg) were dispensed in Northern Ireland. This equates to almost 16 tablets for every person living in the country, and is significantly higher than the rate seen in England (which

is around 4 tablets per head).¹ Equally, in Northern Ireland there were 15,521,802 tramadol 50mg capsules dispensed in 2012. This equates to almost 9 capsules for every person living in the country. In this instance, rates in England are higher, at around 11 capsules per head.

Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

We have reports and information relating the misuse of prescription drugs to the following issues, though it is difficult to put firm figures against these:

- Drug related harm including overdoses, admission to hospital, and deaths.
- Family difficulties.
- Hidden harm (children living with substance misusing parents).
- Work difficulties and debt.
- Potential interaction with criminal networks.
- Demands for increased supply of meds.
- Reluctance to reduce consumption.
- Anti-social behaviour.
- Criminal behaviour and links with organised crime.

Prescription drugs are mentioned on over two and a half times as many death certificates as heroin, methadone, cocaine, amphetamines and mephedrone combined (503 deaths between 2002 and 2012), with benzodiazepines specifically accounting for almost half of all death certificates where a specific substance is named. Another area of significant growth is that of deaths where tramadol is mentioned on the death certificate. These deaths have almost doubled between 2011 and 2012 in NI, and have increased by 182% between 2008 and 2012 (up from 11 in 2008 to 31 in 2012). This increase is mirrored in England and Wales where the figure has increased by 86% between 2008 and 2011 (up from 83 to 154).

Individuals who have originally been prescribed these drugs may now have issues

¹ Information derived from publicly available prescription data - <http://www.hscbusiness.hscni.net/services/1806.htm> and <http://www.hscic.gov.uk/searchcatalogue?productid=11412&q=title%3a%22prescription+cost+analysis%22&sort=Relevance&size=10&page=1#top>

with addiction but may be unwilling to seek medical help due to embarrassment, denial or the perceived stigma attached to drug addiction. Deaths seem to be increasing, potentially due to addicted individuals failing to seek treatment and instead taking tablets from an unreliable source (which may lead to users taking tablets with more active ingredients than they are used to, taking counterfeit tablets or taking more tablets than would normally be prescribed by a GP) and/or increasing poly drug use. The growth in an illicit market for prescription drugs has led to growing concerns over polydrug use in Northern Ireland. This is an issue noted globally², and in Northern Ireland 61% of those presenting with problem drug misuse in 2012/13 recorded misusing more than one drug. Polydrug use increases the risk of adverse effects and accidental overdose.

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

- The problem of illicit supply appears to have arisen partially as a result of increased availability of medicines over the internet. The majority of websites are hosted outside of the UK, with counterfeit, unlicensed and diverted products being imported via the postal system. Law enforcement intervention is required in respect of websites and also seizures at ports and postal hubs.
- Prioritisation of enforcement activity – Misuse of Drugs Act and Medicines Regulations.
- Ensuring prescribing is only undertaken as clinically indicated and in line with appropriate guidelines.
- Control legitimate supply of drugs by ensuring prescription security and that patients who are prescribed controlled drugs or other drugs subject to abuse should be taking them and know how to take them. This can include educating prescribers on the abuse potential of drugs and monitoring for inappropriate prescribing at through prescribing data.
- The need to identify those who are misusing prescribed substances, provide advice and support, brief interventions, and referral to treatment and support.
- Offer alternatives – such as CBT etc
- Increase the number of prescribed medication practitioners in community

² United Nations Office on Drugs and Crime (2013). *World Drug Report 2013*.

addiction teams

- Opioid/ substitute treatment services have traditionally treated street drug addiction in particular heroin. The focus of such services may need to change or widen to include diverted and illicit prescription drugs
- Increase the flow of information through early warning systems of changing trends in prescription drug misuse
- Educate the public and respond to local needs through community led initiatives such as drug disposal bins.

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

- Encourage and fund the above (Q.5)
- Measures to stop people keeping/stockpiling unwanted/unused medicines (drug bins, etc)
- Raise public awareness of dangers
- Tackle illicit supply/availability, including work with international partners.
- Ensure that sufficient resources are deployed to detect and take appropriate enforcement action against those unlawfully importing or supplying medicines.
- Support enhanced collaborative working between Healthcare, law enforcement and other relevant sectors.

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

- Prevalence rates are higher for older respondents (35–64 yrs) than younger respondents (15–34 yrs) for both tranquillisers or sedatives and anti-depressants.
- In relation to sedatives or tranquillisers, females reported higher significant prevalence rates than males for lifetime prevalence and last year prevalence.
- There were significant differences between males and females for all three prevalence rates for anti-depressants, females having higher prevalence rates than males.
- The average (median) age that respondents reported they had first used sedatives or tranquillisers was 32 years – 31 years for males and 32 years for females.
- Over two-thirds (69%) of current users of sedatives or tranquillisers and over nine in ten (94%) current users of anti-depressants took them daily or almost daily.

- Those who are divorced, widowed or separated reported high prevalence rates for sedatives or tranquillisers and anti-depressants.

Action Plan

Scope: The group is keen to identify 5-8 key activities or actions, within our direct control, that can be taken forward. Wider action on improving mental health or the availability of mental health services will not be within the scope of this work. Actions can then be built on and further developed as progress is made.

Target Audience for Actions/Interventions: Discussions have identified three different target groups: (a) the general public / recreational misusers; (b) those on long-term prescriptions who may or may not be “topping up”; and (c) those dependent on prescription drugs / polydrug misusers / complex cases.

Drugs: To date much of the focus has been on benzodiazepines and the “Z Drugs”. If we look at trends elsewhere, and emerging issues in NI, we may see increases in misuse of other prescription drugs and thus we need to consider the full range of substances – including opioids, steroids, etc.

Areas of Action: The group has also identified a number of overarching areas for action and these include Data; Prevention/Awareness Raising (including workforce development); Reducing Supply; and Intervention and Treatment.

Implementation: Implementation will be overseen via the existing NSD Phase 2 structures.

Areas of Action: Data			
Issue	Information	Action	Lead
Current level of prescribing and misuse.	<p>It has been noted that it is very difficult to get robust information in the area.</p> <p>We have been provided information and presentations from:</p> <ul style="list-style-type: none"> • Addicts’ Index, Drug Misuse Database, Drug Prevalence Survey • Prescribing Rates (COMPASS) • Homeless Services • Forensics 	<ul style="list-style-type: none"> • Need to collate available information to produce a best estimate paper of current position. • Consideration given to work with Forensic Services to consider if information can be provided on levels of active ingredients in seized substances and share information as appropriate 	<ul style="list-style-type: none"> • IAD with input from HSCB/PHA • PHA
Information and Research.	<p>There may be a need for further research, identification of good practice and the consideration of developments elsewhere. There may be a particular need to try to identify the actual level of misuse compared to legitimate use of prescribed drugs/OTC medicines.</p>	<ul style="list-style-type: none"> • Consideration given to research calls in this area. 	<ul style="list-style-type: none"> • PHA

Areas of Action: Prevention/Awareness Raising			
Issue	Information	Action	Lead
Raising awareness among professionals.	There are a range of schemes, initiatives and models already in place however often these are ad hoc and vary from area to area. It would be very useful if we could bring greater consistency to work on this issue and share learning and best practice.	<ul style="list-style-type: none"> • Develop a range of specific prescription drug misuse workshops, starting with prescribing of benzos, to share information and best practice and improve consistency across NI. • Following on from the workshops, consider the development of audits or guidelines that can be disseminated to professionals 	<ul style="list-style-type: none"> • DHSSPS with input from PHA
Workforce Development	There a number of key groups and stakeholders who need to be engaged on this issue within the HSC workforce including community pharmacies, other key professionals, and the community/voluntary sector.	<ul style="list-style-type: none"> • Workforce development on prescription drug misuse should be a key element of the Alcohol and Drug Services Commissioning Framework. 	<ul style="list-style-type: none"> • PHA/HSCB
Awareness Raising among the public and prescription drug misusers	There are varied perspectives on the use of prescription drugs, and there may be a need to challenge some of the attitudes in this area – in particular, people may feel because these substances are available on prescription that they are “safe” for use by those not prescribed them.	<ul style="list-style-type: none"> • Support and dissemination of the MRG campaign in relation to the use of substances not prescribed for you. • Prevention and Education section of the Alcohol and Drug Services Commissioning Framework should reference issues around prescription drug misuse. • Engage community pharmacies in campaigns to raise awareness of the issues associated with prescription and OTC medicines including the display of promotional materials, provision of information and advice in the pharmacy and outreach to local communities. 	<ul style="list-style-type: none"> • MRG with input from HDPB and PHA • PHA • PHA/HSCB

Areas of Action: Reducing Supply			
Issue	Information	Action	Lead
Schemes to support appropriate reductions in prescribing levels	There are currently a number of schemes in place in different areas in relation to prescribing by Health Professionals.	<ul style="list-style-type: none"> • Use of annual prescribing visits to promote and support appropriate prescribing practices. • Support the update and dissemination of the HSCB Benzodiazepine Resource Pack. • The forthcoming PHA/HSCB regional addiction services commissioning framework should support local initiatives including the Prescribed Drug Misuse Practitioners. • Development of a regional 'minimal intervention'¹ benzodiazepine reduction plan for implementation in all GP practices during 14/15. • Consideration of further work in due course with pain clinics etc. 	<ul style="list-style-type: none"> • PHA/HSCB • HSCB • DHSSPS
Reduce OTC medication misuse	Over-the-counter (OTC) medication misuse often occurs in combination with prescribed and unprescribed medication misuse. Reduction strategy is often limited to refusal of a sale.	<ul style="list-style-type: none"> • Raise awareness of OTC misuse with pharmacists and GPs, including implication of opioid prescribing decisions • Investigate use of in-pharmacy information for patients • Commission community pharmacies to provide brief interventions as a tool by pharmacists and pharmacy staff including signposting to other services. 	<ul style="list-style-type: none"> • PHA/HSCB
Displacement, illicit markets, and internet purchases	Many of these substances are available through illicit markets, and via the internet.	<ul style="list-style-type: none"> • Continuation of seizures and operations to disrupt the market. • Support for this issue to have a raised profile within PSNI/UKBA/OCTF, etc. • Ongoing involvement in Operation Pangea. 	<ul style="list-style-type: none"> • MRG/PSNI

1. **See Minimal interventions to decrease long-term use of benzodiazepines in primary care: a systematic review and meta-analysis** Br J Gen Pract. 2011 September; 61(590): e573–e578

Areas of Action: Intervention and Treatment			
Issue	Information	Action	
Treatment and Support Services	Currently most people who require treatment or support in relation to their misuse for prescription drugs are picked up through existing addiction services. However, the needs of those who misuse prescription drugs may be different from tradition illegal drug users,	<ul style="list-style-type: none"> Alcohol and Drug Services Commissioning Framework should consider the consistency of approaches across NI. Further consideration given to emerging evidence around the treatment of prescription drug misuse. 	<ul style="list-style-type: none"> PHA/HSCB Treatment and Support Advisory Committee
Harm Reduction	For those who can't or won't stop misusing these substances, harm reduction techniques should be available.	<ul style="list-style-type: none"> Provision of clean needles for those who inject. Targeted harm reduction messages issued those at risk. Access to substitute prescribing where appropriate. 	<ul style="list-style-type: none"> PHA/HSCB
Liaison Services	Many people who misuse prescription drugs may come into contact with the Health Service in a range of settings. The HSC should be able to screen those in contact with services for prescription drug misuse and provide appropriate advice and support.	<ul style="list-style-type: none"> Work is currently underway to consider the roll-out of Substance Misuse Liaison Posts across Northern Ireland – these posts should also consider and support those with prescription drug misuse. 	<ul style="list-style-type: none"> PPHA/HSCB

ACMD - Diversion & Illicit Supply of Medicines Inquiry.

Written Evidence from Professor Matt Griffiths RGN, A&E Cert, FAETC, NISP, BA (Hons), PHECC. Independent Nurse Consultant, Emergency Nurse Practitioner, Consultant Adviser to the Royal College of Nursing on Prescribing & Medicines Management.

Correspondence via – matt@matt-griffiths.com

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

From personal experience the extent of diversion seems to be considerable, medications such as Ketamine (Special K) are widespread.

The supply of illicit medicines certainly appears to be widespread in the UK. Collecting statistical data will inevitably be difficult as this is illegal activity, and therefore much of the evidence will be based on personal experience and case studies.

Dosing of powder formulations is variable as users don't know the purity (as many substances are cut down), and many naïve users take multiple substances at the same time. This does inevitably cause health problems which are highlighted later in this submission.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

We don't generally ask patients where they get their illicit medicines from, however I am aware through personal experience of patients who have ordered medicines via the internet. These include anabolic steroids which seem to be available in every gym in the country and users really don't see any harm in.

In the Shipman committee workstream on private prescriptions (which was multi agency) , it was highlighted that some private providers of substance misuse and weight loss services were prescribing excessive supplies to their private patients, these were highlighted and some of these health providers were known to the police who were investigating this.

From extensive personal clinical experience, Ketamine (Special K, or K) abuse seems to be extremely popular at present. I am not aware of any specific cases of Ketamine being diverted from UK hospitals or clinics but believe theft from Veterinary surgeries is extremely common in some countries, such as the USA.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

Codeine, diazepam, temazepam, morphine, ketamine, anabolic steroids. In fact anything that has the ability to be abused.

Illicit drug use tends to focus on 'fashionable' drugs of the times, for example acid/LSD use seems relatively low at present, with Ketamine use being very popular and easily accessible.

Medicines that are diverted are sometimes in pill form or often in a powder formulation. Powders are sometimes snorted, sometimes wrapped in a rizla paper (called a Bomb) and then swallowed, and more commonly now medicines such as cocaine in a powder form are used via 'Coke Bullets' which allow small doses to be used easily in everyday situations covertly without needing to cut the powder and roll up banknotes etc to snort.

I have been involved in several cases of clinicians diverting medicines. There are good procedures in place for higher schedule CDs, however lower schedule CDs such as codeine tablets, and diazepam have less stringent storage and checking requirements. It is only usually highlighted that this goes missing when large quantities are being used. One trust that I worked in used biometric drug cabinets, this allowed us to easily identify who was removing the stock, as the system used fingerprint recognition. The Nurse practitioner involved was arrested by the police and reported to the NMC.

In another case which I was involved in, a nurse has been stealing morphine for her own use. This was picked up much quicker as the checking procedures are much more stringent for the higher schedule medications. The nurse went to court, but as her name was spelt slightly differently and the nurse wasn't originally reported to the NMC. This allowed the nurse to avoid the NMC's ruling on her practice. I did report the nurse to the NMC with her knowledge and after approx. 18 months her case was heard in a disciplinary hearing. Despite a conviction for stealing CDs, she had no restrictions placed on her practice whatsoever by the NMC. This was extremely surprising, as after 8 years of working on the Shipman working groups for the Department of Health, and the knowledge that Harold Shipman even had restrictions placed upon him by the GMC when he was prosecuted for stealing drugs to support his pethadine addiction, this nurse was free to continue practicing.

Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

Obviously there is a cost to health service, patients taking illicit medicines often have impaired judgement, they become injured. One example is a patient who was on acid, decided to climb an electricity pylon. The electricity arced and gave the patient significant electrical burns through his hands and exiting through his thigh. This patient required resuscitation facilities, an escharotomy as the thigh burns caused significant swelling to his compartments, and specialist burns and plastics resources as he had some third degree burns.

On a wider scale, most A&E and Ambulance services deal with problems as a result of illicit medicines usage. These include

Another problem which appears to be on the increase is the use of 'date rape' drugs such as Rohypnol. I have seen a rise in patients attending believing that they may have been drugged without consent. If patients have received these types of medicines, then they often have a

timelapse which they can't account for. Often they will start getting flashbacks over the following few days. I believe that urine samples can be taken for up to 72 hours after the event which will demonstrate whether this medication is in their system. In different areas of the country there are varying services for these victims. SARC centres (Sexual Assault Referral Centres) allow patients to have some forensic tests undertaken and collected without involvement of the police. As patients often know that something is wrong, but can't specify exactly what has happened, and sometimes flashbacks occur at a later stage after forensic material is often lost or unavailable. The health service offering such a service should be rolled out wider to care for patients in this vital period, as they often don't feel like they can go to the police .

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

In clinical practice these medicines are required for good analgesia, sedation and anaesthesia. We need these medicines to be available to clinicians (the vast majority of whom are law abiding citizens, and will not divert the medicines for their own or someone else's use).

Healthcare staff do have good procedures in place for the higher schedule CDs, however increased use of biometric cabinets would ensure that medicines were accessible, but that a health balance is obtained so that the systems aren't overly onerous, and we can still access the medicines required in a timely manner for our patients.

A balance needs to be struck with the private prescription of Controlled Drugs. As a result of the work that I helped with to implement better safeguards and audit on the private prescribing of CDs, I found it virtually impossible to obtain CDs for clinical use. I worked as a BASICs practitioner for 12 years. In the last 2 years I moved to South West Ambulance trust as a volunteer BASICS practitioner attending Road Traffic Collisions (RTCs) and medical emergencies on 999 calls. I wasn't able to obtain morphine from the trust as I didn't have a trust vehicle, and after a year of trying to gain a private controlled Drug prescription pad from the person responsible in the PCT and obstruction from the Accountable Officer, I eventually gave up. I was first on scene at an RTC when a patients leg had been impaled on a door support. The patient was hysterical and in significant pain, I was able to start care, yet I had no morphine, neither did the next clinician on scene, or the following vehicle as this was staffed by technicians. The air ambulance managed to arrive after approx. 20 minutes, and they were able to administer morphine to the patient, however even they were unable to administer ketamine as at the time they were unable to carry it. The patient required cutting out of the vehicle with the impaled metal bar being cut at both ends for removal in hospital.

Access to CDs needs to be balanced.

Although it won't affect the diversion or illicit supply, it is vital that frontline healthcare staff should be made aware of the 'street' names of drugs, and approximate prices. Very often patients attend with poor history giving skills due to their mental or conscious state. Understanding what they have taken and how much would be really helpful in managing these patients.

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

Obtaining medicines over the internet anecdotally appears to be an issue. How this is tackled is not easy. Many medicines such as so called lifestyle drugs such as Viagra are widely advertised. These sites often offer other medications such as stronger analgesics such as codeine and hypnotics such as diazepam. Other medicines which aren't licenced as medicines elsewhere in the world are also available through reputable online pharmacies that are as close geographically as the Channel Islands and near continental Europe, yet crucially outside of the UK's legislative framework and the jurisdiction of agencies such as the MHRA. Medicines such as melatonin although not a Controlled Drug or abused are an example as they are categorised as supplements in the USA, but are licenced as a prescription only medicine here in the UK. Other supplements/herbal medicines such as diet pills, diazepam and anabolic steroids were recently seized as part of a crackdown with Interpol and the MHRA as part of Operation Pangea VII which was conducted between 11 May and 21 May 2014. Other medicines requiring specialist clinical skills and significant monitoring such as roacutaine (used for acne and should only be prescribed by specialists) are easily obtained. Obtaining these medicines ought to be restricted however I have come across many patients who have obtained them over the internet with ease.

The World Health Organisation estimates that globally one in ten of all prescription only medicines are fake or counterfeit. Due to good surveillance this is less common in the UK, however ever increasing sophistication by the fraudsters makes it harder to identify, and with internet trade as well as parallel imports (medicines being traded internationally) this requires a greater degree of vigilance by all health staff and awareness needs to be increased amongst patients.

Public awareness is going to be key here. With all medicines (and supplements) obtained over the internet, we need to ensure that patients are aware of the dubious quality of these products, and that having Controlled Drugs without them being prescribed for you would be unlawful. It would be helpful for the government as well as healthcare staff to highlight the risks to patients.

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

The problems associated with the illicit supply of medicines is from my experience definitely on the increase. From my own practice I have noted that the availability and use of illicit substances goes across all ages, both sexes, classes, professions and geographical areas. Prices of substances (both prescription medications and street drugs) will inevitably have some effect on the amount and types of medication that is diverted as opposed to other street drugs.

Cannabis – (Hash, Grass etc) mainly in 'weed' form as opposed to resin – 1/8 costs approx. £25-£30 – although many dealers will do '£10 deals'. Freely available and not widely prescribed due to restrictions.

MDMA – (Ecstasy, E, Molly, Mandy, Doves etc) approx £3-£5 per tablet

Cocaine – (Charlie, Coke, Chan) High quality - £100/gram, low grade (Often cut with Benzene – which can cause leukaemia) approx. £40/gram – users will generally use the length and width of a

matchstick. (n.b. many sophisticated dealers can test for purity 'in house', many users just generally start with small amounts, often on a 'friend' who is willing to have some for free!

Ketamine - (Special K, K) – approx. £40/gram, users use a tiny amount.

Trends to move to 'designer drugs' and so called 'legal highs' has certainly increased and the problems legislating for these is well known.

I have worked as a clinician at major rock festivals for over 25 years, and as a clinician in emergency and first contact care for the same period. Ketamine and cocaine are now freely available in every village, town and city, they are used 'recreationally' by a huge number of people. Cocaine is often used in toilets of pubs and some pub landlords trying to stop use in their toilets, use oils such as WD40 to spray on the toilet cisterns so that any powder based substances are absorbed and can't be used. With increased use of 'bullets' users are now getting around this.

I believe that the Home Office have good links with Rock Festival organisers, and although security and policing to reduce illicit drug use has been partially successful these practices remain. Monitoring of the use of illicit or diverted medicines should be undertaken at these events in an anonymous and non-punitive way (perhaps by non-clinical and non- Home Office staff) to be able to more accurately assess the scale of this problem, as well as to look at where the medicines are sourced from.

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9 June 2014

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Dear Professor Iverson

Re: Call for Evidence - ACMD Diversion & Illicit Supply of Medicines Inquiry

Thank you for your invitation to submit written evidence as part of the above Inquiry and to take part in the Evidence Gathering Meeting/Inquiry on 12th June 2014.

I have read, with interest, the details of the review and the areas on which you are seeking to gather evidence. We welcome any initiative that seeks to consider and potentially reduce the medical and social harms arising from the illicit supply of medicines. While we are not able to attend on 12 June, I have set out some information below, which I hope will assist the panel in its discussions.

To clarify, the RCVS is the regulatory body for veterinary surgeons in the UK and its role is to safeguard the health and welfare of animals committed to veterinary care through the regulation of the educational, ethical and clinical standards of veterinary surgeons and nurses, thereby protecting the interests of those dependent on animals, and assuring public health. It also acts as an impartial source of informed opinion on relevant veterinary matters.

Regulating the profession

The Veterinary Surgeons Act 1966 sets out the powers and functions which Parliament has granted to the RCVS to regulate veterinary surgeons in the UK. In order to ensure such regulation, the Act establishes a Disciplinary Committee to hear cases referred to it by the RCVS Preliminary Investigation Committee, and provides the Disciplinary Committee with statutory powers to remove or restrict a veterinary surgeon's right to practise if he/she is found guilty of disgraceful conduct in a professional respect or found guilty of a conviction that renders him/her unfit to practise.

The RCVS is notified of criminal activity by veterinary surgeon in various ways.

First, veterinary surgeons, and those applying to be registered as veterinary surgeons, must disclose to the RCVS any caution or conviction, including absolute and conditional discharges and spent convictions, or adverse finding which may affect registration, whether in the UK or overseas (except for minor offences excluded from disclosure by the RCVS).

Second, if a veterinary surgeon is convicted or cautioned, or investigated for serious alleged criminal activity the police inform the RCVS as part of the Notifiable Occupations Scheme. This Scheme relates to professions or occupations that involve special trust or responsibility, in which the public interest in the disclosure of the investigation, conviction or caution, and other relevant information, outweighs the normal duty of confidentiality owed to the individual. The veterinary profession has been included in the Notifiable Occupations Scheme since April 2006. However, the operation of the Scheme does not negate the requirement for veterinary surgeons to make full disclosure to the RCVS.

Complaints are investigated in line with our standard procedures. The RCVS does not have powers of entry or seizure powers, although veterinary surgeons must comply with reasonable requests from the RCVS as part of the regulation of the profession.

Ensuring practice standards

The RCVS also operates a Practice Standards Scheme (PSS), which is a voluntary initiative to accredit veterinary practices in the UK. Through setting standards and carrying out regular inspections, the Scheme aims to promote and maintain the highest standards of veterinary care.

Over half the practices in the UK are members of the Scheme and are subject to regular premises inspections carried out by the RCVS. Areas covered in the inspections include compliance with the Misuse of Drugs Regulations and Veterinary Medicines Regulations, for example, safe custody and storage of veterinary medicines.

Registration of veterinary practices

From 1 April 2009, veterinary practice premises have had to be registered in order for veterinary surgeons to supply medicines from them. The purpose of the Register is to enable the Veterinary Medicines Directorate (VMD) to fulfil its obligations under European law to maintain and improve traceability of, and accountability for, veterinary medicines. We hold the Register of Veterinary Practice Premises on behalf of the VMD. Registered premises are inspected by the VMD (those in the Practice Standards Scheme are inspected by the RCVS).

Bogus veterinary practitioners

Only veterinary surgeons registered with the RCVS can legally practise veterinary surgery in the UK. Section 19 of the Veterinary Surgeons Act restricts the practice of veterinary surgery by unqualified persons unless there is a suitable exemption. Section 20 of the Act prohibits the use of practitioners' titles by unqualified persons and makes it an offence for any person not registered in the RCVS Register to take or use the title of veterinary surgeon or any name, title, addition or description implying registration. In some cases where unqualified people are purporting to be registered professionals, there may be additional criminal offences such as fraud by misrepresentation or illegal possession or supply of veterinary medicines.

As the statutory regulator, we only have jurisdiction over our registered members and we have no authority to prosecute lay people. However, we regularly assist other enforcement bodies such as the Police and Trading Standards with their investigations.

Comments on your specific questions

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

We do not feel we can provide useful comment here. While we have some experience of assisting other enforcement bodies, we do not hold detailed information about the illicit supply of medicines, the prevalence of misuse of medicines obtained through these means, demographic of users, or the most prevalent drugs being misused etc.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

The RCVS has assisted the Police and DEFRA Investigation Service (DIS) during the execution of search warrants for the seizure of illegally imported and illegally obtained veterinary medicines. One modus operandi is for offenders to assume the identity of an appropriately registered veterinary surgeon, or register animals and birds with European veterinary practices, occasionally visiting the European veterinary practice and transporting medicines into the UK.

Bogus veterinary practitioners who steal the identities of UK registered veterinary surgeons may receive supplies of veterinary medicines from legitimate veterinary medicine wholesalers located in the UK (using the details of legitimately registered veterinary surgeons) or with a fraudulent prescription via the internet pharmacy sites in the UK and other jurisdictions.

The RCVS is also aware that some animal owners are involved in prescription misuse. This includes alteration of an existing prescription, or, fraud, such as supplying the same prescription to multiple retailers or forging the signature of a vet/pharmacist/suitably qualified person. The RCVS has statutory jurisdiction only in relation to registered members and therefore cases of this nature (involving lay people) are referred to the Police, Trading Standards or the Veterinary Medicines Directorate. The RCVS assists with such investigations on a regular basis.

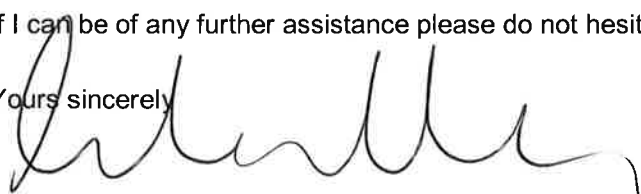
Veterinary practices may also be targeted by criminals / drug abusers / suppliers. The RCVS does not hold information about the number of veterinary practices burgled (in Scotland 'Housebreaking'), but when we have been made aware of such cases, representatives from the RCVS have visited practices and provided advice and guidance, including advice on storage and security.

The RCVS has also liaised and assisted police with suicide investigations. Often, this involves the misuse of veterinary medicines by an employee or employer.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?
Examples of veterinary medicines involved when RCVS has investigated or assisted in the investigation are: ketamine / pentobarbital / buprenorphine / tramadol / pethidine / phenobarbitone and antibiotics.
Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?
Of the cases we have investigated, or assisted with, we have identified issues such as illness and death, loss of revenue for the business/practice, and /or disruption of the practice / business.
Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?
We would welcome steps to: <ul style="list-style-type: none"> • Encourage co-operation between regulators and enforcement agencies to reduce diversion and illicit supply • Increase practitioners' awareness of the issues and how to detect potential misuse • Introduce appropriate controls on legitimate drug suppliers (wholesale and retail suppliers) to identify potential risk and reduce illegal activity (e.g. the need to carry out registration checks and to ensure deliveries are signed by an authorised signatory, increased in-house security and awareness of police crime prevention surveys etc) • Encourage a Memorandum of Understanding to increase information flow between organisations involved in the supply of medicines – sharing of intelligence and central information data about offences and geographical hot spots.
Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?
Increased publicity about detection and conviction of offenders.
Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?
We do not feel we can provide useful comment, as we do not hold data on offences and offenders.

If I can be of any further assistance please do not hesitate to get in touch.

Yours sincerely



Gordon Hockey

Registrar / Legal Services Director

Advisory Council on the Misuse of Drugs Inquiry into Diversion & Illicit Supply of Medicine: Reckitt Benckiser Pharmaceuticals Submission



We would like to thank the Council for the opportunity to submit evidence for your Inquiry on the diversion and illicit supply of medicines. Reckitt Benckiser Pharmaceuticals (RBP) is a research-based specialty pharmaceutical company committed to improving the lives of people affected by the chronic diseases of addiction with long-standing history of supporting the addiction medicine community worldwide. RBP discovered buprenorphine in 1966 and since 2000, it has manufactured and supplied buprenorphine-based products which have been used to treat millions of opioid-dependent patients worldwide. Our mission is to improve access to and quality of treatment for addicted patients around the world.

Along with central nervous system depressants (such as benzodiazepines and barbiturates) and central nervous system stimulants (such as amphetamine), opioids are one of the most commonly abused prescription medications. The focus of RBP's submission is related to the problem of opioid-containing medications including those used to treat opioid dependence (OD). The diagnostic criteria for Opioid Use Disorder are 'a problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of a series of behaviours occurring within a 12-month period', which include strong desires to use opioids, recurrent use in situations that are physically hazardous and use taking priority over other activities and obligations, among others [1]. With opioid treatment, either for pain or OD, comes the associated risks of abuse and diversion, both of prescription (e.g. tramadol, oxycodone, and codeine) and over-the-counter opioid painkillers (e.g. codeine plus paracetamol) and of opioid substitution treatments (e.g. methadone, buprenorphine). It is RBP's opinion that any inquiry into the diversion and illicit supply of medicines must thoroughly review both of these two aspects as the evidence suggests that both are increasingly common in the UK.

Q1: In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

Prescription opioid diversion and abuse are an important public health issue. There is not one clearly defined and agreed definition of diversion that we are aware of. Diversion, as defined by ACTION, is 'Any intentional act that results in transferring a drug product from lawful to unlawful distribution or possession' [2]. Diversion relates to the way people obtain medication, for example 'doctor shopping', on the 'black' market, or received or stolen from a friend or family member. This could include diversion of methadone or buprenorphine out of the opioid dependence treatment system or diversion of codeine, tramadol, oxycodone or any other analgesic from pain treatment. Although empirical data on the exact scope and magnitude of diversion of opioids are limited and there are no Government-sponsored data sources, valuable insights can be gained by reviewing the published reports and data, including drug-related mortality data, national surveys of drug-related use and individual case reports from physicians.

Related to the diversion of opioids out of the opioid dependence treatment system, a recent European survey provides insights into the frequency and risk associated with misuse and diversion of opioid dependence medications and the reasons why patients may divert their medicines [3, 4]. European Quality

Audit of Opioid Treatment (EQUATOR) was a multinational survey, the largest survey of its kind in Europe, involving the combined analysis of data from across 10 European countries, including the UK [3]. A total of 3888 people were recruited and included in the EQUATOR data, including 703 physicians, 2298 patients and 887 out-of-treatment opioid users. One of the aims was to generate real-world data on the state of opioid dependence treatment, including gaining data on diversion.

The reported rates of diversion and misuse in the UK were slightly higher than in other European countries despite patients reporting higher rates of dose supervision [4]. The rates of reported misuse and diversion of medications used in OD treatment by patients in Europe was substantial: approximately 21% of patients had misused—i.e. injected or snorted—their medication in the past and 24% had diverted—i.e. sold, swapped or given away—their medicine [4] and this was despite 62% of them reporting dose supervision[5]. In the UK, 23% reported misusing their medication and 30% reported diversion while 71% reported some dose supervision [6]. It is clear that in both Europe and the UK, diversion of medication from OD treatment is a significant problem.

Relating to the diversion of opioid analgesics from pain treatment, there has been a significant increase in the prescription of opioids and there is a concern that there has been a corresponding increase in prescription drug diversion and misuse as evidenced by a marked increase in mortality related to opioid analgesics. Insights into the extent of the problem can be gained from detailed reviews of drug poisoning deaths over the last decade [7, 8]. The Office for National Statistics (ONS) records data on all drug-related deaths. Mortality trends in the UK, in particular in England and Wales, show a steady increase in deaths from opioid analgesics [7].

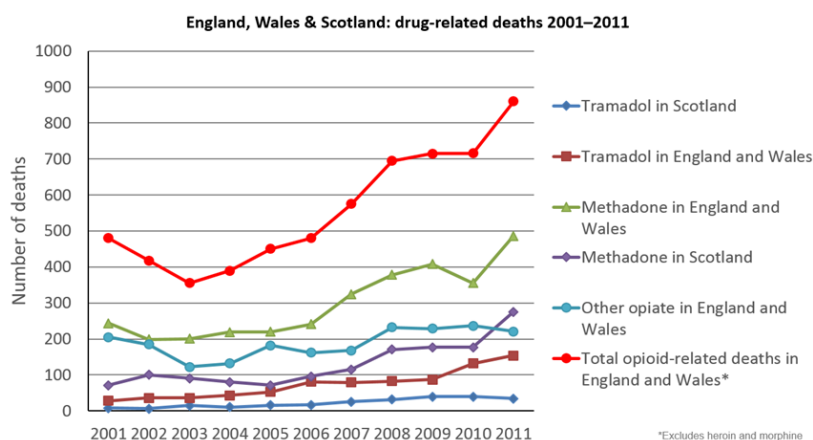


Figure 1. Drug-related deaths by selected drugs reported in England, Wales and Scotland, 2001–2011 (modified from Giraudon et al, 2013) [7].

This published analysis of ONS figures [Figure 1] shows, overall, that opioid analgesics such as codeine, tramadol and methadone, were involved in more than one in two drug-related deaths (1439 deaths) in 2011, confirming the predominant role opioid medications play in drug overdose deaths [7]. What is unclear from reviewing these mortality figures in isolation is how the number of deaths from opioid painkillers (>850 in England and Wales in 2011) relates to the number of patients with opioid painkiller dependence, and by extension, the degree to which that dependence is fed by illicit supply of opioid painkillers diverted from pain treatment. The annual report of the National Programme on Substance Abuse Deaths (NPSAD) published by the International Centre for Drug Policy (ICDP) at St George’s,

University of London, reviewed mortality data in more detail and provided data on the relationship between these deaths and diversion [8].

The ICDP report describes a record number of deaths from opioid painkillers in 2011 from oxycodone, fentanyl, buprenorphine and tramadol [Figure 2] at 222, which then declined to 160 in 2012 [8]. In England, other opiates/opioid analgesics (not heroin/morphine or methadone), alone and in combination with other drugs, were implicated in 276 deaths. Of these, taking into account known prescription status of individuals, 159 (57.6%) may have obtained the drug by illicit means, compared to 117 (42.4%) who were known to be prescribed other opiates/opioid analgesics. Other opiates/opioid analgesics alone were implicated in 47 cases. In 25 (53.2%) of these cases the drugs were listed as prescribed to the individual in whose death the drugs were implicated; however, for the remaining 22 (46.8%) cases, the drugs appear to have been obtained by other means.

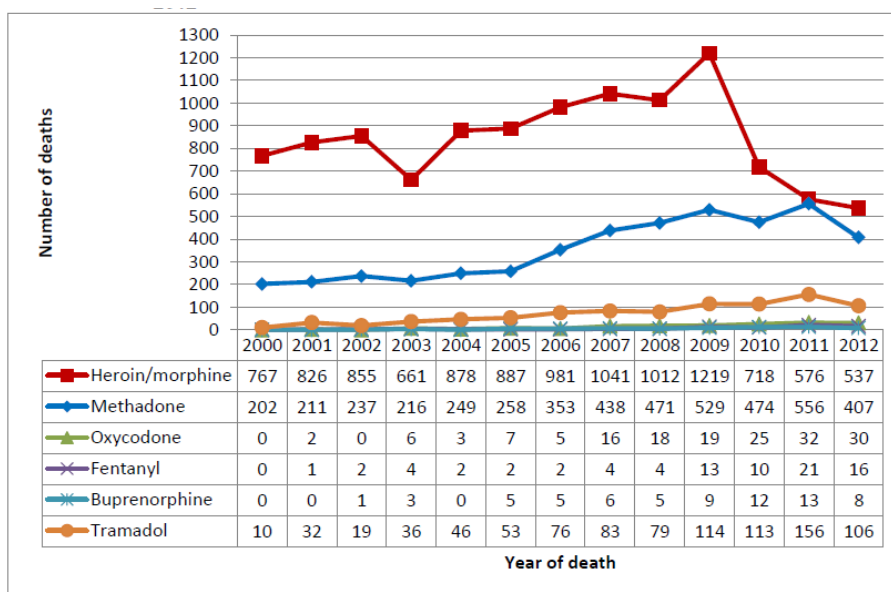


Figure 2: Trend in UK deaths involving opiate/opioid analgesics—NPSAD data, 2000–2012 (from Annual Report 2013 of National Programme on Substance Abuse Deaths (NPSAD) [8].

Tramadol-related deaths have increased markedly, to a peak of 156 in 2011, causing much concern and stimulating a recent recommendation for reclassification as a Schedule 3 controlled drug. It remains to be seen if this will lower the tramadol-associated mortality. These numbers continue to be dwarfed by the deaths in which methadone is implicated (556 in 2011 and 406 in 2012). The ICDP provided further detail on 234 methadone-related deaths in England and, of these, 156 people (66.7%) may have obtained methadone from illicit sources, compared to 78 (33.3%) who were known to be receiving prescribed methadone prior to their death.

The National Drug-related Deaths Database (Scotland) Report 2011 reported that in Scotland, methadone-related deaths increased from 71 in 2001 to 275 in 2011 [9]. Further analysis of deaths point to a problem with diverted methadone in Scotland of a similar magnitude to England—in 2011, the majority of individuals who died (150, 60.7%) with methadone found in their toxicology were not in receipt of a methadone prescription at the time of death [9].

By assessing the above trends in mortality related to opioid medications, there is an opportunity to explore preventative measures, reinforce surveillance systems to track opioid misuse and to put in place screening and treatment protocols for people dependent on opioid analgesics. There is also an opportunity to evaluate the differential mortality risk associated with buprenorphine and methadone to see if stricter controls on the prescribing of methadone could have a positive impact by lowering mortality rates.

Q2. Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

And

Q3. Which medicines/drugs do you consider are being diverted and supplied illicitly?

And

Q7. How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

Misuse and diversion of medications used in the treatment of opioid dependence

According to the available data, methadone and mono-buprenorphine (Subutex® and generic) are the opioid dependence treatments most frequently diverted. This supply is most frequently diverted from the treatment system by patients or pseudopatients (i.e. people posing as patients in order to get medication for the purpose of diversion or trafficking). As discussed above, a recent European survey can provide insights into the significance of the risks of misuse and diversion and the reasons why patients may divert their medicines [3, 4]. The European Quality Audit of Opioid Treatment (EQUATOR) survey combined survey data from across 10 European countries, including the UK [3]. A total of 3888 people were included in the EQUATOR data, including 703 physicians, 2298 patients and 887 out-of-treatment opioid users [3]. One of the aims was to generate real-world data on the state of opioid dependence treatment, including gaining data on diversion. There were more than 500 respondents from the UK arm ('Project ACCESS UK'), including treating physicians (n=100), opioid-dependent patients currently receiving MAT (n=248), as well as opioid users not receiving MAT and outside of the treatment system (n=196) [6].

The reported rates of diversion and misuse in the UK were slightly higher than in other European countries despite patients in the UK reporting higher rates of dose supervision. The rates of reported misuse and diversion of medications used in OD treatment by patients in the UK was substantial: approximately 23% of patients had misused—i.e. injected or snorted—their medication in the past and 30% per cent had diverted—i.e. sold, swapped or given away—their medicine and this was despite 71% of them reporting dose supervision [6]. In the European sample from EQUATOR, among the responses given (n=550) to the question 'if you have ever sold, swapped or given your opiate substitution medication to someone else, please indicate your reason or reasons for doing this' (i.e. reasons for diverting), the most frequently cited reason for diversion from the three options provided was to help others to treat themselves (52% of responses) [4]. Incidental earnings/source of money made up 40% of responses [4]. Helping others to satisfy their cravings/get high constituted 39% of responses [4]. This finding is similar to other studies that have described 'apparently altruistic diversion' to allow others to self-treat withdrawal symptoms [10, 11]. Of note, 26% of out-of-treatment users in the UK data reported current use of diverted medications; of these, 21% used diverted methadone (5% reported using another diverted medication) [4]. This confirms the data reported by patients currently in opioid dependence treatment around the prevalence of diverting their prescribed medication onto the black market or to out-of-treatment users [4].

More precise estimates of methadone diversion are available from a study conducted in Merseyside of past-year methadone users, which indicated the presence of a relatively large, active 'black market' for

methadone [10]. Questionnaires were completed by almost 900 participants recruited from 28 sites that included primary prescribing services, agencies providing treatment specifically for offenders, and services providing accommodation for drug users. The participants were aged between 18 and 64 years old (mean age 38 years). This study found that methadone diversion was widespread; 60% of participants had obtained illicit methadone in the past year and 20% in the past 4 weeks.

The size of the market is also indicated by reports from Merseyside clients about the number of people they knew who regularly provided or obtained methadone illegally [10]. Three quarters of participants knew at least one person who provided their methadone to others at least once a month and at least one person who obtained illicit methadone at least once a month. For both obtaining and providing methadone, more than three in ten participants said they knew more than five people who engaged in this activity at least once a month. The source of the methadone was also reported. Almost all diversion of methadone was reported to take place between friends or associates. Small proportions of participants undertook transactions with an individual they identified as a 'dealer'.

These data on medication diversion are consistent with the findings of a 2-year audit of press coverage of misuse, diversion and trafficking of opioid dependence treatments in Europe over the period September 2010 to September 2012 [12]. Analysis of the volume and content of media coverage of drug-related issues does give some indication of the impact on public health and criminal justice resources although the prevalence is likely understated due to the nature of media reporting. During the audit period, a total of 994 articles mentioned MAT medication misuse, diversion or illicit supply in the UK over this 2-year period. Methadone was cited most often (794 reports), followed by Subutex and generic buprenorphine (143 reports), and other MAT (51 reports); Suboxone was the least cited (seven reports). There were 590 original cases of methadone misuse, diversion or illicit supply reported by the UK media. Buprenorphine was the drug most associated with smuggling in the UK, accounting for over half of all reported smuggling incidences; many of which involved diversion of medication into prisons.

In their 2011 Recommendations to Governments, the International Narcotics Control Board (INCB) confirm that misuse and diversion of buprenorphine occurs across multiple countries, with the Board urging Governments of all countries in which buprenorphine is used for medical purposes to remain vigilant and adopt appropriate control measures while making it available for medical treatment [13]. The INCB stated 'One growing problem is the diversion of preparations containing buprenorphine from domestic distribution channels, to be subsequently abused in the countries of diversion or smuggled into other countries where there is illicit demand for them'. The phenomenon of buprenorphine diversion, misuse and trafficking is well documented in the U.S., France, Germany and in the Nordic countries, particularly Finland. In 2003, the Finnish Government restricted Subutex to named patient use only (specifically noting its use in pregnancy) because of the illicit use, diversion and trafficking of Subutex in Finland. In 2013, Simojocki et al. published new data from Finland in which they confirmed that *'Buprenorphine is still the most commonly used illicit opioid in Finland. Restrictions on the access of mono-buprenorphine and the lower street price of buprenorphine/naloxone did not significantly alter the illicit use of this drug over several years of its availability on the street'* [14].

Similar data in the U.S. from the Researched Abuse, Diversion and Addiction-Related Surveillance System (R.A.D.A.R.S) suggesting high levels of diversion of Suboxone® (buprenorphine/naloxone) and Subutex concluded that generally Suboxone diversion took place for self-treatment while Subutex (mono-buprenorphine) diversion took place for the purposes of abuse. Richard Dart, Executive Director of R.A.D.A.R.S. told the audience at their 2011 annual meeting *'There is debate over getting high vs. treating*

underlying withdrawal and concern about buprenorphine as drug of abuse. However, the data are clear—Subutex is preferred, people pay more for it, and it is abused more than Suboxone’ [15].

In the UK specifically, there is a history of mono-buprenorphine (Subutex and Temgesic®) abuse in Scotland such that a Scottish Drug Specialists Committee advised the Scottish Executive against use of mono-buprenorphine [16]. This well-documented history in Scotland, the above mentioned media audit and prior evidence submitted to this Inquiry at the June meeting demonstrate that the diversion and misuse of mono-buprenorphine, that is well documented elsewhere around the world, is also prevalent here in the UK, particularly in secure environments like prisons [17]. In fact, the HM Chief Inspector of Prisons for England and Wales is currently looking at the diversion of Subutex and other medications in prisons [18].

All of this data suggests that methadone and mono-buprenorphine (Subutex and generic) are the medications most commonly diverted from the opioid dependence treatment system and that current methods of control and supervision should be evaluated as they appear to be inadequate to address this issue.

Diversion of prescription and over-the-counter opioid painkillers

Between 2004 and 2012, the number of opioid painkiller prescriptions in England more than doubled [19, 20]. With respect to the problem of opioid painkiller dependence, the levels of dependence do not appear to be at epidemic proportions in the UK as is the case in the United States, but as noted in our response to *Question 1*, deaths from prescription opioid abuse are significantly increasing.

RBP are aware of a number of cases of people prescribed opioids who have become painkiller dependent, with the consequence that non-prescribed opioid painkillers have been diverted and/or illicitly sourced. Specifically, RBP are aware of two cases that have recently been submitted to peer-review journals for publication that provide useful insights into the diversion and illicit supply of prescription opioid painkillers.

In the first case, a young female in her twenties was prescribed opioid painkillers for myalgic encephalopathy. Over the period of 4 years, the patient became intensely medication seeking from their General Practitioner, as well as from the local accident and emergency department and frequently presented at multiple sites seeking codeine-containing painkillers. Ultimately, after begging and borrowing opioid medications from friends and relatives, she turned to purchasing prescription opioids off the street to sustain her addiction [21].

In the second case, a young lady first prescribed dihydrocodeine after elective surgery began using on top of her prescribed dose. This quickly escalated; her need for opioids was detected by her GP and her prescriptions were stopped without support. This precipitated an intense withdrawal and acted as a gateway to heroin use, before she sourced an illicit supply of prescription opioids off the street that was used for several years [22].

Although these cases could be considered anecdotal, the British Pain Society have confirmed ‘the enormous clinical challenge and healthcare burden in relation to patients with persistent pain on unhelpful and very-high-dose opioids who, in some cases for years, are burdened by all the harms and none of the benefits of opioid treatment. *We do not know what the scale of the opioid-related harms is, but all of us see patients in this trap in almost every clinic’ [23].*

Cases of codeine dependency from over-the-counter (OTC) combination analgesics have been reported [24, 25] across the globe. In the UK and the Republic of Ireland, medications containing codeine became Pharmacy Medicines (P) within the last few years, available only in consultation from a pharmacist, due to concerns about misuse and diversion. Similarly, cases in New Zealand and Scotland have been reported in the literature and suggest a need for increased pharmacovigilance around OTC medications that contain codeine [24, 25]. In addition, the Government of South Africa has started the Codeine Care Initiative promoting responsible prescription and use of codeine products and raise awareness about the risks of around codeine diversion, misuse and dependence [26]. Lastly, the EU commission has provided €2 million for King's College London to lead a multidisciplinary project across three countries to look into the patterns of codeine use [27]. The King's lead for the project, Dr. Paolo DeLuca stated 'CODEMISUSED [The project] aims to estimate levels of therapeutic and non-therapeutic codeine use, misuse and dependence in partner countries. Our study will investigate the 'hidden nature' of codeine misuse - as a legitimate product, the extent of codeine misuse is not adequately reflected in national or international prevalence or treatment data' [27].

Although the data surrounding the prevalence, trends and sources of diversion are not as robust as we would like, the data that does exist and the level of activity at the Governmental level globally indicate what we all suspect is the case: the diversion of medications is a growing problem that is having a significant impact on individuals and public health.

Q4. What problems have diversion and illicit supply of medicines caused for public, patients and clinicians?

Diversion and misuse of opioids poses significant risks to opioid-dependent individuals, some of which are outlined below, but beyond that, diversion can have a wider negative impact on society through compromising the integrity of treatment services and with a potential increase in societal aversion to the treatment of opioid dependence.

The most serious problems diversion and illicit supply of medicines causes for public, patients and clinicians discussed below are:

- I. Mortality
- II. Unintended child exposure and child mortality
- III. Failure of Recovery
- IV. Criminality and recidivism
- V. Drug dealing in diverted opioid painkillers

I. Mortality

As included in our response to Question 1:

Insights into the extent of the problem can be gained from detailed reviews of drug poisoning deaths over the last decade [5, 6]. The Office for National Statistics (ONS) records data on all drug-related deaths. Mortality trends in the UK, in particular in England and Wales, show a steady increase in deaths from opioid analgesics [5].

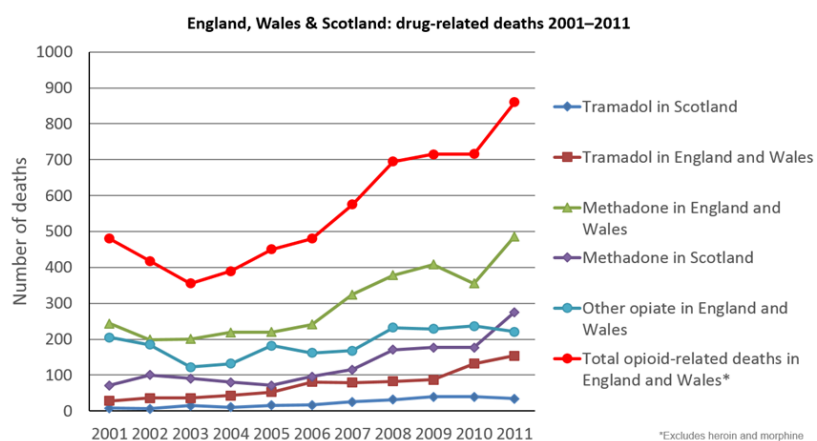


Figure 1. Drug-related deaths by selected drugs reported in England, Wales and Scotland, 2001–2011 (modified from Giraudon et al, 2013) [5].

This published analysis of ONS figures [Figure 1] shows, overall, that opioid analgesics such as codeine, tramadol and methadone, were involved in more than one in two drug-related deaths (1439 deaths) in 2011, confirming the predominant role opioid medications play in drug overdose deaths [5]. What is unclear from reviewing these mortality figures in isolation is how the number of deaths from opioid painkillers (>850 in England and Wales in 2011) relates to the number of patients with opioid painkiller dependence, and by extension, the degree to which that dependence is fed by illicit supply of opioid painkillers diverted from pain treatment. The annual report of the National Programme on Substance Abuse Deaths (NPSAD) published by the International Centre for Drug Policy (ICDP) at St George’s, University of London, reviewed mortality data in more detail and provided data on the relationship between these deaths and diversion [6].

The ICDP report describes a record number of deaths from opioid painkillers in 2011 from oxycodone, fentanyl, buprenorphine and tramadol [Figure 2] at 222, which then declined to 160 in 2012 [6]. In England, other opiates/opioid analgesics (not heroin/morphine or methadone), alone and in combination with other drugs, were implicated in 276 deaths. Of these, taking into account known prescription status of individuals, 159 (57.6%) may have obtained the drug by illicit means, compared to 117 (42.4%) who were known to be prescribed other opiates/opioid analgesics. Other opiates/opioid analgesics alone were implicated in 47 cases. In 25 (53.2%) of these cases the drugs were listed as prescribed to the individual in whose death the drugs were implicated; however, for the remaining 22 (46.8%) cases, the drugs appear to have been obtained by other means.

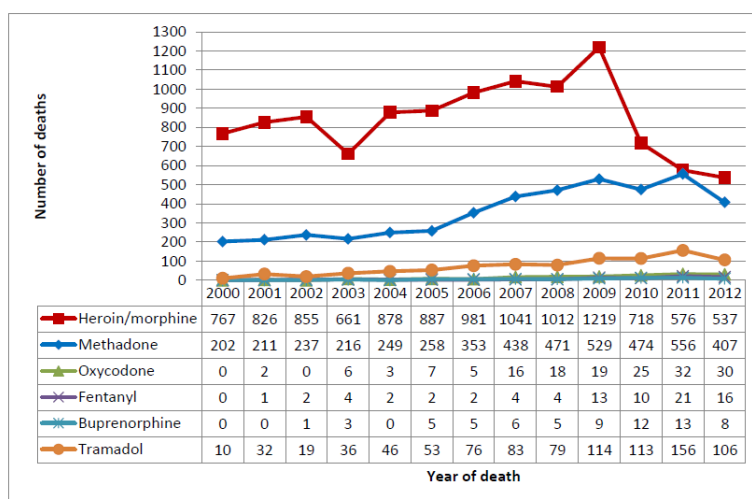


Figure 2: Trend in UK deaths involving opiate/opioid analgesics—NPSAD data, 2000–2012 (from Annual Report 2013 of National Programme on Substance Abuse Deaths (NPSAD) [6].

Tramadol-related deaths have increased markedly, to a peak of 156 in 2011, causing much concern and stimulating a recent recommendation for reclassification as a Schedule 3 controlled drug. It remains to be seen if this will lower the tramadol-associated mortality. These numbers continue to be dwarfed by the deaths in which methadone is implicated (556 in 2011 and 406 in 2012). The ICDP provided further detail on 234 methadone-related deaths in England and, of these, 156 people (66.7%) may have obtained methadone from illicit sources, compared to 78 (33.3%) who were known to be receiving prescribed methadone prior to their death.

The National Drug-related Deaths Database (Scotland) Report 2011 reported that in Scotland, methadone-related deaths increased from 71 in 2001 to 275 in 2011 [7]. Further analysis of deaths point to a problem with diverted methadone in Scotland of a similar magnitude to England—in 2011, the majority of individuals who died (150, 60.7%) with methadone found in their toxicology were not in receipt of a methadone prescription at the time of death [7].

By assessing the above trends in mortality related to opioid medications, there is an opportunity to explore preventative measures, reinforce surveillance systems to track opioid misuse and to put in place screening and treatment protocols for people dependent on opioid analgesics. There is also an opportunity to evaluate the differential mortality risk associated with buprenorphine and methadone to see if stricter controls on the prescribing of methadone could have a positive impact by lowering mortality rates.

II. Unintended child exposure and child mortality

The Department of Health UK Guidelines on drug misuse estimated there were between 250,000 and 350,000 children of problem drug misusers in the UK in 2003 [28], quoted in the Hidden Harm Report by the Advisory Council on the Misuse of Drugs (ACMD) [29].

In their recent report ‘Medications in drug treatment: tackling the risks to children’, Adfam, the Charity for families affected by drug and alcohol use, examined cases where children have died or come to harm from ingesting opioid substitution treatments [30]. Adfam identified 17 serious case reviews (SCRs) involving the ingestion of these drugs by children in the last five years alone, and pointed out that potentially more incidents do not reach that level of inquiry. There were 20 SCRs involving opioid substitution treatment

(OST) during the 10-year review period that concerned 23 children, of whom 17 died. The median age of these children was 2 years, and methadone was involved in 18 of these cases. One suicide death was attributed to buprenorphine (in addition to several other medications). Most often, methadone had been prescribed to the child's mother. In their report Adfam notes that 'Toxicity in very small doses, possible attractiveness to children, the chance of unsafe storage in chaotic households and the rare but real use as a pacifier form a group of risks specific to methadone, and this must be recognised.'

NICE emphasised the risk of diversion of OSTs to non-drug users, especially children, and recognises the high risk of mortality associated with methadone in opioid-naïve individuals such as children [31]. Although NICE stipulates that the dangers to children should be taken into account in the risk assessment when prescribing methadone or buprenorphine, the Adfam research shows that this is not always followed through into clinical practice. The Adfam research suggests that these safeguarding concerns may not be properly prioritised in reality and calls for greater emphasis on implementation at the local level. Adfam concluded that not enough is being done on a practical level to make sure that children are protected, 'We can't just accept that 'these things happen' and we must be louder and more challenging' [30].

There is little data related to unintentional exposures and/or poisonings of children under 18 admitted to the hospital due to ingestion of prescribed and OTC medications in the UK. Amongst its recommendations, Adfam suggests that this information be collected on a systematic basis and that the recommendation in NICE HTA 114 are implemented at the local level. RBP believes these are relevant and practical next steps for the Government to take.

III. Failure of recovery

The UK arm of the EQUATOR survey found that 30% of patients had diverted their medicines in the past and that 64% of these had given their medicines away [6]. In Merseyside, similarly reported cases of diversion to allow others to self-treat withdrawal symptoms were found [10]. Patients diverting their medicines may jeopardise their progress towards recovery since the dose of medicine that they are receiving should have been carefully titrated to ensure that cravings for opioid drugs remain largely controlled. Diverting part of the medicine thus results in sub-therapeutic doses for the patient in treatment, with the risk of destabilisation and failed recovery, and may also reinforce links with drug-seeking social circles, a risk factor for relapse. Diversion of medication has led some prisons to prevent prisoners from accessing certain treatment options in contravention of NICE guidance. The HM inspectorate report states 'Some prisons attempted to prevent the diversion of Subutex (an effective licensed opiate substitute) by not offering it as an option for opiate-dependent prisoners. However, patients should be offered the clinically most appropriate medication for their treatment to be effective, and establishments should manage the diversion risk through more suitable mechanisms' [18].

The diversion of OST medication to users outside of treatment will also likely prevent people from accessing treatment as they can often access diverted medication without the requirements of a formal treatment programme. Thusly, diversion puts the recovery of two parties at risk, the diverter and the person to whom the product is diverted. As stated in a recent commentary, 'In the push for recovery, the issue of diversion needs to be considered as a key risk to achieving treatment goals' [11].

IV. Criminality and recidivism

There have been challenges within the criminal justice system and HM Prisons with significant problems related to diversion of and illicit trade in methadone, which for many is the only OST available. For many, the misuse of methadone, mono-buprenorphine and heroin often coincide and are interchangeable as part of the lifestyle and culture surrounding opioid dependence. The failure of long-term methadone use as a treatment for heroin addiction in prison has been described as ‘as predictable as the next offences and the ongoing prison sentences these individuals will commit and serve’ [32].

Diversion of prisoner’s OST, most often methadone or mono-buprenorphine (Subutex or generic), has contributed to violence, bullying, drug debts and overdose and in many cases has contributed little to the well-being of the prisoner with no plan for an effective recovery. Since 2012, HM Inspectorate of Prisons has asked adult prisoners if they have developed a problem with diverted medication in their current prison [18]. An average of 7% of prisoners across all types of prisons said they had. HM Inspectorate of Prisons noted that in many prisons inspected, several factors contributed to medication diversion—high levels of prescribing of medications liable to abuse; divertible medication inappropriately given to prisoners in possession; poor supervision of medication queues; and a lack of secure in-cell storage for medications. In several prisons, the strategic approach to the problem was poor.

There is a significant need to better understand the impact on criminality and recidivism related to the diversion of methadone and mono-buprenorphine both in the community and in prisons.

V. Drug dealing in diverted opioid painkillers

The cycling of opioid dependent people between licit and illicit opioids requires us to recognise that the problem is not simply a prescription drug problem, but a drug addiction problem with similar risk factors associated with drugs. In the case of the young lady described previously who became opioid-painkiller dependent after elective surgery, termination of her prescription by her GP acted as a gateway to heroin use before a source of illicit prescription opioid painkillers from a street dealer became available [22].

Q5. What actions should the healthcare and other relevant sectors take to resolve the issue?

RBP believe that commissioners and healthcare professionals have the responsibility to promote the utilisation of medications that have the lowest potential for misuse and diversion, and the greatest public health benefit.

Specific actions the healthcare sector can take to resolve the issue are:

- I. Implement the NICE guidance
- II. Improve patient assessment
- III. Address stigma and other barriers to treatment
- IV. Encourage therapeutic dosing
- V. Screen for and treat opioid painkiller dependence

I. Implement the NICE guidance

National Institute for Health and Clinical Excellence (NICE) guidance notes that opioid substitution therapy choice should be made on a case-by-case basis, taking into account a risk–benefit analysis performed by the responsible clinician in consultation with the patient [31]. The risk-benefit should account for the person’s lifestyle and family situation (for example, whether they are considered chaotic and might put

children and other opioid-naïve individuals living with them at risk). The NICE guidance acknowledges in particular the high mortality risk associated with methadone [31]. Of particular concern, the Adfam research found no awareness of the link between this NICE guidance and child safety [30]. Indeed, 17 out of 18 deaths—and all of those concerning very young children—involved methadone. As different opioid substitution medicines have different risk profiles with regard to misuse and diversion, it is important that medication reviews are conducted as a person's circumstances change. Alongside other clinical considerations, the risk to children in the home should be taken into account when making and reviewing decisions about the appropriate OST for opioid dependent patients. Training for drug services, pharmacies and GPs must highlight the possible dangers of OST to children.

As a partial mu agonist, buprenorphine binds to the mu opioid receptors in the brain and activates them, but not to the same degree as full agonists like methadone or heroin. The consequence is a ceiling effect on euphoria and respiratory depression that is not increased further even with increasing doses of buprenorphine which is an associated safety benefit. This pharmacological difference between the partial agonist, buprenorphine, and the full agonists, methadone and heroin, is substantially responsible for the differential mortality risk seen in the evidence presented earlier.

In their report, Adfam recognises the importance of 'safeguarding children as a primary factor in making and reviewing decisions about OST.' RBP supports this view and believes that as a partial opioid agonist with a ceiling effect on respiratory depression, which is administered as a sublingually dissolving tablet, buprenorphine has significant safety benefits over liquid (and all other) preparations of the full agonist methadone and should therefore be the preferred OST medication in situations where minor children are present and in cases where there is limited opportunity for monitoring or supervision of dosing. If methadone is clinically indicated, RBP believes that it should not be given for take home to patients with children in the home.

II. Improve patient assessment

The NICE Quality Standard for Drug Use Disorders published in 2012 state that *'People with drug use disorders have a better chance of recovery, and of maintaining recovery in the longer term, if their resources for recovery are assessed and tailored advice and support is provided. An assessment is intended to identify needs and determine appropriate interventions and the key resources available and needed to support recovery and prevent relapse'* [33].

There is a significant amount of guidance from NICE, the NTA, in the 2010 Drug Strategy and from the Recovery Oriented Drug Treatment Expert Group's (RODT) Medications in Recovery document; however, Adfam's research and the data from the EQUATOR survey seem to indicate that Health Care Practitioners are having difficulty putting all that guidance into practice. The findings from the EQUATOR survey suggest that high quality patient assessment is not taking place and that the choice of OST is often being driven by patient requests. In the European sample, 60% of patients report requesting a specific medication and having the request granted 84% of the time [34]. This is particularly concerning in light of the finding that awareness of some treatment options among patients is low. Also, the fact that UK patients have cycled through treatment on average 4.6 times (including their current treatment episode) which was the 2nd highest in Europe amongst the countries surveyed [4]. These data suggest that patient assessment in the UK is not as thorough as it could be such that treatment is not being tailored to the needs of the individual.

III. Address stigma and other barriers to treatment

Some people dependent on illicit opioids choose not to enter structured treatment. The UK arm of the EQUATOR survey suggests that this may be due in part to conditions of treatment, including the requirement for supervised dosing—around half of the drug users outside treatment who were surveyed reported that the main barrier to entering into treatment was the requirement for daily supervision [6]. Among patients in treatment, the requirement for dose supervision was the aspect of treatment delivery having the biggest impact on their daily life. Although some healthcare professionals may argue that a high degree of supervision is essential, supervision appears to prevent some individuals from entering treatment, but does not stop them from accessing medicines on the black market [11].

Another important consideration is stigma—many patients do not want to stand in a pharmacy to be seen by all taking their medication; why do we treat these patients in this way rather than providing normalised medication provision as any other chronic relapsing medical condition. If treatment is not easily accessible or available through normal GP channels in the same way as other medications, or if patients are placed in a 'stigmatised' situation, arguably there will always be a market for diverted medication from those patients unwilling to access the treatment system. The irony is that supervised dosing is intended to enhance compliance and reduce diversion but may be having the opposite effect of creating demand for diverted medication because users do not want to access the current treatment system. The authors of the EQUATOR analysis suggested similar 'Whilst supervision undoubtedly can make it more difficult to divert medication, all of the sampled countries showed at least some degree of unsupervised dosing. This analysis failed to show clear evidence that countries investing in supervision derive a substantial benefit with respect to the proportion of patients who engage in diversion of their OMT.' [6]

The need for normalised treatment settings is reflected in the recent RCGP guidance on Addiction to Medicines (see below) and in a recent commentary from experts in New Zealand who suggested '*that the availability of Suboxone may facilitate a further shift in treatment from primarily siloed specialist addiction services to integrated primary care services. This shift will help reduce stigma, promote patient self-management and community integration and align opioid substitution treatment with treatment for other chronic health conditions such as diabetes and asthma*' [35].

IV. Encourage therapeutic dosing

The UK arm of the EQUATOR survey found that more than half of patients said that they continued to use illicit drugs on top of their OST, with methadone users reporting the highest on-top use of illicit drugs (64%) [6]. This suggests that while patients are motivated towards recovery, it appears that opportunities to exploit the full potential of treatment are being missed. On-top use of illicit drugs should not be acceptable within integrated treatment programs and can be a by-product of problem 'leakage' outside the treatment system. Self-medication due to restricted access to treatment and sub-therapeutic dosing are frequent motivators for diversion and misuse [36].

Survey data published by Bacha et al. in 2010 reported average maintenance doses of 11 mg for buprenorphine and 51.3 mg for methadone in the UK [37]. This is outside the therapeutic dosing range for buprenorphine, which for most patients is 12–24 mg per day; with better retention in treatment and lower illicit drug use most often found at doses >16mg per day [38]. These data suggest that systematic under-dosing of buprenorphine (and probably methadone) is likely one cause of diversion and/or misuse of OST medications.

It seems counterintuitive to encourage increasing doses as a means to minimise diversion and misuse; however, there is a significant body of evidence that suggests that sub-therapeutic dosing encourages diversion as patients seek to top up their dose, encourages misuse as patient will inject or snort to get higher bioavailability and better effect from low dosages and encourages use of heroin on top to control withdrawal and cravings.

V. Screen for and treat opioid painkiller dependence

A recent survey of pharmacists, 33% of them reported daily suspicion of a patient diverting and abusing OTC medicines, many of them believing it is 'endemic' in the UK [39].

In the patient cases presented earlier, painkiller dependency developed after initial legitimate prescribing by GPs who failed to detect the dependency [21]. Clearly, in the second case, the GP did not have an appreciation of the potential severity of her addiction and the likelihood that, with complete withdrawal of her source of opioids, she would source illicit opioids from the streets [22].

There is a paucity of guidance on how to recognise or deal with prescription opioid dependency, but the Royal College of General Practitioners recently issued a series of four factsheets to provide new guidance to GPs on addiction to medicines [20, 40–42]. Factsheets 3 and 4 [41, 42] deal with identifying and treating patients with addiction, advising GPs, amongst other important information that:

- 1) *'Early interventions are important so that drug misuse and dependence may be tackled early on before more serious problems develop'*
- 2) *'Patients who misuse medicines often prefer to be managed in primary care, to avoid the stigma that can be associated with attending an addiction service associated with illicit drug dependence'*
- 3) *'[M]edically assisted treatment (also known as opioid substitution treatment (OST)) is the preferred treatment for opioid dependence, and can in some instances involve abstinence achieved through gradual tapering of dosages; this is similar to the preferred treatment approach for benzodiazepine dependence.'*
- 4) *'Clinical experience suggests that patients presenting with dependence on codeine preparations benefit from buprenorphine. The risk of patients misusing mono-buprenorphine, either by injection or intranasally, or of diverting (selling or giving away their medication) may be reduced by use of the buprenorphine-naloxone combination product...'*

More training, awareness and guidance for healthcare professionals on this issue is needed such that diversion of medications for illicit use and/or the risks of opioid painkiller dependence can be eliminated or at least managed.

In addition to these much needed recommendations from the RCGP, care pathways for pain should be constructed that include access to addiction services as required, opioid prescribing should be reviewed and patients routinely assessed for dependence [43], and cases of prescription drug addiction should be recorded on the National Drug Treatment Monitoring System in order to identify the scale of the problem.

Q6. What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

RBP feels strongly that Governments have a responsibility to take into account the risks of misuse and diversion when making risk/benefit decisions about what medications to allow the use of. In theory, making widely available those medications that pose the lowest risk to public health and restricting access to those that have the highest potential for misuse, diversion and/or causing overdose deaths makes sense. However, in practice in the UK, unlike in other countries, other factors like cost seem to play a bigger part in medication selection.

In our view, the most important actions that the UK Government should take to resolve the issues of diversion and illicit supply of medicines are:

- I. Promote the development and implementation of abuse-deterrent formulations
- II. Implement overdose death prevention programmes
- III. Prioritise the identification and treatment of addiction to medicines

I. Promote the development and implementation of abuse-deterrent formulations

In the UK, methadone is currently the most common substitution treatment used for opioid dependence. The abuse potential of methadone has been long recognised. Historically, methadone was available as tablets or a concentrated solution of thin, non-viscous fluid. Past problems with diversion of methadone led the UK and most other countries to ban the broad use of methadone tablets in OST in favour of a less divertible methadone formulation involving a high-volume, low-concentration (1 mg/ml) liquid solution with increased viscosity. The ACMD in 2000 recognised these characteristics make it more difficult to abuse the medication due to the difficulty of diverting and injecting high-volume sticky liquid methadone [11,44]. The Orange Book states that 'Methadone tablets are not licensed for the treatment of drug dependence and should not normally be prescribed due to the increased potential for diversion.' [28]

Similarly, at the request of the U.S. Food and Drug Administration (FDA), RBP reformulated buprenorphine to add naloxone (creating Suboxone®) to address concerns about misuse and diversion of buprenorphine. Suboxone was specifically developed in an attempt to address the problem of misuse and diversion and hence preserve the integrity of buprenorphine and access to treatment. The formulation ensures that if the tablet is taken sublingually as prescribed, then naloxone has low bioavailability and does not interfere with the therapeutic effect of buprenorphine. However, if Suboxone is injected, then naloxone has high bioavailability and will likely precipitate withdrawal in opioid dependent individuals, thereby discouraging further misuse. As such, it was anticipated that Suboxone would provide the same therapeutic benefit as buprenorphine alone but reduce the liability for misuse and diversion. The Orange Book guidance supports this view by stating 'Tablet forms, especially of methadone and buprenorphine, carry a risk of being inappropriately crushed, dissolved and injected. Buprenorphine-naloxone (Suboxone®) carries a lower risk of being abused in this manner by opiate dependent users on account of its naloxone component.' [28]

While centres in the UK follow the Orange Book guidance by using the least divertible form of methadone as the formulation of choice, few follow this same guidance for buprenorphine despite Suboxone's demonstrated lower abuse liability [14, 15, 45]. The UK arm of the EQUATOR survey suggests that fewer patients receiving Suboxone have ever diverted their medicine (20%) compared with those receiving mono-buprenorphine (47%). Also, Among patients who had previously diverted their MAT medication (n=75), 88% said that liquid methadone was easy or very easy to obtain locally on the streets or black market. Buprenorphine was viewed as less available on the streets: 71% of patients who had previously diverted

medication reported that mono - buprenorphine was easy or very easy to buy on the streets and only 39% of patients said that buprenorphine–naloxone was easy or very easy to buy [6].

These findings are supported by post-marketing surveillance recently reported in Australia, which observed a lower rate of injection of Suboxone than of buprenorphine among both patients and users, and less diversion among patients on Suboxone than those being prescribed buprenorphine [45].

In the United States, the US FDA has recently issued new guidance intended to assist sponsors who wish to develop formulations of opioid drug products with potentially abuse-deterrent properties (abuse-deterrent formulations). Specifically, the guidance explains the FDA's current thinking about the studies that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how those studies will be evaluated, and what labelling claims may be approved based on the results of those studies. In a similar vein, the Government should consider directing the MHRA to issue similar guidance to promote the development and implementation of abuse-deterrent treatments. This would be consonant with NHS England's 'Innovation Health & Wealth' that promises the uptake of innovative medicines.

Abuse deterrent formulations of buprenorphine, like Suboxone tablet can provide positive contribution to the problem of misuse and diversion, and RBP believes that these products continue to provide significant patient and public health benefits over methadone and mono-buprenorphine.

II. Implement overdose death prevention programmes

Opioid induced overdose deaths are a problem all over Europe and many countries are experimenting with various strategies to combat the increasing trends. One of the major initiatives under consideration in several countries is the distribution of naloxone. Denmark, Norway, Scotland, Wales and several other countries are exploring liberalised means of distributing naloxone to opioid users, patients in treatment, families, carers and first responders. The ACMD made a positive recommendation to the Government supporting the availability of naloxone in May 2012 and an Independent Drugs Commission initiated by Caroline Lucas, MP, has made similar recommendations including a call for more training for people to be able to administer naloxone as a life-saving overdose antidote. For those just released from prison, the high risk of death from overdose is well known. During the first two weeks after release from prison, the risk of dying from an accidental drug overdose is up to 50 times higher compared to the population as a whole and ten times higher than that of released prisoners one year after release [47].

By implementing overdose death prevention programmes like wide distribution of take-home naloxone, the Government could reduce the demand for diverted medication by better supporting drug users and their families through their recovery journey.

III. Prioritise the identification and treatment of addiction to medicines

As discussed above there is relatively little guidance from either Public Health England or NHS England related to the issue of addiction to medicines and particularly around opioid painkiller dependence. There should be a significant investment of time and resources at the national level by these two organisations to determine the best way to address this significant issue in consultation with the Royal Colleges of General Practice and Psychiatry, British Pain Society, NICE and other relevant stakeholders.

Summary of Recommendations to Address the Diversion & Illicit Supply of Medicine

Healthcare sector should:-

1. Implement the NICE guidance through the education of healthcare professionals and evidence its implementation in service specifications.
2. Improve patient assessment through the development and implementation of national guidance
3. Commissioners to ensure that services address stigma and other barriers to treatment particularly for the development of services for opioid painkiller dependent patients.
4. Education of healthcare professionals to encourage appropriate therapeutic dosing
5. General Practitioners to screen for and treat opioid painkiller dependence.

UK Government should:

1. Ensure that the NICE HTA 114 is fully implemented and integrated in to clinical assessments and that there is a requirement to evidence its implementation in service specifications.
2. Ensure that the recommendations from this Inquiry are integrated into the development of the new National Clinical Guidelines – Orange Book
3. Implement and fund a national overdose death prevention programme
4. Data related to unintentional exposures and/or poisonings of children under 18 admitted to the hospital due to ingestion of prescribed and OTC medications are collected and acted upon in the UK to help safeguard children.
5. Ensure that one government department has responsibility to ensure that services are available locally that identify and treat patients addiction to medicines in particular opioid painkiller dependency.
6. Care pathways for pain extended to ensure that patients with opioid dependency are managed in primary care, to avoid the stigma.
7. Work with the pharmaceutical industry to promote innovation in treatment options including the development and implementation of abuse-deterrent formulations

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6th June 2014

Dear Mohammed Ali

Re: Call for Evidence - ACMD Diversion & Illicit Supply of Medicines Inquiry

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists in Great Britain. We represent all sectors of pharmacy in Great Britain and we lead and support the development of the pharmacy profession including the advancement of science, practice, education and knowledge in pharmacy. In addition, we promote the profession's policies and views to a range of external stakeholders in a number of different forums.

The RPS has endorsed the Guild of Healthcare Pharmacists' response (sent to you directly from the Guild of Healthcare Pharmacists). This response is referencing the North East of the country, however we are aware other parts of the country are also affected.

Kind regards,



Rakhee Amin
Senior Professional Development Pharmacist

Scottish Government

Submission to Advisory Council on the Misuse of Drugs Review of Diversion and Illicit Supply of Medicines

The Advisory Council on the Misuse of Drugs (ACMD) has been asked to undertake an inquiry into the diversion and illicit supply of medicines. In formulating the Scottish Government submission to this review, stakeholders from across Scotland were invited to complete an online survey, sharing their knowledge of the issue. Their responses indicate that this is an underdeveloped area of policy, lacking a strong evidence base. However, the experiences of stakeholders suggest that diversion and misuse of medicines is a growing problem in Scotland.

It should be noted that the following submission is based on a limited survey. The responses outlined below largely draw on anecdotal evidence and professional opinion. For this reason, it is difficult to draw any definitive conclusions around the scale and nature of the problem in Scotland.

1. In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

There is a degree of uncertainty around the scale of diversion and illicit supply of medicines within Scotland. As evidence is largely anecdotal and incomplete, it is difficult to quantify the true extent of the problem. Collated data from a variety of sources is needed to address this, including traditional prescribing data, information from street level, service users and providers, Police Scotland and drug death data. Stakeholders, though, were able to offer the following information.

- Reports from GPs, pharmacists, drug treatment services and police suggest that the misuse of prescribed medication takes a number of forms. This includes: consumption in excess of the prescribed regime; continuing to consume when there is no longer a clinical need; abuse of the prescribed medication to obtain a 'high'; and diversion of prescribed medication to others.
- Drug treatment services have seen an increase in the number of patients presenting with addiction to prescribed medicines. This may be through excessive consumption of legitimately prescribed medicines or diverted/illicitly supplied medicines.
- Prescribed medicines (whether obtained legally or illicitly) have been implicated or a contributing factor in a number of drug related deaths (DRDs) for 2013.
- One health board reported that around half of those on opiate substitute prescriptions were believed to be taking diverted diazepam. Health services have seen regular presentations with dependence on dihydrocodeine, as well as patients who are intoxicated with gabapentin and pregabalin.
- Police Scotland seizures suggest that the illicit supply of medicines is a significant problem within Scotland.

- Responses indicate that the diversion and illicit supply of medicines varies from area to area, due to variations in supply, demand and the preference of users within the geographical area.

2. Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

Medicines may be diverted and supplied illicitly from a number of sources.

- Family and friends with a legitimate prescription may be the source of prescribed medicines for drug users. At times, individuals may mistakenly assume that because the drug is prescribed it is 'safe'.
- Purchasing/stealing medicines legitimately prescribed to others.
 - Of 247 methadone-implicated DRDs in Scotland in 2012, 102 involved methadone that had not been prescribed to the victim. Responses indicate that illicit methadone consumption is largely the result of the diversion of prescribed medicines, as opposed to supply from organised crime.
 - There are anecdotal reports that dihydrocodeine and similar drugs are traded by patients in exchange for alcohol. Cases of individuals being approached in pharmacies for sale of their script were also noted.
- The internet is believed to be an important source for illicit prescription medications, as well as drugs which are controlled in the UK, e.g. certain kinds of benzodiazepines.
- A number of organised crime groups are believed to be involved in the illicit supply of medicines. A large proportion of street diazepam is trafficked into Scotland from overseas, with some pills also being illicitly produced within Scotland. Responses indicate that a small percentage of prescribed drugs are diverted from the legitimate UK medicine market, either by diversion of legitimate prescription or as a result of theft within drug distribution and drug dispensing structures.

3. Which medicines/drugs do you consider are being diverted and supplied illicitly?

Stakeholders indicated that a complete range of medicines/drugs are currently diverted and supplied illicitly within Scotland. The most common of these are listed below.

- Opiates, ranging from methadone, oxycodone, morphine sulphate and fentanyl, to weaker preparations such as co-codamol, and dihydrocodeine.
- Benzodiazepines, z-drugs and other sedation medications, including antihistamines such as promethazine. There are also a number of street drugs which contain illicit benzodiazepines not licenced or available in the UK, such as phenazepam and etizolam.

- Anti-depressants, e.g. mirtazapine, and antipsychotics, such as quetiapine.
- Pregabalin and gabapentin: it was suggested that the diversion and illicit use of methadone is currently less of an issue than that of gabapentin, which seems to be climbing significantly.

There are also anecdotal reports that less obvious drugs, like cimetidine, for example, are being used to potentiate the effects of methadone by increasing the plasma concentration. In addition to this, the misuse of diuretics, insulin and anti-obesity medicines by people in prison, who may be body building, was also noted.

4. What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

This multi-faceted issue reaches into different spheres, affecting patients, clinicians and the wider public.

- When patients consume prescription only medicines without a medical assessment or intervention, there is the potential for subtherapeutic or excessive doses.
 - Patients diverting their prescribed medication may also be at risk of subtherapeutic dosage.
 - Medicines obtained through diversion or illicit sources may be contaminated, inconsistent or contain adulterants. For example, diazepam purchased on the street may contain varying levels of the drug, as well as other substance, such as etizolam, phenazepam, amitriptyline or warfarin (or a combination).
- Those who misuse prescription drugs open themselves to a number of risks.
 - Drug treatment services have reported increased numbers of patients presenting with addiction to prescribed medicines.
 - Dangers of polypharmacy and interactions between medications/drugs: existing drug addiction issues create a ready market for prescribed medicines, such as benzodiazepines, methadone, and other opiates, whether diverted or illicit. Polydrug use is believed to be common and this brings with it severe health risks to users. In a significant number of DRDs this year, diverted medicines were implicated alongside street drugs and alcohol. Risk of accidental overdose is also increased by uncertainty over purity and strength of medicines purchased illicitly.
 - Patients taking in excess of the prescribed doses of medicine through illicit supply are difficult to treat effectively as clinicians are unable to establish the true extent of their misuse.
- Aside from the wider societal effects of drug misuse and illicit supply networks, medicine diversion may cause damage to the professional/patient therapeutic relationship. Strategies implemented to restrict access to medications may bring unanticipated consequences. For example, tight restrictions may create an atmosphere of distrust between patient and clinician when prescribing a specific

drug. In extremes this may create barriers to access and treatment, as patients may be reluctant to accept a medicine perceived to be one of abuse. All of these real or perceived problems may have implications for the patient, clinician and the wider community.

- Identifying cases of prescription medicine misuse and/or diversion is a problem for clinicians. Prescribers may inadvertently supply medication for the illicit market. For example, some patients present to GPs with very plausible symptoms, such as neuropathic pain, which often require maximum doses of 'desirable' medication. The knowledge that certain drugs are abused may compromise the clinician's ability to prescribe them.
- Increased costs due to the treatment of harms associated with the misuse of diverted and illicitly supplied medicines places further pressure on health services.

5. What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

As already noted, information on the diversion and illicit supply of prescribed medicines is largely anecdotal. Addressing the evidence gap on the extent and dimensions of this problem is critical to devising a lasting solution. Action should be taken by healthcare and other relevant sectors, then, to review all existing available data sources on this issue, and identify which aspects require further investigation. Stakeholders also suggested the following measures:

- Clinicians can improve practice by closer monitoring of commonly abused prescription drugs, implementation of regular medication reviews and the development of guidelines on what action to take if diversion is suspected. Regular information on trends of misuse and the street value of 'desirable' medicines could aid these processes by increasing awareness among prescribers.
- Enhanced links between community pharmacies and clinicians can also help in this regard. The community pharmacist may be the first professional to identify an issue through, for example, early requests for repeat supplies, excessive consumption of over-the-counter medications and repeated requests for emergency supplies.
- Inter-organisational links should be improved across the board. All sectors should work together to critically appraise information. Presently this is done to some extent through Drug Death Groups (consisting of representatives from Alcohol Drug Partnerships, pharmacy, medicine, substance misuse, public health, police, ambulance service and social work) and Local Intelligence Networks (consisting of representatives from private healthcare, prison, police, General Pharmaceutical Council, and health). However, further links between other relevant agencies also need to be developed.
- Stricter guidelines around the prescription of certain medicines may reduce misuse and diversion. For example, daily dispensing, more frequent

prescriptions for smaller amounts, and contacting the police (or encouraging patients to contact the police) when tablets are 'stolen'. However, as outlined previously, additional control measures may have unanticipated and negative consequences for patients and clinicians.

- Safer dosage forms, e.g. slow release medicines and matrix formulations, as well as improved treatment pathways, i.e. referrals to other services, such as physiotherapy and occupational therapy, may reduce the likelihood of abuse of legitimately prescribed medicines.
- It is important that current and future systems used by the healthcare sector to review and monitor repeat prescription, particularly with regard to methadone, benzodiazepines and other similar drugs, are robust and can effectively identify the diversion of prescribed medicine. For example, a nationwide system for stock control and storage could be introduced to more easily identify potential problems. In regards to methadone specifically, assessments on the source of non-prescribed methadone would suggest local prescribing and supervision regimes are not sufficiently robust to reduce opportunities for diversion.

6. What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

Government should take the lead in coordinating stakeholder organisations to address the diversion and illicit supply of medicines. As stated in the previous section, action is needed to improve the evidence base on the prevalence and dimensions of this problem. There are, though, existing sources of information on the issue, which can be more fully exploited. For example, prescribing and dispensing data, street level information and reports from prescribers and pharmacists, harm reduction services, drug treatment services, information gathered from needle exchanges, police seizure data and DRD toxicology reports. The Government is best placed to pull together these agencies, and coordinate all aspects of monitoring and commissioning of research in this area.

The Government might also consider:

- Additional legal measures on prescribed medicines.
 - Tighter controls of internet purchases and delivery of medicines by post and courier services.
 - Penalties for individuals and organised crime groups involved in the supply and distribution of diverted medication should be examined; ensuring penalties reflect the harms currently caused by such drugs. This is particularly pressing with regard to the impact of diverted and illicit medication on DRDs in Scotland.
- There is a need to ensure greater awareness and information among the public on the dangers of diverted and illicitly supplied medicines. The Government should also improve communication of such information with stakeholders, including provision of advice to services and prescribers on identification, prevention and treatment. Furthermore, the establishment of a central database that allows collation of local intelligence from a variety of agencies, including

health, police, voluntary sector, and community groups, would support the work of frontline staff.

- Government should engage jointly with healthcare and law enforcement to review current healthcare prescription arrangements and anti-diversion strategies relating to methadone, benzodiazepines, and other similar medicines. This would help to ensure that opportunities to share information, intelligence, and best practice are maximised, supporting robust structures that reduce the opportunity for the diversion and illicit supply of medicines. The review of vetting procedures relating to parties involved in the distribution and supply of medicines may also be of benefit.

7. How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

As discussed previously, there is a lack of strong evidence on the diversion and illicit supply of medicines in Scotland. There appears to be widespread agreement, though, that there is a general upward trend in prevalence. The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) identified an increasing trend in use of prescribed medications in Europe and, while there is no reliable data on this problem in Scotland, it is reasonable to assume that similar dynamics are at play. Anecdotal reports support this assumption.

Information on demographics of use is also incomplete. Stakeholders suggested, though, that the problem affects a wide range of ages and demographics depending upon the substance being misused. It is difficult to quantify general medicine drug trends as each drug has its own unique trend linked to its effects and demand from varying types of drug users, e.g. recreational or chaotic drug users. Scottish Government drug seizure data and DRD analysis provides some indication of the prevalence of specific drugs and their interaction with drug markets and drug users.

ACMD Diversion & Illicit Supply of Medicines Inquiry

Thank you very much for inviting the UK Clinical Pharmacy Association (UKCPA) to provide evidence for your Inquiry on the diversion and illicit supply of medicines. The response below is from the UKCPA Pain Management Group, a specialist group under the UKCPA organisational umbrella.

The UKCPA is a member association for clinical pharmacy practitioners. We encourage, support and promote advanced practice in pharmacy. The UKCPA actively develops clinical pharmacy practice as well as developing individual practitioners, and we are frequently at the forefront of initiatives such as establishing professional curricula, developing professional recognition (credentialing) processes, and developing professional tools and frameworks for practitioners. Leading UKCPA members are frequently called on to provide expertise and comment on national consultations and policies.

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?
Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?
Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?
Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?
Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?
Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?
Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

Specialists in pain management acknowledge that diversion and illicit supply of analgesic medicines does occur in the UK, however it is extremely difficult to quantify the extent of this. There are no data that tell us what happens to a prescription after it has been dispensed by a pharmacist. In part this is due to lack of identifying cases, inadequate appropriate recording and under-reporting cases to the National Drug Treatment Monitoring System. In addition, it is extremely difficult to examine the trends in diversion and illicit use of medicines as there is no centralised data resource.

The increasing number of deaths associated with tramadol is a concern and its availability over the internet has been identified as a source by which individuals may obtain excessive supplies. The recent change in legislation and its classification as a Schedule 3 controlled drug should bring this route of supply to an end. In addition, there needs to be much greater discussion and collaboration with other EU countries as tramadol is readily available over the counter in some European countries notably Spain.

It would be unhelpful if concern regarding illicit use or diversion of prescription drugs resulted in reticence to prescribe the drugs to those who genuinely need and derive benefit from them. Other countries, namely the United States of America and Australia, have developed prescription monitoring schemes for controlled drugs. Such schemes allow greater sharing prescribing and dispensing information between healthcare professionals, including community pharmacists.

Experience from the United States points up a clear relationship between quantity of controlled drugs prescribed and their misuse and associated morbidity and mortality. We do not know whether such a relationship pertains in the UK. Healthcare professionals play an important role in ensuring that prescription of controlled drugs is considered only when informed by knowledge of the risks of misuse for an individual. Controlled drugs for pain relief are not, on the whole, effective for the majority of people with pain in the long term. Sensible prescribing restricted for only those patients who demonstrate clear benefit from the drugs and adherence to dosing regimens for which safety data are available should mitigate the upward trend in prescribing which might be expected to limit the availability of these drugs for misuse.

The British Pain Society and Faculty of Pain Medicine, in collaboration with RCGP and the Faculty of Addictions Royal College of Psychiatrists, have previously published guidance on the appropriate use of opioids for pain and also on pain management in substance misuse. Both of these documents are scheduled for revision. We are aware that guidelines in the UK and elsewhere have had little if any impact on opioid prescribing trends and may have the unwanted effect of falsely reassuring prescribers and eroding sound patient-centred clinical decision making.

Rather than updating existing guidance the British Pain Society, the Faculty of Pain Medicine and other clinical and policy stakeholder groups propose to develop a central opioid prescribing resource, based on the best available evidence, regarding the benefits and harms of opioids which prescribers can then draw on to make a good clinical decision for an individual patient, influenced of course by the individual's clinical presentation, comorbidities and circumstances. This key resource can be drawn on to produce a suite of documents and educational materials in different formats for a variety of audiences including patients, which in turn should promote sensible prescribing to minimise risk.

The careful selection of stakeholder groups will ensure that advice on opioid prescribing is consistent, regardless of the information source. The document will be co-sponsored and published by PHE/NHS England who will support the administrative team at the Faculty of Pain Medicine, Royal College of Anaesthetists. Stakeholder partners in this project include RCGP, Faculty of Addiction RCPsych, The British Pain Society, RPS, CQC, Chronic Pain Policy Coalition, NICE, MHRA, ACPO and the Department for Transport.

Advisory Council on the Misuse of Drugs: Inquiry on diversion and illicit supply of medicines – call for evidence

Walgreens Boots Alliance (formerly Boots Alliance)

Further to the request from the Advisory Council on the Misuse of Drugs, we are pleased to make the following written submission to the inquiry on diversion and illicit supply of medicines.

Q.1 In your view, to what extent is diversion and illicit supply of medicines a problem in the UK?

We have no specific information on the scale or extent of diversion or illicit supply. One proxy for this might be the level of commissioning from community pharmacies of services that have the aim of reducing diversion of Controlled Drugs at risk of misuse.

According to Government figures for England [Health and Social Care Information Centre, General Pharmaceutical Services, 2003-2013] 5,359 community pharmacies were commissioned in 2012-13 to provide supervised administration services. This was 18.8% of all pharmacies, an increase from 2,563 in 2005-06, but a slight decrease from 5,601 pharmacies in 2011-12. They are the second most commonly commissioned services after smoking cessation.

The purpose of these services is for pharmacists to personally supervise the administration and consumption of individual doses of medicines that are at risk of diversion – principally opiate-substitutes such as methadone, buprenorphine and suboxone. Service specifications vary by location (see Q6), but typically involve confirming the identity of service users, checking that they are not intoxicated or otherwise ill, supplying individual doses of prescribed Controlled Drugs, watching the consumption of the product, and confirming that it has been used or swallowed (normally by talking with users after they have taken the product with a drink of water) so that it cannot be resold or otherwise diverted when the user leaves the pharmacy.

According to one service specification [Inspire, East Lancashire, available as exemplar via PSNC website] pharmacists play a “key and unique role in the care of substance misusers” – “key” because they help users maintain adherence with their prescribed regime, while reducing the risks of misdirection, and “unique” because they have daily contact with them and they are able to monitor health and wellbeing. These services help to normalise behaviour and users are treated with respect and confidentiality, as long as

they adhere to agreed standards of timeliness and good behaviour in the pharmacy.

Feedback from Boots field managers indicates that commissioning of these services has remained broadly stable, despite recent changes in NHS structures that has seen responsibility for many pharmacy services move from local NHS bodies to local authorities.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

We have no information to offer on this.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

As stated under Q1, opiate-substitutes are the medicines that are normally covered by supervised administration services. Community pharmacies can hold their own lists of products where increased care and attention is required when making sales. These are generally drawn up using pharmacists' own understanding of local issues together with information supplied by local NHS, public health or police.

Q.4 What problems have diversion and illicit supply of medicines caused for the public, patients and clinicians?

One example is the concern that pseudoephedrine might be being diverted for use in making illicit substances (ie, "crystal meth") which has led to greater restrictions on the sale of products containing this active ingredient. This includes restrictions on the number or quantity of products (or ingredient) that can be sold at one time and restricting the display of the product (ie, keeping it behind the pharmacy counter). These restrictions have helped contain potential illicit use of pseudoephedrine and the product remains available in Pharmacy (P) medicines that can be purchased without prescription, but at the cost of additional procedures for pharmacy staff and restrictions for customers.

We understand the additional restrictions introduced by the MHRA on pseudoephedrine to have resolved the concerns regarding sales through pharmacy.

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

We would like to see more pharmacies being able to offer supervised administration services. (See Q6).

Q.6 What action should the Government take to resolve the issues of diversion and illicit supply of medicines?

Although there has been a steady growth in the commissioning of supervised administration services from community pharmacies, the overall figures disguise wide regional variations at a local level. In addition, there is considerable variation in the specification of services (eg, which products are covered, requirements for identification, supplies for weekends/holidays, levels of payment, paperwork, training, etc) from place to place. We recommend that the ACMD works with Public Health England to harmonise the

specifications in order to support wider uptake of these services.

Q.7 How prevalent is diversion and illicit supply of medicines, what are the demographics of users and is the trend rising or falling?

We have no information to offer on this.

Response submitted by Alliance Boots
6 June 2014

About Alliance Boots

Alliance Boots is a leading international pharmacy-led health and beauty group, employing around 60,000 people in the UK. The group's businesses in the UK include the Boots pharmacy chain and our full-line wholesaler, Alliance Healthcare (Distribution) Ltd.

Boots UK operates the largest chain of community pharmacies in the United Kingdom. It is synonymous with pharmacy in the public mind and Boots is one of the country's most trusted brands.

Our company has 2,487 health and beauty stores trading under the Boots brand, of which 2,385 include a pharmacy¹. These are located in all the places where people live, shop, work and travel, with many open well beyond normal office hours and across weekends. Almost all of our stores hold contracts to provide NHS services.

Boots pharmacies are well distributed across the country. Our chain encompasses those which serve small local communities, including some of the most deprived locations in the country, and health centres through to high streets and those which are part of the largest retail and destination shopping centres. This provides easy access for the widest range of customers.

Alliance Healthcare (Distribution) Ltd is the only UK wholesaler delivering medicines to all pharmacies, dispensing doctors and hospitals, operating out of 12 service centres across the country.

¹ Figures at 31st March 2014 including joint ventures and associates, Alliance Boots Annual Report 2013-14