FROM THE MINISTER OF HEALTH

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Dear Colm,

LEGISLATIVE CONSENT MOTION - MANDATORY PUBLICATION AND/OR REPORTING OF HEALTHCARE PAYMENT DATA PROVISIONS IN THE HEALTH AND CARE BILL

It is my intention to bring forward a Legislative Consent Motion (LCM) as soon as possible in respect of the following provisions in the Westminster Health and Care Bill, which were finalised and tabled on 24 January at House of Lords Committee Stage:

- New clause 312B – to enable regulations to require the reporting and publication of information about payments and other benefits provided to persons in the health care sector by manufacturers and suppliers of healthcare products.
- New clause 312C – to enable provision to be made for the enforcement of requirements relating to information about payments, etc, to persons in the health care sector, including through the imposition of civil penalties.
- New clause 312D – requiring the Secretary of State for Health and Care to obtain consent of the Scottish Ministers, the Welsh Ministers or the Department of Health in Northern Ireland (as appropriate) before making provision within devolved legislative competence in regulations relating to information about payments etc to persons in the health care sector.
- New clause 313B – which provides for regulations relating to the reporting and publication of information about payments and other benefits provided to persons in the health care sector, to be able to make different provision for different parts of the UK.
- New clause 313C – which provides for regulations relating to the reporting and publication of information about payments and other benefits provided to persons in the health care sector to be subject to affirmative procedure.
- New clause 314ZB – which provides for the powers relating to the reporting and publication of information about payments and other benefits provided to persons in the health care sector to extend to the whole of the United Kingdom.

I attach a full briefing note to this letter.

It will be necessary for the LCM to be debated in the Assembly before the relevant part of Report Stage in the House of Lords. At present, DHSC estimate that this will take place during the weeks commencing 21 and 28 February 2022, although the exact date of the proceedings in respect of the above clauses is yet to be confirmed.

My officials will keep in touch with the Committee Clerk regarding timings as this matter progresses.

Officials will also be happy to brief the Committee if that would be helpful.

Robin Swann MLA
Minister of Health

BRIEFING FOR ASSEMBLY HEALTH COMMITTEE: LEGISLATIVE CONSENT MOTION - MANDATORY PUBLICATION AND/OR REPORTING OF HEALTHCARE PAYMENT DATA PROVISIONS IN THE HEALTH AND CARE BILL

Background

1. In February 2018 the then Secretary of State for Health established a Medicines and Medical Device Safety Review. This review was to look into how to improve the way the NHS in England and the Medicines and Healthcare products Regulatory Agency (the MHRA), responded to patient-reported concerns more effectively and in a way that ensures those raising concerns are properly heard. Whilst the primary focus of this review was on the NHS in England the Review Team, led by Baroness Cumberlege, visited Northern Ireland in December 2018 and evidence from patients here in NI was heard by the panel.

2. The review centred on matters relating to the use of vaginal mesh[1], sodium valproate[2] and hormone pregnancy tests such as Primodos[3] and was chaired by Baroness Cumberlege. The panel's report, *First Do No Harm*, was published on 8 July 2020.

3. In her report, Baroness Cumberlege set out a total of nine recommendations relevant to all three of the interventions the Review Panel was asked to look at. The recommendations are targeted to improve patient safety, provide help to those who have been harmed and improve practice and learning.

4. The Minister of Health will shortly be issuing a Written Statement to the Assembly on progress made to date to implement the nine recommendations in Northern Ireland.

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[1] Per the First Do No Harm report: "pelvic mesh implants – used in the surgical repair of pelvic organ prolapse and to manage stress urinary incontinence. Its use has been linked to crippling, life-changing complications".
[2] Per the First Do No Harm report: "an effective, anti-epileptic drug which causes physical malformations, autism and developmental delay in many children when it is taken by their mothers during pregnancy".
[3] Per the First Do No Harm report: these "were withdrawn from the market in the late 1970s and which are thought to be associated with birth defects and miscarriages".

5. Recommendation 8 stated that:

   "transparency of payments made to clinicians needs to improve. The register of the General Medical Council (GMC) should be expanded to include a list of financial and non-pecuniary interests for all doctors, as well as doctors' particular clinical interests and their recognised and accredited specialisms. **In addition, there should be mandatory reporting for pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians" (DoH NI emphasis).**

6. Recommendation 8 is being implemented in two parts. This paper relates to the second part of that recommendation, which is in bold above.

7. This recommendation is to address the perceived and real conflicts of interest in the provision of health care and treatment when health care professionals and others have financial links with pharmaceutical and medical device companies and that responsibility for transparency should not only lie with the medical profession, but also with the pharmaceutical and medical devices industries.

Health and Care Bill

8. In December 2021, DHSC proposed that it would legislate to implement this part of recommendation 8 on a UK-wide basis, by making amendments to the Health and Social Care Bill, which is currently going through its Parliamentary stages. It is currently at Committee Stage in the House of Lords. The provisions which are subject to the Legislative Consent Motion were only finalised and tabled on 24 January 2022.

9. Report Stage is scheduled for weeks commencing 21 and 28 February, and it is at this stage that Devolved Administrations' Legislative Consent needs to be in place.

Proposed legislative provisions

10. On 24 January 2022, the Minister for Health and Social Care in the House of Lords tabled the following new clauses at the Lords Committee Stage of the Health and Care Bill:

- New clause 312B – to enable regulations to require the reporting and publication of information about payments and other benefits provided to persons in the health care sector by manufacturers and suppliers of healthcare products.
- New clause 312C – to enable provision to be made for the enforcement of requirements relating to information about payments, etc, to persons in the health care sector, including through the imposition of civil penalties.
- New clause 312D – requiring the Secretary of State for Health and Care to obtain consent of the Scottish Ministers, the Welsh Ministers or the Department of Health in Northern Ireland (as appropriate) before making provision within devolved legislative competence in regulations relating to information about payments etc to persons in the health care sector.
- New clause 313B – which provides for regulations relating to the reporting and publication of information about payments and other benefits provided to persons in the health care sector, to be able to make different provision for different parts of the UK.
- New clause 313C – which provides for regulations relating to the reporting and publication of information about payments and other benefits provided to persons in the health care sector to be subject to affirmative procedure.
- New clause 314ZB – which provides for the powers relating to the reporting and publication of information about payments and other benefits provided to persons in the health care sector to extend to the whole of the United Kingdom.

8. “Health care product” is defined as “a medicine, medical device or other product which is supplied in the course of a provision of health care”. DHSC’s intention is that this includes “borderline substances”, which DHSC consider are another area where professionals can prescribe products to patients and where transfers of value may influence those decisions. This will include products such as dermatological and nutritional products used to treat medical conditions which are prescribed to patients along with nutritional borderline substances such as enteral feeds, oral nutritional supplements, specialist infant formulas, gluten free products and products for patients with metabolic conditions.

9. The proposed legislative provisions would provide the necessary power for the UK Government (in particular, the Secretary of State for Health and Social Care, to make regulations that will require pharmaceutical companies, the manufacturers of borderline substances and the manufacturers, importers and distributers of medical devices to report payments (and other transfers of value) that they make to teaching hospitals, research institutions and healthcare professionals.

10. The intention is for the legislation to capture payments which relate to specific medicines, substances and devices, and other payments which may not relate to a specific product.

11. The intention is that this information would then either be published by relevant companies on their websites or submitted to the DHSC for publication in a searchable, publicly available database (or databases) for greater transparency and help to address any perceived conflicts of interest.

12. It is proposed that an exception to the reporting requirement would be available for those that already report to an industry-run scheme recognised by the Secretary of State for Health and Social Care as an appropriate alternative.

13. There are currently a number of voluntary reporting schemes for pharmaceutical companies and medical device manufacturers, run by trade bodies. However it is felt that they are not comprehensive, partly because they do not cover all types of transfers of value, partly because they are voluntary but also because they rely on consent in order for the name of the recipient to be disclosed. It is considered that a statutory requirement to report information would help to resolve these problems.

Provisions which deal with a Devolution Matter

11. DHSC officials have advised that the purpose of the clauses does not appear to directly relate to any of the reserved matters in the Scotland Act 1998, Government of Wales Act 2006, or the Northern Ireland Act 1998 and the overarching purpose appears to relate to the provision of healthcare, which is a devolved matter.

Reasons for utilising the Bill rather than an Act of the Assembly

17. It is considered that having UK-wide legislation for these provisions will be in the best interests of UK patients, as it will ensure a consistent legal framework for the information system, providing for improvements in patient health and safety outcomes in a way that ensures effective use of data. The Health and Care Bill provides for such a consistent approach across the UK.

Consultation

18. As part of preparing the UK Government's response to the Cumberlege Review, the DHSC consulted extensively with patient representatives to inform the development of this clause. Following the publication of the Review, the UK Government has spoken with medicines and medical devices associations to gather initial feedback on this duty.

19. DHSC acknowledges that there is more to do to inform the development of regulations and ensure that the needs of patients, the healthcare sector and industry are heard. Therefore the UK Government will be conducting a full public consultation in advance of making regulations. The devolved administrations will be strongly involved in this work.

Human Rights and Equality

21. The provisions of the Bill are compatible with the European Convention of Human Rights. The DHSC does not currently anticipate significant human rights or equalities impacts, but will complete a full equalities impact assessment alongside secondary legislation. The primary legislation provisions have no detrimental impact on particular protected groups or on health inequalities. No adverse impact on any of the groups listed under section 75 has been identified.

Financial Implications

22. These are enabling provisions and there are no known financial implications. There may be financial implications in the development and implementation of any secondary legislation. These costs have not yet been assessed. An assessment of impacts on businesses, including small or micro businesses, and wider impacts such as those on the environment, trade and competition, will be completed where appropriate alongside secondary legislation.

Summary of Regulatory Impact

23. DHSC have advised that it has engaged extensively with the medicines industry, and advise the industry is generally supportive of the principle, but would want a chance to inform regulations and the detail of how a reporting obligation would be fulfilled. This includes ensuring the business burden is managed and proportional to the risk, and that certain transfer of value may be withheld from publication (for example, commercial deals or payments for research and development).

24. With regard to devices DHSC have advised that a collective of SME device manufacturers seemed very supportive of plans because they see an opportunity to level the playing field with larger manufacturers through increased transparency.

25. Further engagement with industry is planned by DHSC.

26. There has been no regulatory impact assessment on the new proposals. DHSC has confirmed that it will be conducting one before making regulations once the detail of the policy is clear, and will work with the Department of Health in Northern Ireland to complete this. The proposed Bill provisions would not place any burden on businesses, as the requirement to report information will only come into force once regulations are made.

27. DHSC has also pointed out that the Association of the British Pharmaceutical Industry (ABPI) already runs a disclosure system for branded pharmaceutical companies, and the extent to which any new obligations cause additional burden will be considered once the detail of the requirement is clear. DHSC has also engaged with devices manufacturers, many of whom have apparently suggested that collection of this information is fairly routine. DHSC accept that none of this negates the need to conduct a full regulatory impact assessment (alongside a data protection impact assessment and equality impact assessment), before making regulations.

Conclusion

27. The Minister of Health is supportive of the provisions, and that, in the interests of good government across the UK, in so far as the above provisions of the Bill deal with a devolution matter, they should be considered by the UK Parliament, particularly considering the policy basis for the proposals, which was a report commissioned in mainly in respect of the NHS in England (albeit with input from Northern Ireland).

28. There is reassurance in the new clauses in that the consent of the Department of Health in Northern Ireland is required before the making of regulations on matters within the Assembly's competence. The new provisions will allow for different provision for different parts of the UK. The regulations would be subject to the affirmative procedure, which allows for close scrutiny of any provisions by Parliament.

Department of Health NI

26 January 2022