Committee for Health

Report on the Medicines and Medical Devices Bill: Further Legislative Consent Motion

This report is the property of the Committee for Health.
Ordered by the Committee for Health to be published 19 November 2020

Report: NIA 60/17-20 Committee for Health

Contents

Introduction

1. The *Medicines and Medical Devices Bill 2019-20*, was introduced in the House of Commons on 13 February 2020. It is currently at Committee stage in the House of Lords, which commenced on 19 October 2020.

2. The Bill derives from the UK decision in 2016 to withdraw from the EU; matters covered by the Bill have been within EU competence for the duration of the UK's membership.

3. Section 2(2) of the European Communities Act 1972 has provided for the exercise of delegated powers to make regulations to transpose, amend and update relevant legislation.

4. Human medicines and veterinary medicines are transferred matters. The main regulations transposing the EU legislative framework on human medicines were enacted on a UK-wide basis, however, and a single UK-wide regulator is in place – the Medicines and Healthcare Regulatory Authority (MHRA) - but the regulations are amended or updated regularly by statutory rules made at devolved level. The main (UK-wide) regulations are:

    - The Human Medicines Regulations 2012; and
    - The Medicines for Human Use (Clinical Trials) Regulations 2004.

5. Once section 2(2) of the European Communities Act 1972 is repealed at the end of the transition period, currently 31 December 2020, a new power in primary legislation would be required to continue updating or amending these regulations.

6. The Medicines and Medical Devices Bill therefore provides replacement delegated powers to the Department of Health (the Department) in respect of human medicines (Part 1 of the Bill, Clauses 1 - 7) and to the Department of Agriculture, Environment and Rural Affairs in respect of veterinary medicines (Part 2 of the Bill, Clauses 8 - 11). As such, the Bill

was described to the Committee as an 'enabling bill'. In both cases, powers may be exercised by the Minister, acting along, or jointly by the Minister and the Secretary of State.

7. A Legislative Consent Motion (LCM) was brought in respect of this Bill in April 2020. The Committee reported on this on 15 June 2020, and declined to come to a position, due to the limited time the Committee had to consider the LCM and the importance of the issues connected to it.

8. The Minister of Health wrote to the Committee on 15 July, advising that a further legislative consent motion would be required in respect of an amendment made at the report stage of the Bill in the House of Commons. The Minister wrote again to the Committee on 5 October and 20 October, advising the Committee of amendments tabled in the House of Lords that would also require legislative consent.

9. The Legislative Consent Memorandum was laid in the Assembly on 5 November 2020. The Department cited the following as its rationale for utilising the Bill rather than an Act of the Assembly:

    - the need for a legislative vehicle to provide a consistent approach across GB and NI to enable the existing regulatory framework for human and veterinary medicines to be updated following the UK's departure from the EU;
    - UK-wide legislation for a medical devices information system (MDIS) will provide a consistent legal framework, providing for improvements in both product safety and patient health outcomes and ensures an effective use of data; and
    - it would not have been possible to progress legislation through the Assembly in a similar timeframe.

Consideration by Committee for Health

10. The memorandum was laid on 5 November and Departmental officials briefed the Committee on 12 November 2020. A copy of the Hansard of the evidence session with the departmental officials will be available at *http://aims.niassembly.gov.uk/officialreport/minutesofevidence.aspx?&cid=10*

11. On 12 November, the Committee invited the Committee on Agriculture, Environment and Rural Affairs to submit its views in relation to Part 2 of the Bill - Veterinary Medicines. Details of the AERA Committee's consideration of the LCM are at paragraphs 22-24 below.

12. Officials briefed the Committee for Health on the amendments for which legislative consent is now required. These are:

- a new Clause 16, which provides a power by regulation to establish a Medical Devices Information System (MDIS) under the operation of NHS Digital. This amendment was made in response to the Cumberlege Review[1] into the safety of medicines and medical devices. Although medical devices are a reserved matter, the Department advised that an MDIS will require information that relates to devolved matters, and domestic healthcare, and that, in time, the information system could also be used for devolved purposes;

- an amendment under Clause 41 to require the Secretary of State to consult the devolved administrations on regulations made under the new Clause 16, to ensure that the governance arrangements around medical devices and patient safety are taken into account. The Department advised the Committee of a

[1] *First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review, Chaired by Baroness Cumberlege, 8 July 2020*.

separate non-legislative commitment from the Department of Health and Social Care (DHSC), to ensure that the Department of Health is engaged in MDIS policy and operational discussions, and the development of draft regulations; and

- provision for a statutory information-sharing gateway to ensure vital information can be shared with bodies outside the UK, such as overseas regulators.

13. The Department advised that a number of amendments have been tabled in the House of Lords in response to concerns raised by the Delegated Powers and Regulatory Reform Committee, in relation to the scrutiny and the oversight of the use of delegated powers contained in the Bill. These are:

- to provide an overarching duty to have regard to the importance of promoting the health and safety of the public; the Secretary of State or Minister of Health must be satisfied that regulations made under Clause 1(relating to human medicines), and Clause 8 (relating to veterinary medicines) would promote the health and safety of the public or health and welfare of animals, whilst having regard to three principles: safety, availability and attractiveness. In addition, the principle of attractiveness is clarified to mean the likelihood of the relevant part of the UK being seen as an attractive or favourable place to conduct trials or develop or supply medicines;

- to amend the requirement in Clause 41 on the Secretary of State or Minister of Health to consult with those they consider most appropriate, to a requirement for public consultation;

- to amend clause 42 of the Bill to apply draft affirmative procedure in Westminster and in the Northern Ireland Assembly, to all regulations made under clause 1 and 8, except for those relating

solely to fees, and to apply made affirmative (or confirmatory procedure in the Northern Ireland Assembly) to urgent regulations made under clause 6;

- changes to the criminal sanctions powers in Clauses 1-8, to clarify that regulations cannot provide for prison sentences over two years; and

- to provide for a reporting obligation on the Secretary of State in respect of the operation of regulations regarding human and veterinary medicines once every two years, and a separate obligation on NI Ministers to report to the NI Assembly in respect of regulations made by NI Departments.

14. The Committee enquired if the Department had any concerns around the collection and sharing of patient information with NHS Digital, in terms of data security and ownership of the data, and how patients would be protected by the MDIS. In its response, the Department advised that, the purposes for which data can be shared and the types of organisations that can receive this information, will be specified in the regulations made under the powers contained in the Bill and that the Department will be fully consulted in the making of these regulations, which will determine the scope and limitations on data-sharing. The Department is content that patients' data shall be held securely, controlled and processed in compliance with data protection laws and General Data Protection Regulation (GDPR) that will ensure patient information will be protected.

15. The Department further advised that the aim of the MDIS is to improve the safety and standards of medical devices, by ensuring better information can be captured and shared on implanted devices, in order to identify risks posed by specific devices much earlier.

16. The Committee enquired about the governance and patient safety arrangements for medical devices, and if the Minister was content with assurances received that that the devolved regions will be consulted on these regulations. In response, the Department referred to the statutory duty to consult Ministers in Scotland, Wales and Northern Ireland which will be written into the Bill, and to the non-legislative commitment from DHSC to ongoing discussions on the MDIS governance arrangements and other operational details that will ensure that the Department of Health in NI is engaged in relevant policy and operational discussions and the development of draft regulations. The Department advised that it is content with these assurances.

17. Members raised a number of issues relating to Brexit and the Protocol on Ireland/ Northern Ireland[2] (the Protocol) in relation to the MDIS, whether any of the amendments to the Bill had implications for the Protocol, and the contingency planning around this. The Department advised that there were no such implications for the amendments for which legislative consent was being sought. The Department confirmed that medical devices appear in the list of subject areas in Annex 2 to the Protocol, and that consideration had been given to whether the amendment to provide for a MDIS may be subject to a different "regime" in Northern Ireland, but stated that this will not be the case.

18. The Department also confirmed that the Bill's powers will be exercised in compliance with the Protocol and advised that the MDIS does not deal with the placement of medical devices on the market and that its purpose is to record the post-market use of the medical device by healthcare providers, enabling track and trace of patients who have

[2] The Protocol on Ireland/Northern Ireland may be viewed here: *https://www.gov.uk/government/publications/new-protocol-on-irelandnorthern-ireland-and-political-declaration*

medical devices implanted. The Department emphasised that the system is about improving patient safety, and not the supply of goods.

19. The potential impact of any future divergence in standards between the EU and GB was raised. The Department advised that NI's involvement in the MDIS will not be affected; the MHRA, as regulator for the whole of the UK, will continue to regulate devices on the marketplace which should mitigate any potential divergence in standards between GB and NI, particularly as NI will remain part of the EU acquis for medicines. The Department referred to a number of actions that, in its view, will mitigate against any risk of divergence in regulations for patient data: the inclusion of a statutory duty to consult in the Bill, and the non-legislative commitment by the DHSC to engage with the Minister of Health on relevant policy and operational discussions and the development of draft regulations.

20. Members asked if NI could potentially be subject to two information-sharing systems within the EU and UK in the future. In its response, the Department advised that NI will be part of the UK information-sharing system, provided through the MDIS, which relates to the sharing of patient data on implanted devices within a central UK system only, for the provision of direct care to a patient and subsequent care if needed in the future. The EU does not require the storage of patient data at a central level and its forthcoming regulations only require that service providers record (preferably by electronic means) where, and on whom, implantable devices have been used; the Department advised that the MDIS will assist service providers in meeting this requirement in NI. Individual EU member states are responsible for their own healthcare systems, including the use of any devices on the EU market. Each member state's regulator for devices monitors compliance with the EU regulations. The MHRA will remain the regulator for NI (and GB) after the end of the Transition Period.

21. The issue of the supply of medicines and medical devices, and the attractiveness of NI as a favourable location for clinical trials after the UK's exit from the EU was raised. The Department advised that there are long-term implications for both the supply and regulation of medicines in NI, where the large majority of medicines supplies are drawn from the UK market via GB, but that NI is part of a UK-wide medical supplies contingency programme for EU Exit which is led by the DHSC, with the involvement of the Devolved Administrations. The Department further advised that the UK and the EU have agreed to allow the pharmaceutical industry twelve months from 1 January 2021 to comply with new regulatory requirements which apply only to NI and are a consequence of the Protocol. This will allow industry time to adapt to the new arrangements and to mitigate risks to barriers to trade. The Department further advised that the DHSC and the MHRA will work with the Department of Health in relation to compliance with the Protocol and future relations with the EU. This will include consideration of the optimal supply and logistics models for medical supplies for Northern Ireland, the attractiveness of Northern Ireland for clinical trials and opportunities that may arise for the life science industry.

Consideration by Committee for Agriculture, Environment & Rural Affairs

22. On 12 November, the AERA Committee considered oral and written evidence on the LCM from the Department of Agriculture, Environment and Rural Affairs and decided that it was content to support the motion in relation to veterinary medicines. Members raised a query in relation to the amendments proposed in respect of information-sharing in order for information to be shared with bodies outside the UK in pursuance of international agreements and arrangements, asking how this would comply with the Data Protection Act. Departmental

officials advised that Bill would be fully compliant with all aspects of the Data Protection Act in the sharing of information.

23. Members also raised a query in relation to the lengthy list of matters on which regulations might be made and sought reassurance that any procedures in relation to this are put in place by the end of the transition period. Officials confirmed that this would this would be the case.

24. The response from the AERA Committee can be found in Appendix 3 to this report.

Conclusion

25. The Health Committee acknowledges that, in recent months, the Department of Health has been under enormous pressure to deal with COVID-19, and this has had an impact on the opportunity for scrutiny. However, in view of the importance of the issues addressed by the amendments to the Bill, including the significance of an MDIS in assisting with patient safety in the event of a recall of a medical device, the inclusion of the statutory duty to consult the Minister of Health on any regulations made in connection with this, and the improved scrutiny of regulations, the Committee decided that it was content to support the motion in relation to human medicines and medical devices.

26. The Committee for Health agreed this report to be published on 19 November 2020.

Links to relevant documents

The latest version of the Medicines and Medical Devices Bill may be found here:

https://services.parliament.uk/Bills/2019-21/medicinesandmedicaldevices.html

Minutes of Evidence of the Committee for Health may be found here:

http://aims.niassembly.gov.uk/officialreport/minutesofevidence.aspx?&cid=10

Minutes of Proceedings of the Committee for Health may be found here:

http://www.niassembly.gov.uk/assembly-business/committees/2017-2022/health/minutes-of-proceedings/session-2020---2021/

Appendices

Appendix 1 - Correspondence from the Department of Health

From the Chief Pharmaceutical Officer
Mrs Cathy Harrison

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Dear Éilis

Date: 17th November 2020

CORR-3722-2020: Medicines and Medical Devices Bill – Follow up questions from the Health Committee

Thank you for forwarding the list of questions from the Health Committee on the amendments to the Medicines and Medical Devices Bill that requires legislative consent from the NI Assembly.

It was unfortunate that we experienced the technical difficulties and poor sound quality on Thursday 12th November at our briefing, and I hope the following answers to the questions asked by the Committee member, assists in their consideration of the legislative consent memorandum and progress with their report to the Assembly.

Please see responses provided at Annex A.

Yours sincerely,

Mrs Cathy Harrison

Working for a Healthier People

ANNEX A

DoH responses to Health Committee Questions

Chair, Colm Gildernew

1. **The Minister has sought assurances that the regulations to be developed to implement the Medical Devices Information System take account of the governance arrangements around medical devices and patient safety in NI. What particular governance arrangements is the Minister referring to, and is the Department content with the assurances received, that the devolved regions will be consulted on these regulations?**

   Northern Ireland has in place strong information governance and privacy systems on the sharing of patient identifiable information both for direct care and secondary use to ensure informed patient consent and privacy of patient data. It is these governance arrangements that the Minister is referring to and to which draft regulations would need to conform.

   An amendment to the Bill has been proposed whereby the Secretary of State will have a statutory duty to consult Scottish Ministers, Welsh Ministers and the Department of Health in Northern Ireland. This will be written into the Bill.

   In addition to this amendment there is also a separate non-legislative commitment from the Department of Health and Social Care to ongoing discussions on the medical devices information system governance arrangements and other operational details that will ensure that the Department of Health in NI is engaged in relevant policy and operational discussions and the development of draft regulations.

   The Department is content the assurances received with this legislative and non-legislative approach.

Deputy Chair, Pam Cameron

2. **Is it the case that laws covered by this Bill are covered by Annex 2 to the Protocol?**

   The Bill's powers will be exercised in compliance with the NI Protocol. Medical devices appear in the list of subject areas in Annex 2 to the NI Protocol, and consideration has been given to whether the amendment to provide for a Medical Devices Information System may be subject to a different "regime" in Northern Ireland, but this will not be the case.

   The UK-wide Medical Device Information system (MDIS) does not deal with the placement of medical devices on the market. The MDIS is to record to the post-market use of the medical device by healthcare providers, enabling track and trace of patients who have medical devices with an identified issue implanted, and

monitoring of the efficacy of the device in use. Therefore this system is to improve patient safety.

3. How would Northern Ireland's role in the medical device information system be complicated by future divergence in standards between GB and EU in future years?

NI's involvement in the MDIS will not be affected by any divergence in standards between EU and GB. The MDIS relates to the post-market safety of devices and is completely separate from Medical Device Regulations. The MHRA, as regulator for the whole of the UK, will continue to regulate devices on the marketplace and this should mitigate any potential divergence in standards between GB and NI, particularly as NI will remain part of the EU acquis for medicines.

There have been a number of actions taken that will mitigate against any risk of divergence in regulations for patient data. In response to concerns raised by the Devolved Administrations that regulations to be developed to implement the Medical Device Information System take account of the governance arrangements in their respective administrations, the UK Government is taking forward an amendment whereby the Secretary of State will have a statutory duty to consult Scottish Ministers, Welsh Ministers and the Department of Health in Northern Ireland.

In addition to this amendment there is also a separate non-legislative commitment from the Department of Health and Social Care to ongoing discussions on the MDIS governance arrangements and other operational details that will ensure that the Department of Health in NI is engaged in relevant policy and operational discussions and the development of draft regulations.

4. How would patients be protected under this new system?

The purposes for which data can be shared and the types of organisations that can receive this information will be specified in the regulations made under the powers contained in the Bill.

DoH will be fully consulted in the making of these regulations which will determine the scope and limitations on data-sharing. Patient's data shall be held securely, controlled and processed in compliance with data protection laws and General Data Protection Regulation (GDPR) that will ensure patient information will be protected.

The aim of a Medical Device Information System is to improve the safety and standards of medical devices, by ensuring better information can be captured and shared on implanted devices, in order to identify risks posed by specific devices much earlier.

The Medical Device Information System will provide some critical benefits to patients who have been, or will be in the future, implanted with medical devices. These include:

- the collection and storing of information linking unique device identifiers to patients, clinicians, and the specific surgical procedure that implanted the device; and

- establishing systems that will enable health providers to trace patients who have been treated by, or implanted with, a medical device so that the patient can be provided with appropriate medical treatment, if a safety issue subsequently occurs with the device.

These improvements to the information that is gathered about the use of these devices will increase patient safety by identifying issues with individual devices or types of procedures, which can then be addressed at the earliest possible time.

5. Will NI end up governed by two information sharing systems within the EU and UK?

No, NI will be part of the UK information sharing system, provided through the Medical Devices Information System. The MDIS relates to the sharing of patient data on implanted devices within a central UK system only. It relates to the provision of direct care to a patient and subsequent care if needed in the future.

The EU does not require the storage of patient data at a central level and its forthcoming regulations only require that service providers record (preferably by electronic means) where, and on whom, implantable devices have been used. The MDIS will assist our service providers in meeting this requirement.

Individual EU member states are responsible for their own healthcare systems, including the use of any devices on the EU market. Each member state's regulator for devices monitors compliance with the EU regulations. The MHRA will remain the regulator for NI (and GB) after the end of the Transition Period.

6. How can the attractiveness of NI in terms of supply of medicines and medical devices be promoted if there are barriers to trade between GB and NI in the first place?

The UK is currently aligned with the EU acquis for medicines and medical devices. This will change after transition when NI will remain aligned with the EU and Great Britain (GB) will not. There are long term implications for both the supply and regulation of medicines in NI, where the large majority of medicines supplies are drawn from the UK market via GB.

Northern Ireland is part of a UK-wide medical supplies contingency programme for EU Exit which is led by the Department of Health and Social Care, with the involvement of the Devolved Administrations.

At the fourth meeting of the Ireland/Northern Ireland Specialised Committee on 5 November 2020, the UK Government and the EU Commission reached an agreement to allow the pharmaceutical industry twelve months from 1 January 2021 to comply with new regulatory requirements which apply only to NI and are a consequence of the NIP. This will allow industry time to adapt to the new arrangements and to mitigate risks to barriers to trade.

The MHRA will continue to regulate medicines for Northern Ireland and as the UK regulator will represent all parts of the UK in ensuring their attractiveness as a place to trade.

To respond specifically to concerns about the absence of a definition of 'attractiveness' of the UK in the Medicines and Medical Devices Bill, the UK Government intends to clarify that this is a consideration of the likelihood of the relevant part of the United Kingdom being seen as an attractive or favourable place in which to supply and conduct clinical trials for human medicines and develop and supply veterinary medicines.

The Department of Health will continue to work with both the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA) in relation to compliance with the Northern Ireland Protocol and future relations with the EU. This will include consideration of the optimal supply and logistics models for medical supplies for Northern Ireland, the attractiveness of Northern Ireland for clinical trials and opportunities that may arise for the life science industry.

Committee Member's questions:

7. **What reporting mechanisms does the MDIS have arranged with the assembly? Does it only report to Westminster and are we here in the north reliant on reporting from NHS England or Public Health England?**

   Full consultation with all stakeholders will be required before regulations on MDIS can be drafted. The Department will be involved in the development of these regulations and, as part of this process, will input into decision making regarding what we consider to be the most appropriate reporting mechanism for the system.

8. **How does the MDIS interrelate with the EU medical devices alert system.**

   Medical device alert systems are operated by national regulators, and in the case of the UK, this is the MHRA. The MHRA generate medical device alerts on the basis of post market surveillance involving legal requirements on manufacturers to report any faults in their device. Once MDIS is operational, the MHRA will be able to gather intelligence on the efficacy of devices from the new information system that will help improve patient safety.

9. Is there any interplay between the MDIS and the Irish Protocol? Surely medical devices count as "goods" and so would come under its remit. If so, would it not be better for the North to have its own system, in order to facilitate continuing standards alignment with the EU.

The Bill's powers will be exercised in compliance with the NI Protocol. The UK-wide Medical Device Information system (MDIS) does not deal with the placement of medical devices on the market. It is to record the post-market use of the medical device by healthcare providers, enabling track and trace of patients who have medical devices implanted. This system is about improving patient safety, not the supply of goods.

FROM THE MINISTER OF HEALTH

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Your Ref:
Our Ref: COR/3332/2020
Date: 20th October 2020

Dear Colm,

I wrote to you on 15th July and again on the 5th October to outline the need for a further Legislative Consent Motion (LCM) in relation of the Medicines and Medical Devices Bill which was introduced in Parliament on 13 February 2020. You will recall at its meeting of 22 April 2020, the Executive gave its agreement in principle to the need for a Legislative Consent Motion for transferred matters within the Bill relating to Human Medicines and Veterinary Medicines. The Assembly subsequently debated the Legislative Consent Motion on 16 June and agreed the Motion.

Following this I received correspondence from Lord Bethell (Parliamentary Under Secretary of State for Innovation (Lords) in DHSC) on the 18th June, with a request to bring forward a further Legislative Consent Motion in the Northern Ireland Assembly in respect of an amendment to the Bill to provide for a medical devices information system (MDIS), in advance of the Bill completing its amending stage in the House of Lords. The MDIS would be operated by NHS Digital and the amendment is mainly in response to the report from the Independent Medicines and Medical Devices Safety Review, chaired by Baroness Julia Cumberlege which was published on 8th July 2020. An information system is to be established for purposes relating to the efficacy and safety of medical devices; the safety of individuals who have received or been treated with a medical device, or into whom a medical device has been implanted; and/or the improvement of medical devices through advances in technology.

The Medicines and Medical Devices Bill has now reached the Committee Stage in House of Lords, which commenced on Monday 19th October.

In my correspondence to you on the 5th October, I explained, in addition to the need to have an LCM on the MDIS, there had been discussions between officials on other possible amendments that may require legislative consent from the NI Executive and NI Assembly. Lord Bethell has now written to me to provide further details on these amendments and ask that I seek legislative consent from the NI Assembly. I plan to table an Executive Paper on 22nd October to ask the Executive for their agreement in principle in order to commence the legislative consent process, which needs to be completed by Lord's Report Stage, which is anticipated to be at the end of November 2020.

The new proposed amendments requiring legislative consent are summarised below.

Essential amendment related to information sharing
In order that the UK, and in particular the regulators, Medicines Healthcare products and Regulatory Agency (MHRA) and the Veterinary Medicines Directorate, can continue to work with international partners to ensure the safety of medicines in the UK, there is a need to strengthen the legal basis for sharing information internationally. This would be in the form of a statutory information-gateway inserted into the Bill to ensure that vital information can be shared with bodies outside the UK, such as overseas regulators, in pursuance of international agreements and arrangements.

Regulation Making Powers
The Bill has three tests or considerations which need to be taken into account when making regulations in respect of Human Medicines, Veterinary Medicines and Medical Devices - focussing on safety, availability of medicines / devices and the attractiveness of the relevant part of the UK. It is intended the appropriate authority must be satisfied that the regulations would promote the health and safety of the public, and in relation to veterinary medicines, the health and welfare of animals, and have regard to the considerations currently in clauses 1(2) (Human Medicines) and 8(2) (Veterinary Medicines) when determining whether they would.

Furthermore, in order to respond specifically to concern about the absence of a definition of 'attractiveness' of the UK, this will be clarified as a consideration of the likelihood of the relevant part of the UK being seen as an attractive or favourable place in which to supply and conduct clinical trials for human medicines and develop and supply veterinary medicines.

The appropriate authority will also be required to include in its consultation document an initial assessment as to how the considerations have been taken into account. This would include the consideration that the regulations will promote the health and safety of the public/animals. The consultation duty in clause 41 will be amended from a requirement to only consult those the appropriate authority considers it appropriate to consult, to a requirement for public consultation. This will allow for an unlimited scope of consultation responses. These amendments will apply to the NI Departments when making regulations under clause 1 for Human Medicines and clause 8 for Veterinary Medicines.

Legislative procedures
Concerns have been raised about the use of the negative procedure in relation to regulations made under clauses 1 (Human Medicines) and 8 (Veterinary Medicines), and in particular those relying on clauses 2(1)(n) and 9(1)(f) (persons who may supply medicines and related prohibitions).

It is intended to amend clause 42 of the Bill to apply the draft affirmative procedure in Westminster, and in the Northern Ireland Assembly, to all regulations made under clauses 1 and 8, except for those solely relating to fees and any urgent regulations made relying on clause 6.

It is also intended to amend clause 42 of the Bill so that urgent regulations relying on clause 6 are subject to the made affirmative procedure. This is similar to the confirmatory procedure in the Northern Ireland Assembly, whereby regulations are laid after being made and cease to have effect unless they are approved within a 40-day period.

Offences
A particular criticism of the UK Delegated Powers and Regulatory Reform Committee (DPRRC) was the ability to create new criminal offences through the regulation-making powers, with an additional concern expressed by the DPRRC was that the powers may be used to amend the penalties for existing offences with no restriction on the maximum

that can be set. Amendments are to be tabled to make it clear that the powers in clauses 1 and 8 cannot be used to provide for an offence to be punishable with a sentence of imprisonment of more than two years. This maximum will then apply equally to penalties for new and existing offences. Again, as these amendments relate to the exercise of the powers under clause 1 (Human Medicines) and clause 8 (Veterinary Medicines) will require legislative consent. Officials have consulted with officials in DoJ, as they had previously considered the Bill for the first LCM, and they remain content with the current offences and penalties contained in the Bill.

Other considerations – Reporting Obligation
It is intended to provide for a reporting obligation on the Secretary of State, that would consider the operation of regulations made under clauses 1 (Human Medicines), 8 (Veterinary Medicines) and 12 (Medical Devices) within the (once in two years) reporting period, setting out the views of those who have been consulted, and whether change has been made as a result of consultation, including a look ahead at further proposed regulatory change known at the time within the forthcoming reporting period.

At the moment this obligation on the Secretary of State would be only in relation to regulations that the Secretary of State has made and those jointly made with NI Departments. The obligation would not extend to the Secretary of State reporting on the operation of regulations made under the Bill by the NI Departments acting alone. Lord Bethell has asked if we would like a similar reporting obligation to be placed on Northern Ireland Ministers in respect of regulations made by the NI Departments, and I have asked him this to include this in the Bill in order to ensure the NI Assembly has the same level of scrutiny as Parliament. This provision will also require legislative consent.

The amendments in relation to Human Medicines fall under the remit of the Department of Health (DoH) and the amendments in relation to Veterinary Medicines fall to the Department of Agriculture, Environment and Rural Affairs (DAERA) respectively. In terms of the handling arrangements, the DoH is content to take the lead with input from DAERA colleagues on any of the provisions that relate to veterinary medicines.

I understand that Minister Poots will be also writing to the Chair of the Committee for Agriculture, Environment and Rural Affairs to advise the Committee about the Bill.

Yours sincerely

Robin Swann MLA
Minister of Health

FROM THE MINISTER OF HEALTH

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Your Ref:
Our Ref: CORR-2984-2020
Date: 5 October 2020

Dear Colm

I am following up on my correspondence to you of 15th July that advised of the requirement for a further Legislative Consent Motion in relation to the Medicines and Medical Devices Bill which was introduced in Parliament on 13 February 2020.

You will recall at its meeting of 22 April 2020, the Executive gave its agreement in principle to the need for a Legislative Consent Motion for transferred matters within the Bill. The Assembly subsequently debated the Legislative Consent Motion on 16 June and agreed the Motion.

Following this I received correspondence from Lord Bethell (Parliamentary Under Secretary of State for Innovation (Lords) in DHSC) on the 18th June, with a request to bring forward a further Legislative Consent Motion in the Northern Ireland Assembly in respect of an amendment to the Bill to provide for a medical devices information system, in advance of the Bill completing its amending stage in the House of Lords.

The purpose of this letter to you is to give you and members of the Health Committee an update on the current position.

The UK Government amendment seeking to provide a power by regulations to establish a "medical device information system" operated by NHS Digital was mainly in response to the report from the Independent Medicines and Medical Devices Safety Review, chaired by Baroness Julia Cumberlege which was published on 8th July 2020. An information system is to be established for purposes relating to the efficacy and safety of medical devices; the safety of individuals who have received or been treated with a medical device, or into whom a medical device has been implanted; and/or the improvement of medical devices through advances in technology.

The creation of a UK-wide Medical Device Information System (MDIS), is to be welcomed, however it is important to ensure that the regulations to be developed to

implement this take account of the governance arrangements around medical devices and patient safety in Northern Ireland and in the other Devolved Administrations, and I wrote to Lord Bethell on this point on 15th July. He responded on 14th September 2020 to give these necessary assurances to me that the Bill will reflect a statutory duty to consult with all the Devolved Administrations in the development of regulations to support the establishment of the MDIS operational model.

The Medicines and Medical Devices Bill has reached the Committee Stage in House of Lords – although the date regarding when the Committee Stage will commence has yet to be formally announced. There have been approximately 100 amendments to the Bill proposed for Lord's Committee Stage and a link to these is available on the UK Parliamentary website:
https://publications.parliament.uk/pa/bills/lbill/58-01/116/5801116-RL.pdf

There have been discussions between officials on further possible amendments that may require legislative consent from the NI Executive and NI Assembly. It is for this reason I have not yet tabled the Executive paper for agreement in principle on the Legislative Consent Motion to allow it to proceed, as Lord Bethell needs to write formally to me on the content of these amendments. I have written to Lord Bethell to emphasise the need to have this information in a timely manner highlighting the number of Northern Ireland Assembly statutory procedures that need to be adhered to for any agreement by the legislative consent process.

I will, of course, continue to keep you apprised of developments.

Yours sincerely

Robin Swann MLA
Minister of Health

FROM THE MINISTER OF HEALTH

Department of Health
An Roinn Sláinte
Männystrie O Poustie
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Colm Gildernew MLA
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Tel: 028 9052 2556

Email: private.office@health-ni.gov.uk

Our ref: SUB-1640-2020

Your ref:

Date: 15th July 2020

Dear Colm

WESTMINSTER HEALTH MEDICINES AND MEDICAL DEVICES BILL – FURTHER LEGISLATIVE CONSENT MOTION

I wish to advise you about the requirement for a further Legislative Consent Motion in relation to the Medicines and Medical Devices Bill which was introduced in Parliament on 13 February 2020. At its meeting of 22 April 2020, the Executive gave its agreement in principle to the need for a Legislative Consent Motion for transferred matters within the Bill. The Assembly subsequently debated the Legislative Consent Motion on 16 June and agreed the Motion.

I received formal correspondence from Lord Bethell (Parliamentary Under Secretary of State for Innovation (Lords) in DHSC) on the 18th June, following a telephone conversation on the 17th June, with a request to bring forward a further Legislative Consent Motion in the Northern Ireland Assembly in respect of an amendment to the Bill to provide for a medical devices information system, in advance of the Bill completing its amending stage in the House of Lords.

The amendment to the Medicines and Medical Devices Bill was made and passed during the Commons Report stage on the 23rd June 2020 and it has reached its 2nd Reading Stage in the House of Lords. A link to the Bill as amended in Parliament is available on the UK Parliamentary website:

https://publications.parliament.uk/pa/bills/lbill/58-01/116/5801116_en_1.html

By way of background to the amendment, in February 2018, the then Secretary of State for Health and Social Care, the Rt Hon Jeremy Hunt MP, announced a review into how the health system responds to reports from patients about the harmful side effects from medicines and medical devices. The announcement in the House of Commons followed a number of patient-led campaigns on the use of the hormone pregnancy test Primodos, the anti-epileptic drug sodium valproate and surgical mesh.

The Independent Medicines and Medical Devices Safety Review was chaired by Baroness Julia Cumberlege and its report was published on the 8th July 2020. The report highlights failure of the healthcare system in a number of areas including the need to listen and understand patients' voices and their concerns raised around certain treatments.

The proposed Government amendment is in response to the report and seeks to provide a power to by regulations establish a "medical device information system" operated by NHS Digital. The information system would be established for purposes relating to the efficacy and safety of medical devices; the safety of individuals who have received or been treated with a medical device, or into whom a medical device has been implanted; and/or the improvement of medical devices through advances in technology.

The regulations made under the power introduced by this amendment would provide the legal underpinning for a UK-wide system to capture the unique identifier of a specific medical device and relevant data from a patient's information record, such that in future, we are better able to track and trace medical devices if a safety concern arises.

It will ensure that NHS Digital is able to obtain the information to populate the medical device information system from health providers across the UK, including private health providers. The Department of Health and Social Care (DHSC) sees this amendment as critical in order to mitigate the risk of harm to patients posed by unsafe medical devices.

Whilst the key function of the amendment is to support the effective monitoring of the safety of medical devices, and therefore relates to a reserved matter, DHSC recognises that the information system will require information that relates to devolved matters, domestic healthcare and, in time, the information system could also be used for devolved purposes. For example, to improve patient health outcomes more generally, such as through informing clinical practice as to what devices and clinical procedures are best for patients.

The creation of a UK-wide Medical Device Information System (MDIS), is to be welcomed, however it is important to ensure that the regulations to be developed to implement this take account of the governance arrangements around medical devices and patient safety in Northern Ireland. I have written to Lord Bethell on this point to ensure the necessary assurances are in place.

In terms of timings, DHSC would wish to secure legislative consent before the House of Lords stages of the Medicines and Medical Devices Bill. Whilst DHSC does not yet have any confirmed timings for subsequent stages of the Bill, it is very unlikely that the Bill will reach its Lords Report stage before the autumn.

I will, of course, continue to keep you apprised of all developments and I look forward to working with the Health Committee on this issue. My officials would also be happy to offer a briefing for the Committee on the proposed amendment if that would be of help.

Yours sincerely

Robin Swann MLA
Minister of Health

Appendix 2 - Legislative Consent Memorandum

FROM THE MINISTER OF HEALTH

Department of
Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

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Your Ref:

Our Ref: SUB-2101-2020

Date: 5 November 2020

Assembly Business Office
Room 32
Parliament Buildings,
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Stormont,
BELFAST,
BT4 3XX

Dear Sirs

MEDICINES AND MEDICAL DEVICES BILL – LEGISLATIVE CONSENT MEMORANDUM

Under the provisions of Standing Order 42A (2), please find attached a Legislative Consent Memorandum relating to the Medicines and Medical Devices Bill.

Should the Business Office need to discuss the Memorandum with an official from my Department, the relevant contact is Bernie Duffy, Head of Medicines Policy Branch at telephone number: 028 90 520787.

Yours sincerely

Robin Swann MLA
Minister of Health

LEGISLATIVE CONSENT MEMORANDUM

MEDICINES AND MEDICAL DEVICES BILL

Draft legislative Consent Motion

1. The draft motion, which will be tabled by the Minister of Health, is:

"That this Assembly endorses the principle of the extension to Northern Ireland of the provisions within the Medicines and Medical Devices Bill dealing with human medicines, veterinary medicines and information systems as amended at Committee Stage in the House of Lords"

Background

2. This memorandum has been laid before the Assembly by the Minister of Health under Standing Order 42A(2). The Medicines and Medical Devices Bill was introduced in the House of Commons on 13th February 2020. At its meeting of 22 April 2020, the Northern Ireland Executive gave its agreement in principle to the need for a Legislative Consent Motion for transferred matters within the Bill in respect of human medicines and veterinary medicines. The Assembly subsequently debated the Legislative Consent Motion on 16 June and agreed the Motion. A UK government amendment to the Medicines and Medical Devices Bill was made and passed during the Commons Report stage on the 23rd June 2020 dealing with a Medical Device Information System (MDIS) and as this system will require information that relates to devolved matters, domestic healthcare and, in time, may also be used for devolved purposes, legislative consent is required from Northern Ireland.

3. There are further amendments to the Medicines and Medical Devices Bill that have been proposed by the UK government in relation to human medicines and veterinary medicines and are being tabled at Lord's Committee Stage which commenced on 19th October 2020. These amendments relate to transferred matters and will also require legislative consent from Northern Ireland.

4. The latest version of the Bill can be found on the UK Parliamentary website at:
https://bills.parliament.uk/bills/2700

Summary of the Bill and its policy objectives

5. The UK's regulatory provision governing human medicines and veterinary medicines which are transferred matters, and medical devices which are reserved, is largely provided for in subordinate/ secondary legislation. This legislation has been made under powers within section 2 (2) of the European Communities Act 1972. Primary legislation is needed to ensure that the UK can continue to update and amend regulations.

6. The Bill comprises 5 parts. Part 1 deals with human medicines and contains a power to make regulations relating to human medicines. It sets out an exhaustive list of the matters on which regulations might be made, including making provision for dealing with falsified medicines and clinical trials.

7. Part 2 of the Bill deals with veterinary medicines and, again, sets out an exhaustive list of the matters on which regulations might be made including the manufacturing, marketing and supply, and field trials.

8. Part 3 of the Bill covers medical devices and contains a power to make regulations with regard to medical devices. It sets an exhaustive list of the matters on which regulations might be made and consolidates and makes clear the powers available to the relevant authorities to enforce the regulatory devices regime. Part 4 of the Bill provides for consequential provision, consultation and procedural requirements. Part 5 deals with commencement and includes a power for the relevant Northern Ireland department to make transitional provision in connection with commencement.

9. A UK government amendment passed on 23rd June at Commons Report Stage provides a power by regulations to establish an MDIS operated by NHS Digital. Regulations under clause 16 (information systems) enable the Secretary of State to instruct NHS Digital to create and operate an MDIS.

10. The amendment is in response to the report from the Independent Medicines and Medical Devices Safety Review, chaired by Baroness Julia Cumberlege. The information system would be established for purposes relating to the efficacy and safety of medical devices; the safety of

individuals who have received or been treated with a medical device, or into whom a medical device has been implanted; and/or the improvement of medical devices through advances in technology. The regulations made under the power introduced by this amendment would provide the legal underpinning for a UK-wide system to capture the unique identifier of a specific medical device and relevant data from a patient's information record, such that in future if a safety concern arises there will be an improved ability to track and trace medical devices.

Provisions which deal with a Devolution Matter

11. The subject matter of human and veterinary medicines (including clinical trials of human medicines) is reserved in relation to Scotland and Wales but transferred in relation to Northern Ireland. The Bill reflects this by conferring delegated powers on the "appropriate authority". In relation to England, Scotland and Wales the "appropriate authority" is the Secretary of State. In Northern Ireland the "appropriate authority" is the relevant Northern Ireland Department acting alone, or the Secretary of State and the relevant Northern Ireland Department acting jointly. For human medicines the relevant Northern Ireland Department is the Department of Health and for veterinary medicines is the Department of Agriculture, Environment and Rural Affairs.

12. The subject matter of medical devices is reserved in relation to Scotland, Wales and Northern Ireland. The Bill reflects this by conferring the delegated powers relating to medical devices on the Secretary of State in relation to the whole of the UK. The UK government amendment on 23rd June 2020, however that provides a power by regulations to establish an MDIS will require information that relates to devolved matters, domestic healthcare and, in time, the information system could also be used for devolved purposes.

Reasons for making the Provisions

13. The aim of an MDIS is to improve the safety and standards of medical devices, by ensuring better information can be captured and shared on implanted devices, in order to identify risks of specific devices early. By improving the data available on medical devices as part of post-market surveillance, the MHRA will be better able to take action earlier and more effectively as part of their regulation of devices on the UK market. It would mean in the event of a recall, it would be possible to identify which specific device has been implanted into a patient.

14. However in designing the information system, consideration needs to be given to ensure it reflects the needs of UK patients and the interests of Northern Ireland and the other Devolved Administrations. It is important to ensure that the regulations to be developed to implement the information system take account of the governance arrangements around medical devices and patient safety in Northern Ireland, and in response to concerns raised by the Devolved Administrations on this point, an amendment is being tabled at Lord's Report Stage. When making regulations under clause 16, under this amendment (made under clause 41 - consultation), the Secretary of State is required to consult Scottish Ministers, Welsh Ministers and the Department of Health in Northern Ireland.

15. In addition to the amendment made under clause 41 that has been listed to be tabled by the UK government [to require that the Secretary of State consults Scottish Ministers, Welsh Ministers and the Department of Health in Northern Ireland when making regulations under clause 16], there is also a separate non-legislative commitment from the Department of Health and Social Care to ongoing discussions on the MDIS governance arrangements and other operational details that will ensure that the Department of Health in NI is engaged in MDIS policy and operational discussions and the development of draft regulations.

16. In order that the UK, and in particular the regulators [namely the Medicines Healthcare products and Regulatory Agency (MHRA) and the Veterinary Medicines Directorate] can continue to work with international partners to ensure the safety of medicines in the UK, there is a need to strengthen the legal basis for sharing information internationally. This would be in the form of a statutory information-gateway inserted into the Bill to ensure that vital information can be shared with bodies outside the UK, such as overseas regulators, in pursuance of international agreements and arrangements. An essential amendment on information sharing will therefore be tabled by the UK government during Lord's Committee Stage.

17. The Delegated Powers and Regulatory Reform Committee (DPRRP) in the House of Lords has raised concerns in relation to the scrutiny and oversight of the use of the delegated powers contained in the Bill. In response to this the government has listed a number of amendments to be tabled during Lord's Committee Stage to address these concerns and they will change the way in which the regulation making powers at clauses 1 (human medicines) and 8 (veterinary medicines) can be exercised.

18. In order to address a concern that the Bill provided Ministers with too much discretion in how the powers are exercised, an amendment will be tabled to provide for a reporting obligation on the Secretary of State, that would consider the operation of regulations made under clauses 1, 8 and 12 within the (once in two years) reporting period, setting out the views of those who have been consulted, and whether change has been made as a result of consultation, including a look ahead at further proposed regulatory change known at the time within the forthcoming reporting period. It is proposed a separate report will be taken forward by the NI Departments in respect of regulations made only by NI Departments and this will be laid before the NI Assembly.

19. Concerns have also been raised about the use of the negative procedure in relation to regulations made under clauses 1 and 8, and in particular those relying on clauses 2(1)(n) and 9(1)(f) (persons who may supply medicines and related prohibitions). It is intended to amend clause 42 of the Bill to apply the draft affirmative procedure in Westminster, and in the Northern Ireland Assembly, to all regulations made under clauses 1 and 8, except for those solely relating to fees and any urgent regulations made relying on clause 6. It is also intended to amend clause 42 of the Bill so that urgent regulations relying on clause 6 are subject to the made affirmative procedure. This is similar to the confirmatory procedure in the Northern Ireland Assembly, whereby regulations are laid after being made and cease to have effect unless they are approved within a specified time period. It is proposed this time period will be 40 days.

20. Another matter on which there has been considerable debate prior to the Lord's Committee Stage has been the application of the three considerations that the appropriate authority must have regard to and how these considerations are weighted when making regulations under clauses 1 and 8 (and 12). In order to respond specifically to concern about the absence of a definition of 'attractiveness' of the UK it is intended to clarify that this is a consideration of the likelihood of the relevant part of the United Kingdom being seen as an attractive or favourable place in which to supply and conduct clinical trials for human medicines and develop and

supply veterinary medicines. The amendment to be tabled seeks to clarify the intent in this regard.

21. It is also intended to provide for an overarching duty to have regard to the importance of promoting the health and safety of the public, and in relation to veterinary medicines, the health and welfare of animals. The considerations currently in clauses 1(2) and 8(2) will then form part of satisfying that duty. It is intended to provide that the appropriate authority must be satisfied that the regulations would promote the health and safety of the public, and in relation to veterinary medicines, the health and welfare of animals, and have regard to the considerations currently in clauses 1(2) and 8(2) when determining whether they would. This will strengthen provision around the exercise of these regulation-making powers and provide reassurance that it is only intended to make regulations to amend the current regulatory regimes where those changes promote health and safety.

22. A further concern was the ability to create new criminal offences through the regulation-making powers, and more specifically that the powers may be used to amend the penalties for existing offences with no restriction on the maximum that can be set. Amendments are to be tabled to make it clear that the powers in clauses 1 and 8 cannot be used to provide for an offence to be punishable with a sentence of imprisonment of more than two years. This maximum will then apply equally to penalties for new and existing offences. The Department of Justice in Northern Ireland has previously considered the Medicines and Medical Devices Bill and now more recently the amendments being proposed and is content that the current offences and penalties are necessary and commensurate with the current offences and penalties framework in Northern Ireland.

23. The statutory consultation requirements are set out in clause 41 of the Bill, but there has been some concern with the language at clause 41, which states that the appropriate authority must consult such persons as the appropriate authority considers appropriate. An amendment is being tabled by the UK government that requires the relevant authority to carry out a public consultation before making regulations under any provision of Part 1, 2 or 3, as well as requiring the relevant authority to set out the authority's assessment of the matters to which the authority must have regard in making the regulations. This would include the consideration that the regulations will promote the health and safety of the public/animals. The amendment also provides for the Secretary of State to consult the Devolved Administrations in relation to regulations for information systems under clause 16(1).

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

24. It is appropriate on this occasion for the Department of Health and Social Care (England) to progress legislation on transferred matters as it would not have been possible to legislate for Northern Ireland separately within a similar timescale.

25. Having UK-wide legislation for a medical devices information system 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 both product safety and patient health outcomes in a way that ensures effective use of data.

26. With regards human and veterinary medicines, it is important to have a consistent approach across Great Britain and Northern Ireland in terms of having a legislative vehicle to enable the existing regulatory frameworks relating to human medicines and veterinary medicines to be updated following the UK's departure from the EU. The Medicines and Medical Devices Bill provides for such a consistent approach across the UK.

Consultation

27. As the purpose of the Bill is to provide delegated powers to amend the regulatory frameworks, the Department of Health and Social Care (England) did not consult on the Bill. However, before exercising any of these delegated powers, there is a statutory requirement to consult, as set out in clause 41 of the Bill. The amendments proposed to be tabled by the government to the Medicines and Medical Devices Bill strengthen the duty to consult on regulations that will be made for human medicines, veterinary medicines and information systems. The Secretary of State must consult with the Devolved Administrations on the information systems regulations. The majority of regulations will be subject to the affirmative resolution procedure allowing for appropriate Parliamentary and NI Assembly scrutiny.

Human Rights and Equality

28. The provisions of the Bill are compatible with the European Convention of Human Rights. No adverse impact on any of the groups listed under section 75 has been identified.

Financial Implications

29. These are enabling amendments, and there are no known financial implications. There may be financial implications in the development and implementation of any secondary legislation in relation to Information Systems. These costs have not yet been assessed

Summary of Regulatory Impact

30. The Department of Health and Social Care (England) published an Impact Assessment which is available at: https://publications.parliament.uk/pa/bills/lbill/58-01/116/5801116-IA.pdf

31. No specific impact in Northern Ireland is anticipated on employment, charities, social economy enterprises and the voluntary sector.

32. The Department of Health and Social Care (England) has indicated that the provisions relating to human medicines, veterinary medicines and information systems are not intended or expected to bring about

substantive changes to UK businesses in the medicines or life sciences sector. Any changes would be implemented by subordinate legislation which will be accompanied but its own bespoke economic appraisal.

Engagement to date with the Committee for Health

33. The Health Committee was informed on 15th July 2020 of the Minister of Health's intention to seek Executive agreement to a Legislative Consent Motion in relation to the government amendment to the Medicines and Medical Devices Bill to provide for a Medical Devices Information System. Further correspondence was then forwarded on 5th October and 20th October to provide the Health Committee with an update. In the correspondence of 20th October details were provided on additional amendments proposed to be made at Lord's Committee Stage in relation to human medicines, veterinary medicines and information systems that will require legislative consent from the NI Assembly.

Conclusion

34. The view of the Minister of Health is that, in the interests of good government and consistency across the UK, in so far as the provisions of the Bill that deal with a devolution matter they should be considered by the UK Parliament.

Department of Health
November 2020

Appendix 3 - Memo from Committee for AERA

Northern Ireland Assembly

Committee for Agriculture, Environment and Rural Affairs

Room 244
Parliament Buildings
Tel: +44 (0) 28 905 21475

From: **Stella McArdle**

To: **Éilis Haughey, Clerk Committee for Health**

Date: **13 November 2020**

Subject: **Medicines and Medical Devices Bill – Further LCM**

At its meeting on 12 November 2020, the AERA Committee considered oral and written evidence on the above Bill. It considered the Bill and examined a number of matters with officials on amendments which relate to Veterinary Medicine.

Members raised a query in relation to the amendments proposed in respect of information sharing in order for information to be shared with bodies outside the UK in pursuance of international agreements and arrangements and how this would comply with the Data Protection Act. Departmental officials advised that Bill would be fully compliment with all aspects of the Data Protection Act in the sharing of information.

Members raised a query in relation to the lengthy list of matters on the which regulations might be made and sought reassurance that any procedures in relation to this are put in place by the end of the transition period. Officials confirmed that this would this would be the case.

The Committee agreed that it had no concerns with the further legislative consent motion in so far as it relates to Part 2 of the Bill on Veterinary Medicines.

This Report can be made available in a range of formats including large print, Braille etc. For more information, please contact:

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