

Diversions and Illicit Supply of Medicines

The Government thanks the Advisory Council on the Misuse of Drugs (ACMD) for their advice and very comprehensive report of 15 December 2016 on Diversions and Illicit Supply of Medicines (DISM).

We have considered the ACMD's advice carefully and below set out the range of work we are taking forward to address it.

Introduction

All professionals who prescribe any medicines should act within their scope of practice and comply with their Regulators' standards. All prescribers are required to accept clinical and professional responsibility for their prescribing decisions.

Following the Shipman Inquiry the governance requirements for the safe management of controlled drugs, including the prescribing, requisitioning, supply and storage of controlled drugs were strengthened and guidance was issued by the Department of Health and the National Prescribing Centre. Most recently the National Institute for Health and Care Excellence (NICE) published guidance on the safe use and management of controlled drugs in April 2016 (www.nice.org.uk/guidance/NG46).

Under the Controlled Drugs (Supervision of Management and Use) Regulations 2013, organisations providing health care services within England and Scotland who have been assigned designated body status must appoint a fit, proper and suitably experienced person to be its Controlled Drugs Accountable Officer (CDAO). In England, these organisations include NHS England, NHS and independent hospitals and ambulance trusts. The CDAO has a responsibility to ensure the safe and effective use and management of controlled drugs (CDs) within their own organisations and by any body or person providing services to their organisation. This responsibility includes ensuring adequate and up to date standard operating procedures are in place in relation to the management and use of CDs, and adequate destruction and disposal arrangements for CDs.

Prescription only medicines are, by their very nature, potent and should only be prescribed by a doctor or appropriate healthcare professional. Doctors and other healthcare professionals can make an assessment of an individual's condition and medical history, consider possible risks associated with taking a particular medicine and monitor recovery. Given the potential for harm represented by the misuse of prescription drugs, the Medicines and Healthcare products Regulatory Agency (MHRA) is taking a range of measures to tackle the illegal online sale and supply of medicines, including public awareness campaigns to deter people from buying medicines from unregulated sources.

Recommendation 1: Maintain a watch list of emerging prescribed substances with the potential for DISM.

The Government welcomes ACMD's plans to maintain a watch list of emerging prescribed substances with a potential for DISM and to develop a Standard Operating Procedure (SOP) to ensure timely recommendations can be made should revisions to the control status of substances be required. We agree that all relevant Government agencies with information and data relevant to substances on the watch list will make this information available to ACMD in a timely way.

Recommendation 2: Appropriate education of medical students/non-medical prescribers and, by CPD, existing practitioners.

Government fully acknowledges that medical students, non-medical prescribers and existing practitioners need to be aware that controlled drugs subject to DISM should not be prescribed to patients who no longer derive a therapeutic benefit from them. The General Medical Council (GMC) has already issued guidance on this issue. Doctors must be familiar with this advice and be able to demonstrate their awareness for revalidation purposes, in order to meet the standard required to practise.

The GMC guidance on good practice in prescribing and managing medicines and devices came into effect on 25 February 2013.

The guidance explains how the principles in Good Medical Practice (2006), the GMC's core guidance for doctors, on the standards that must be met in order to

practise medicine in the UK, apply to decisions about prescribing and managing medicines and medical devices. It covers issues including:

- responsibility for prescribing, including repeat prescribing, and prescribing at the recommendation of a colleague or where a patient's care is shared (for example between specialists and GPs);
- making prescribing decisions based on adequate knowledge of the patient's needs, not on demand or for the convenience of those treating or caring for the patient;
- prescribing unlicensed medicines and information for patients about such medicines; and
- promoting patient safety by keeping up to date and reporting adverse drug reactions and medical device adverse incidents.

The guidance also instructs doctors to get advice on training for dispensing support staff from the General Pharmaceutical Council.

The General Pharmaceutical Council's standards of conduct, ethics and performance state the pharmacist is professionally accountable for their practice. In addition, it also states that the professional must recognise the limits of their professional competence. They must practise only in those areas in which they are competent to do so and refer to others if they need.

The professional must maintain and improve the quality of their practice by keeping their knowledge and skills up to date and relevant to their role and responsibilities.

The Royal Pharmaceutical Society published a competence framework for all prescribers in July 2016, which is endorsed by professional bodies representing all prescribers, medical and non-medical, following the one published by the National Prescribing Centre and NICE in 2012. The framework was developed because it became clear that a common set of competencies should underpin prescribing regardless of professional background. This framework sets out the competencies for prescribing. The prescribing competencies help healthcare professionals to be safe, effective prescribers who are able to support patients to get the best outcomes from their medicines.

In relation to medical students, since 2014, all publicly funded undergraduate medical schools in the UK have provided their students with an opportunity to complete the Prescribing Safety Assessment before graduation. Since 2016 all new doctors are required to take the Prescribing Safety Assessment before their first year of practice after graduating (Foundation Year 1) – as announced by the Foundation Programme Office on behalf of the Health Departments of England, Wales, Northern Ireland and Scotland.

In total now, around 36,000 UK medical students have participated in the Prescribing Safety Assessment, with approximately 8,000 students completing the assessment each year. With eight prescriptions as part of the assessment, and further prescriptions set as part of practice papers, it is estimated that participants have written a total of almost 500,000 prescriptions.

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Recommendation 3: Monitor implementation of the NICE Guidelines on the Safe Use and Managements of Controlled Drugs to ensure that prescribers follow best practice.

The regulation of human medicines is the responsibility of the MHRA. The MHRA has identified an issue relating to the large-scale (130 million tablets since January 2014) diversion of benzodiazepines and other hypnotics/anxiolytics from the regulated supply chain to the criminal market. Evidence has shown extensive criminality involving a number of businesses. MHRA is working with regulatory and law enforcement colleagues (including the Home Office, the General Pharmaceutical Council, and the Care Quality Commission (CQC)) to identify how this issue occurred, to prosecute those involved in criminal activity and to implement preventative measures. This comprehensive response highlights the importance attached to this issue and that Government agencies are poised to take immediate action when evidence of diversion and criminality come to light.

In addition, the CQC will continue to monitor how controlled drugs are managed within health and care services as part of their inspection processes, taking account of the NICE Guidelines.

Recommendation 4: Supply the development of tailored treatment for those who misuse or have become dependent on prescription or over-the-counter medicines.

Government agrees that the NICE guidelines on the Safe Use and Management of Controlled Drugs should be monitored to ensure that prescribers are following best practice in reviewing repeat prescribing of medicines on which people may become dependent. In particular, the CQC will continue to monitor how controlled drugs are managed within health and care services as part of their inspection processes, taking account of the NICE Guidelines.

Government is committed to the development of tailored treatment for those who misuse or are dependent on prescription or over the counter medicines. Public Health England (PHE) continues to support the commissioning of locally-appropriate services for drug misuse and dependence, including addiction to medicines (ATM).

PHE's [commissioning guide](#) for the NHS and local authorities sets out the Government's expectation that support should be available in every area for people who misuse or have become dependent on prescription or over-the-counter medicines, based on a full assessment of local need.

This expectation, and the data/tools to support it, is referenced every year in PHE's alcohol and drugs [support packs](#) for local joint strategic needs assessments. The resulting configuration of local services rightly differs from area to area in response to local needs, environment and history. PHE has supported a small number of local areas to improve their commissioning of responses to ATM.

PHE is also supporting an update to the UK guidelines for the clinical management of drug misuse and dependence. An expert group has been leading this process and ATM is one of the subjects it has considered. The revised guidelines will be published alongside the Government Drug Strategy.

Recommendation 5: Ensure up to date and relevant survey information is available on those drugs subject to DISM.

In response to concern about up to date and relevant survey information on drugs subject to DISM, the 2014/15 Crime Survey for England and Wales (CSEW) included a question asking the general population about any misuse of prescription medication. The question was further refined in 2015/16 to be clear whether the misuse was “for medical reasons or for the feeling or experience it gave them”:

The 2015/16 survey estimated that in the last year 7.5 per cent of adults aged 16 to 59 had taken a prescription-only painkiller not prescribed to them: 7.4 per cent (around 2.4 million adults) said that they had taken the painkillers purely for medical reasons, while a small proportion (0.2%, or 33,000 adults) said it was just for the feeling or experience it gave them. A further very small number of adults said it was for both. This tendency was also true for young adults aged 16 to 24.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/564760/drug-misuse-1516.pdf

The same question was asked in the 2016/17 CSEW (so this will be comparable) and has been proposed for inclusion within the 2017/18 survey. The question may be included in future survey years as well. Consideration will be given to the question within the annual review process alongside other policy priorities and pressures across the whole survey.

Recommendation 6: Continue to monitor closely the safety of OTC codeine and dihydrocodeine-containing medicines.

The Government agrees with the recommendation to monitor closely the safety of over the counter (OTC) codeine and dihydrocodeine-containing medicines. A number of measures have already been taken by the MHRA to minimise the risk of deliberate or inadvertent overuse of OTC analgesics containing codeine or dihydrocodeine:

- Limiting the pack size available for sale in pharmacies without prescription to 32, with larger pack sizes only available on prescription and thus supplied under the supervision of a doctor or other healthcare professional qualified to prescribe;
- limiting the indications for non-prescription use to the short term treatment of acute, moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone;
- strengthening warnings on patient information leaflets, labels and advertising about the risk of addiction, the importance of not taking the medicine for more than three days consecutively and the need to seek advice from a doctor if painkillers are needed for longer than three days; and
- providing more information in the patient leaflet about the signs and symptoms of addiction.

The MHRA is continuing to monitor the safety in use of these products through its yellow card reporting scheme, and will take further action if needed to minimise the risk of addiction to these medicines.

Recommendation 7: The BNF and MIMS to consider cautionary information in relation to controlled drugs subject to the risk of DISM following the identification of such ‘watch lists’.

Once the watch list that ACMD propose to develop on controlled drugs subject to risk of DISM has been developed, we will bring these substances to the attention of the British National Formulary and Monthly Index of Medical Specialities (MIMS) and request that they consider including “cautionary information” in relation to them.

Recommendation 8: The ACMD recommends that prison health care commissioners including NHS England should embed responsibility for protecting against diversion and treatment of addiction to prescribed medication into prison healthcare providers specifications.

NHS England fully supports this recommendation. Strategic plans to implement it include the partnership agreement between NHS England, National offender Management Service and PHE (published on NHS England web-site) along with the

prison reforms in the recent White Paper provide the co-commissioning mechanisms to implement this recommendation with Governors.

The service specifications for commissioned substance misuse and mental health services in prisons are being revised during 2017/18 to include:

- treatment for people dependent on or abusing prescribed medicines;
- the provision of multidisciplinary and holistic approach to pain management; and
- formal medicines reconciliation in line with NICE guidance to improve continuity of care.

The introduction of a new clinical information system (HJIS) in 2017 will enable the analysis and reporting of prescribed medicines across all prisons in line with prescribing data available in primary and secondary care.

Conclusion

The ACMD have produced a thorough and detailed report on this important issue. The Government is very grateful for this and will continue to work with the ACMD on implementation of these important recommendations.