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Dear Owen,

Response to the ACMD report on the misuse of fentanyl and fentanyl analogues

Thank you for your very thorough report of 3 January and for your recommendations to combat the serious health risk to people in the UK from fentanyl and fentanyl analogues. I read the conclusions and recommendations of the report with interest.

In considering your advice, my Department has worked with other government departments and agencies and consulted the devolved administrations. The response below collates independent responses from the Scottish Government, the Welsh Government and Northern Ireland Assembly, where relevant. We will continue to work with the devolved administrations where appropriate to implement these recommendations. The following is a partial response to your recommendations as further work is required to implement some of these. I have indicated below where this applies.

Recommendation 1:

Research should be commissioned to study diversion and non-medical use of strong opioids to identify trends, drug products involved and populations at risk.

The Department of Health and Social Care (DHSC) and its relevant executive agency Public Health England (PHE) both agree with this recommendation, provided that an adequate case to undertake the research can be made. DHSC and PHE (or its responsible successor agency) will assess the current state of the evidence on diversion and non-medical use of prescribed opioids to determine where knowledge

gaps could be filled through further research, and where doing so would have actionable policy implications. Any research requirements deemed a priority are likely to be commissioned through the National Institute for Health Research (NIHR), following usual NIHR procedures to ensure high quality, robust and ethical research is carried out. DHSC and PHE intend to submit a research bid to the NIHR in January 2021 and to update the ACMD on progress with this recommendation towards the end of the year.

Response of the Scottish Government

The Scottish Government agrees with this recommendation in principle and recognises ongoing concerns about the diversion and misuse of opioids and the need to develop a clearer understanding of their use and the associated risks. This must, however, be weighed against other issues that are of significant concern in Scotland that would also be a priority for additional research, for example the use of benzodiazepines (including 'street benzodiazepines') and the harms caused by them.

In Scotland, research proposals on such a topic would be expected to be made to the Drug Death Taskforce or the Drug Research Network for Scotland. These would need to show a focus on existing gaps in research or evidence and demonstrate value to policy development. A commitment in the alcohol and drug strategy, published in late 2018, was for the Scottish Government and Drug Research Network Scotland to review and update the 2015 Scottish National Research Framework for Problem Drug Use. This work is likely to begin in late 2020 and will identify priority areas for research.

Response of the Department of Health Northern Ireland

The Department of Health Northern Ireland is supportive of the recommendation for a UK-wide research to be commissioned to study diversion and non-medical use of strong opioids and has offered its support and input into this research as required.

Response of the Welsh Government

The Welsh Government, in collaboration with the University of South Wales, has recently carried out research on the misuse and diversion of prescription only and over the counter medicines. The report, a *Qualitative Study of the Misuse of Diversion of Prescription Only and Over the Counter Medication*, was finalised in June 2020 and has been disseminated to partners along with specific recommendations. This is available on the Wales.Gov website.

Recommendation 2:

<u>Government departments should conduct a full review of international drug strategy approaches to fentanyl markets, in particular, the North American experience, and consider interdiction controls that can be applied to the UK situation.</u>

The Government accepts this recommendation and considers that it is primarily for the Home Office to lead, given the broad scope of the review which includes enforcement and interdiction. The Home Office will liaise with Border Force and the National Crime Agency where necessary.

The issue of fentanyl supply was considered by the previous government as part of the opioid roundtable in 2019 and the Government agrees that more work can be done to examine the work of countries both in their strategic approach and interdiction controls, such as in the United States of America, and Canada to tackle fentanyl. We will discuss this further with international partners and prepare a report based on these findings which we will share with the ACMD. I expect to be able to update the ACMD about the findings from this work in June next year, following the UN Commission on Narcotic Drugs meeting in April.

Recommendation 3:

Ensure that health professionals are trained in the appropriate therapeutic use of strong opioids, as described in the 'Opioids Aware' resource and the forthcoming NICE guidance on management of chronic pain.

In principle, the Government agrees that health professionals should be trained in the appropriate therapeutic use of strong opioids. However, medical training curricula are set by the Royal Colleges or faculties in line with General Medical Council standards rather than by central government and its agencies.

Safe prescribing is already a core element of healthcare professional training to raise awareness among clinicians of the risks of continued opioid prescribing. All trainee doctors must have passed the National Prescribing Safety Assessment before the end of the first year of Foundation training (the stage before specialty training) to progress. It is also a specific requirement of the curriculum for the Foundation programme that a foundation doctor is able to "prescribe controlled drugs using the appropriate legal framework and can describe the management and prescribing of controlled drugs in the community".

Core and Higher training in many specialties provide both detailed theoretical and practical clinical teaching and clinical examples of the use of strong opioids including fentanyls. Trainees in General Practice also undertake these training programmes. Specialties such as Palliative Medicine, Pain Medicine, Rheumatology and Anaesthesia (where day to day use and sometimes complex management of patients requiring these medications are very frequently encountered) provide more in-depth coverage of these areas as appropriate.

Health Education England (HEE) works to promote the latest guidance and best practice to trainees and medical professionals through its e-Learning for healthcare programme. The 'Opioids Aware' resource is currently used on a voluntary basis, and only pain medicine specialists (those under the direct responsibility of the Faculty of Pain Medicine) have this as part of their wider training and learning. DHSC is supportive of Faculties and Royal Colleges considering including this resource as part of the generic training of all healthcare workers involved in opioid prescribing. NICE's guidance on chronic pain management is expected in January 2021, following consultation.

Response of the Scottish Government

Clinical guidance for chronic pain is available from Scottish Intercollegiate Guidelines Network (SIGN) 136. This acknowledges that "within Scotland there is evidence of wide variation in clinical practice, service and resource provision, with a general lack of knowledge about chronic pain and the management options that are available."

In order to address this the Scottish Government published guidelines on "Quality Prescribing for Chronic Pain" in 2018 and will shortly be publishing guidance on "Opioid Prescribing for Chronic Pain". The 2018 guidelines (which cover the use of strong opioids) promote quality improvement in prescribing for adults with chronic pain across primary care in Scotland, particularly focussing on the provision of safe, person-centred care. In addition, they promote self-management and non-pharmaceutical management of chronic pain and disseminate prescribing quality indicators that can be used to monitor and review analgesic prescribing and variation in practice across Scotland.

Response of the Department of Health Northern Ireland

The Health & Social Care Board in Northern Ireland regularly refers to, and promotes, the 'Opioids Aware' resources in training, newsletters, resource packs and other relevant communications regarding appropriate use of opioids. Pain Management training (in conjunction with NI Centre for Pharmacy Learning & Development) for GPs and pharmacists, and changes to the NI Pain Formulary, are planned for autumn and these will provide further opportunities to promote this.

Recommendation 4:

a) Toxicology analysis of samples of all deaths related to drug poisoning should include analysis for fentanyl and fentanyl analogues as non-systematic screening hinders our capacity to understand trends in drug deaths.

b) Toxicology reports from all deaths related to drug poisoning should include a clear statement as to whether fentanyl and/or its analogues were included in the testing. Importantly it should be made explicit if fentanyl and/or its analogues have not been tested for. This would enable meaningful monitoring of trends in fentanyl-associated deaths.

The UK Government agrees with this recommendation in principle. DHSC, through the relevant executive agency (PHE), is exploring the feasibility of possible approaches to improve the screening for fentanyls in suspected overdose deaths with the goal of this becoming routine practice in most if not all such cases (subject to independent judicial decision-making in individual cases by coroners). The matter has also been discussed with the Chief Coroner's Office, with a remit covering England and Wales, which has agreed to obtain feedback from their membership on proposed approaches for doing this. Of central importance to any solution would be the timely sharing of drug screening results for national monitoring and alerting purposes. The Government will update the ACMD on progress by the end of the year.

Response of the Scottish Government

Current practice in Scotland is largely in line with the recommendations made by the ACMD. As a more general point, there is a strong argument that post-mortem toxicology should not be the only vehicle for detecting drug misuse. Consideration should be given to how we are best able to identify and detect specific substances, such as fentanyl, in the drugs people are using. Testing drugs themselves instead of testing blood as a part of toxicology would be easier and would offer higher concentrations. The testing of drugs would allow concerns to be identified and alerts raised at a much earlier stage, before any deaths occur. The Scottish Government supports the introduction of drug checking facilities as an important harm reduction measure and work is already underway in Scotland, approved by the Drug Death Taskforce, to develop proposals for such facilities.

In response to 4(a), the Drugs of Abuse (DOA) screening test has included fentanyl in Scotland since 2017, so every case tested for DOA is tested for fentanyl automatically. Another test ("basic drugs") is included in every case where prescription drugs, or drugs of abuse are requested. This detects drugs which the toxicologists are not specifically looking for. While therapeutic concentrations of fentanyl and its analogues can be very low, there is the capability to assess qualities and toxicologists can detect these in most instances. This test has detected fentanyl analogues on a number of occasions in the past few years. Furthermore, there is also a fentanyls test which is a targeted test and includes 13 individual drugs.

In relation to 4(b), with regards to reporting, toxicology reports provided to the Crown Office and Procurator Fiscal Service (COPFS) make it clear that the DOA Screen includes fentanyl. In addition, when toxicologists do use the more extensive "fentanyls" test they include the following statement: "This analysis does not include all available substances, please contact the laboratory if you require further information on the panel tested." Toxicologists use this to allow them to change the panel of drugs included in the test as trends change. When a pathologist does not have a cause of death and asks for further testing, the fentanyls test is carried out to double check nothing has been missed.

Scotland does not have many fentanyl or fentanyl analogues positive cases, but where these occur a system is in place to ensure that it can be raised with appropriate partners. On the very rare occasions that this has happened, and with Crown permission, this information has been shared with Police Scotland, SPA Forensic Services and NHS Scotland.

Toxicologists are confident that the only cases that could potentially be missed in Scotland are very low concentrations (therefore less likely to be significant from a cause of death perspective) of unusual fentanyl analogues.

Response of the Department of Health Northern Ireland

The Department of Health Northern Ireland has referred this recommendation to coroners and will respond in due course.

Response of the Welsh Government

The Welsh Government will work with PHE on this recommendation.

Recommendation 5:

Research should be commissioned to monitor the local and national prevalence of fentanyl and fentanyl analogues in:

a)(i) drug seizures, including heroin preparations and counterfeit medicines;
a)(ii) non-fatal episodes of heroin toxicity requiring hospital treatment;
b) Increased funding should be made available to the Defence, Science and Technology Laboratory Forensic Early Warning System (DSTL FEWS) programme to increase capacity to analyse un-adopted police and border force seizures.

Recommendation 5(a)(i): The UK Government accepts this in principle and believes that the prevalence of local and national fentanyl and fentanyl analogues in drug seizures can be effectively monitored by enhancing existing processes. Data on all seized drugs that are sent for forensic analysis by police forces in England and Wales or by Border Force is collected by the NCA. Some data on detections of fentanyl and analogues has to date been shared with the ACMD NPS committee via PHE. However, DHSC will contact the ACMD through PHE or its responsible successor agency to establish a protocol on data sharing in accordance with the ACMD's information needs. The ACMD will also be consulted on the adequacy of the information shared through this protocol once implemented and the Government will confirm whether it intends to commission further research by the end of the year in light of this. The Government will also publish an analysis of fentanyl and fentanyl analogues detected in seizures next year.

Recommendation 5(a)(ii): The Government considers that this recommendation is covered by recent activity as PHE has started funding this year the "*Identification of novel psychoactive substances"* (IONA) study. IONA is an acute drug harms surveillance and early warning system in around 30 UK emergency departments. IONA has retained its original function of identifying health harms associated with toxicity from NPS, such as synthetic cannabinoids. It has been broadened to detect fentanyl, fentanyl analogues and other synthetic opioids in episodes of heroin toxicity presenting at participating hospitals. Data from IONA will be shared with the ACMD. The Government will assess the need for further research on non-fatal episodes of heroin toxicity requiring hospital treatment in consultation with the ACMD with a decision by the end of the year.

In relation to part 5(b), the UK Government accepts this recommendation in part and will consider this recommendation again in full once on-going work on fentanyl and fentanyl analogues as part of FEWS has been completed. In the meantime, the Government will use existing funding to carry out this measure. The FEWS project will endeavour to analyse unadopted samples of suspected controlled drugs or NPS submitted under the FEWS project. These unadopted samples will be analysed in order to better characterise drugs entering the UK.

The Home Office will consider methods such as intelligence led targeting of packages (using UK Border Force expertise) to determine if this could enable the

interception of a higher percentage of threat compounds through mini-operations that focus on the origin of packages and other intelligence methods. Detailed chemical analysis of these samples could enable batch matching and source attribution studies. Previous FEWS collection plans largely focussed on NPS only and therefore, this approach should lead to an increased number of samples and improved intelligence to identify manufacturers and traffickers.

The fentanyl element of the FEWS work will inform further consideration about expanding funding to increase capacity to analyse unadopted samples of fentanyl and fentanyl analogues. The Government will write to the ACMD about these findings, with the intention of doing so by June 2021.

Response of the Scottish Government

The Scottish Government accepts the principle of the recommendation and will consider the need for fentanyl related research as part of its work to update its Scottish National Research Framework for Problem Drug Use, as well as through the ongoing work of the Scottish Drug Death Taskforce. There is currently limited evidence of fentanyl use in Scotland, however, there are already a number of processes in place whereby it would be identified. The Scottish Government recognises the need to be prepared for increased prevalence of fentanyl and fentanyl analogues in Scotland.

5(a)(i) When Police Scotland seize drugs, they either presumptively test or, where that is not suitable, they submit these to laboratories. Presumptive testing can only be applied to substances suspected of containing heroin, cocaine, MDMA and cannabis. This testing will not detect fentanyls. Items submitted to laboratories are subject to instrumental analysis which is much more sensitive and specific than presumptive testing. That analysis also detects fentanyl and its analogues, although very low levels are hard to detect.

The Scottish Government would expect any increase in fentanyl found in seized drugs to be highlighted to it and NHS Scotland through existing lines of communication with Police Scotland, as well as with other key partners and service providers (such as drug trend monitoring groups). Work is also underway in Scotland, through the Drug Death Taskforce and its Public Health Surveillance sub-group, to improve the monitoring of relevant data and trends and to ensure that an efficient and effective warning system is in place. This will seek to use data and intelligence from a range of different sources, potentially including drug seizures and hospital admissions in the longer term.

Recommendation 5(a)(ii): this recommendation is satisfied in respect of Scotland, as Scotland is part of the IONA study.

Response of the Department of Health Northern Ireland

The Department of Health Northern Ireland does not agree that commissioning new research would substantively improve its ability to monitor local or national prevalence of fentanyls. The Forensics Service for Northern Ireland (FSNI) has advised that it routinely screens all heroin samples for fentanyls and has seen no evidence that fentanyl is being added to heroin in Northern Ireland. Consequently,

DHNI does not consider that further research is needed to monitor the prevalence of fentanyls in Northern Ireland.

Response of the Welsh Government

The Welsh Government does not agree that commissioning new research would substantively improve its ability to monitor local or national prevalence of fentanyls. The Welsh Government commission the Welsh emerging Drugs and Identification of Novel Substances (WEDINOS) programme. WEDINOS provides a robust mechanism for the collection and testing of substances along with the dissemination of pragmatic harm reduction advice. This advice is provided via the internet, public health alerts and quarterly bulletins.

Recommendation 6:

Agencies with responsibilities relating to drugs of misuse should monitor the international situation and share available UK data. There should also be a comprehensive early warning system which has access to up to date consolidated UK-wide drug misuse data sets.

The UK Government considers that this recommendation is being adequately covered by activity DHSC conducts through the relevant executive agency (PHE). This includes the International Focal Point on Drugs function for reporting to international agencies and the secretariat function for the Drug Harms Assessment and Response Team (DHART). DHART has a broad membership representing a range of professions in health, law enforcement and the civil service from across the UK. DHART reviews intelligence and data gathered by its members and by the Focal Point for evidence of drug-related health threats including from fentanyl and its analogues and considers appropriate responses. DHART inputs include data and intelligence from local, national and international early warning systems. These inputs are also monitored by PHE's drugs team which has a protocol for responding rapidly to immediate threats.

Response of the Scottish Government

The Scottish Government accepts this recommendation, and already works closely with counterparts in the Focal Point team at PHE, as well as feeding into the DHART. Work is also underway in Scotland, through the Drug Death Taskforce and its Public Health Surveillance sub-group, to improve the monitoring of relevant data and trends and to ensure that an efficient and effective warning system is in place.

Response of the Department of Health Northern Ireland

The Department of Health Northern Ireland accepts the recommendation and believes this is currently being met as Northern Ireland provides information to the international Focal Point on Drugs team in PHE.

Wales

The Welsh Government accepts the recommendation and believes that this recommendation is currently being met. The Welsh Government shares this information with PHE.

Recommendation 7:

If materials are encountered in the UK or Europe that retain potency but fall outside the UK generic control on fentanyls, a small amendment to that generic control should be applied to address these.

In relation to recommendation 7, the UK Government agrees with this in principle. Where potent compounds which fall outside the generic control on fentanyls in the Misuse of Drugs Act 1971 are detected, we will consider amendments to the generic control as necessary. The Home Office will seek the ACMD's advice about potential amendments to the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 where such compounds are detected.

Recommendation 8:

Following a consultation with the research community, the Home Office should expand the precursor controls to cover simple variants of ANPP (see Annex 6), the immediate precursor to fentanyl. It is recommended that paragraphs (i) to (v) of the text of the existing generic control on fentanyls be also applied in the precursor legislation, that is that the entry for ANPP be amended to cover:

"Any compound……structurally derived from ANPP by modification in any of the following ways, that is to say:

- *(i) By replacement of the phenyl portion of the phenethyl group by any heterocycle whether or not further substituted in the heterocycle;*
- *(ii) By substitution in the phenethyl group with alkyl, alkenyl, alkoxy, hydroxy, halogeno, haloalkyl, amino or nitro groups;*
- *(iii) By substitution in the piperidine ring with alkyl or alkenyl groups;*
- *(iv) By substitution in the aniline ring with alkyl, alkoxy, alkylenedioxy, halogeno or haloalkyl groups;*
- *(v) By substitution at the 4- position of the piperidine ring with any alkoxycarbonyl or alkoxyalkyl or acyloxy group"*

[Note: para (vi) of the fentanyl generic refers to the propionyl group being replaced by another acyl group, but this feature is absent in ANPP and so is not required here]

In order also to control the benzyl analogues of fentanyl as precursors (see Annex 7), the new control described above should be further expanded by adding a paragraph:

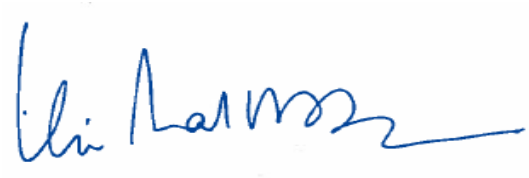
(i)(a) "By replacement of the phenethyl group by a benzyl group;"

And by expansion of para (ii) to:

(ii) By substitution in the phenethyl <u>or benzyl</u> group with alkyl, alkenyl, alkoxy, hydroxy, halogeno, haloalkyl, amino or nitro groups"

The UK Government agrees with this recommendation, subject to the outcome of the consultation. Given that a number of fentanyl derivatives are prepared using variants of ANPP, and that several of the variants which have been identified by the EMCDDA have structural modifications derived from modified versions of the ANPP precursor, the Home Office can commit to undertake a consultation on medicinal, industrial and commercial uses of simple variants of ANPP, the immediate precursor to fentanyl. This will seek views on the controls available under the precursor legislation which were primarily designed to control and manage legitimate trade by licensing and reporting responsibilities of those involved in the supply of the relevant substances. There are a number of complexities about how to capture this in legislation that will also need to be considered alongside the consultation. Officials will update the ACMD on the timings associated with this.

I thank the ACMD for its work during the preparation of this report. As set out above, the Government will respond further on a number of recommendations. We will continue to work across government and update the ACMD on the implementation of the recommendations in due course. My officials would be happy to discuss any areas further should you deem this necessary.



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