Committee for Health

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

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Contents

Introduction

1. The *Medicines and Medical Devices Bill 2019-20*, comprising 45 Clauses and 2 Schedules, was introduced in the House of Commons on 13 February 2020. It had its second reading on 2 March 2020 before moving to Committee Stage; the Public Bill Committee reported on 11 June.

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 Once section 2(2) of the European Communities Act 1972 is repealed at the end of the transition period, currently 31 December 2020, a new power in primary legislation would be required to continue updating or amending these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 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. Part 3 of the Bill deals with medical devices which is a reserved matter so consent is not requested in this area. Regulations made under powers in this Part will therefore be scrutinised in the UK Parliament.

8. The motion seeks the Assembly's consent, in line with the Sewel Convention, for Clauses 1 to 11, dealing with human medicines and veterinary medicines, which are transferred matters, to extend to Northern Ireland.

Consideration by Committee for Health

9. The Minister of Health wrote to the Committee on 1 April, advising that a legislative consent motion would be required.

10. The memorandum was laid on 27 May and Departmental officials briefed the Committee on 4 June 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 2 June, 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. See paragraph 27 below for details of the AERA Committee's consideration of the LCM.

12. Officials briefed the Committee for Health on the background to the Bill and on the nature of the powers to be provided to the Department, under Part 1, Human Medicines.

13. **Clause 1 provides the Northern Ireland Department of Health acting alone, or jointly with the Secretary of State, with delegated powers to make regulations in relation to human medicines**. Clauses 2 to 6 specify the purposes for which such powers may be used:

    - **Clause 2 Manufacture, marketing and supply of medicines**: regulations under Clause 1 may be used to issue authorisations to manufacture, import or distribute as well as to regulate advertising, labelling and packaging;
    - **Clause 3 Falsified medicines**: regulations may be made to help prevent the supply of medicines that falsely represent their source, provenance or identity, e.g. by requiring unique identifiers on packaging;
    - **Clause 4 Clinical trials**: powers may also be used for the purposes of authorisation, notification and reporting requirements of clinical trials similar to EU Clinical Trials Regulation
    - **Clause 5 Fees, offences, powers of inspectors**: this Clause allows such further administrative matters also to be dealt with by regulations under Clause 1.
    - **Clause 6 Emergencies**: the Department is also empowered to use the power in Clause 1 to make regulations providing for the disapplication of human medicines provisions in urgent situations, in order to prevent serious harm to public health.

14. Members were advised that Clause 1(2) requires the Department to consider three factors before making regulations:
    a. the safety of human medicines;
    b. the availability of human medicines; and
    c. the attractiveness of the relevant part of the UK as a place in which to conduct clinical trials or supply human medicines.

15. The Committee's attention was drawn to Clause 40, which requires consultation prior to the exercise of powers in relation to both human medicines and veterinary medicines, except in emergencies as referenced above under Clause 6.

16. Members were assured that, since the Bill is essentially an enabling bill, the regulations to be made under the provisions requiring consent will come back to the Committee for consideration in the usual way and will be subject to the draft affirmative procedure.

17. The Committee discussed with officials:

- the scope of the delegated powers;
- the impact of EU Exit and the Protocol on Ireland/Northern Ireland[1] ('the Protocol') on the matters covered by the Bill, e.g. NI participation in EU-wide clinical trials;
- North-South and East-West co-operation and regulatory alignment; and
- the division of powers to be exercised at UK and Northern Ireland level.

18. Officials confirmed that human medicines **regulations are updated regularly**, usually twice-yearly, and that such updates directly affect prescribing practice.

19. In response to questions about the **impact of EU Exit**, officials confirmed that human medicines is among the areas of EU legislation covered by the Protocol, in respect of which Northern Ireland will continue to apply EU standards.

[1] The Protocol on Ireland/Northern Ireland is available here: ***https://www.gov.uk/government/publications/new-protocol-on-irelandnorthern-ireland-and-political-declaration***

20. Asked about **potential divergence** on a North-South basis, officials therefore stated that there was greater risk of divergence between Northern Ireland and Great Britain. They also advised that work was ongoing between the Department of Health (NI), the UK Department of Health and Social Care and the MHRA, to reduce that risk. By way of example, Northern Ireland will be required to comply with EU standards in relation to falsified medications, whereas GB would be free to diverge.

21. In relation to **clinical trials**, officials stated that the MHRA would continue to manage in this area and that it there is an aspiration to maintain a close link with the EU, though discussions are at an early stage.

22. Officials confirmed that issues around the **supply of, and access to, medicines** were being addressed as part of preparatory work ahead of implementing the Protocol.

23. The Committee enquired if a detailed list could be provided setting out the **limits of devolved authority** to legislate, in terms of the Protocol and UK Government powers. Officials advised that this is a complicated field and that a comprehensive list could not yet be provided but that officials are working through the issues. Officials did confirm, however, that all areas of the Bill address matters that have been within the EU's remit to date.

24. The Committee put further questions to the Department at its meeting on 11 June, in response to which the official confirmed that the implementation of the Protocol would have implications for human medicines but that while that work is ongoing, it is separate from the Bill insofar as the Bill provides replacement delegated powers to continue amending human medicines regulations in line with current practice.

25. Officials undertook to return to the Committee in due course to provide an update on the implementation of the Protocol.

26. The Committee did not take any further evidence on the Bill due to time constraints and its focus on COVID-19. Whereas its deadline to report under Standing Order 42A, would have been 17 June, the Committee was advised that the House of Commons may schedule Report Stage as early as 18 June and that therefore debate on the LCM in the Assembly would be scheduled for 16 June, requiring the Committee to produce its report as quickly as possible.

Consideration by Committee for Agriculture, Environment & Rural Affairs

27. On 11 June, 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, though it emphasised that it had not had the opportunity to consult with stakeholders or consider in full the implications of the clauses, for Northern Ireland. The Committee reports, however, that it asked for, and received, assurances that after the enactment of the Bill, the existing regime would remain largely the same.

28. Appendix 3 sets out the AERA Committee's report on the LCM, providing detail on provisions relevant to veterinary medicines and the issues raised by the Committee.

Conclusion

29. The Health Committee acknowledges that, in recent months, the Department of Health has been under enormous pressure to deal with COVID-19, however, this has had an impact on the opportunity for scrutiny. In view of the lack of prior engagement on the content of the

LCM, the short time available for consideration of the LCM once laid, and the importance of the issues connected to the Bill, the Committee decided it was not in a position to come to a decision on support for the motion.

30. The Committee for Health agreed this report to be published on 15 June.

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-2019---2020/

Appendices

Appendix 1 - Letter from the Minister of Health to the Health Committee

FROM THE MINISTER OF HEALTH

Department of Health
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Our Ref: CORR-1183-2020
Date: 1st April 2020

Dear Colm

WESTMINSTER HEALTH MEDICINES AND MEDICAL DEVICES BILL – LEGISLATIVE CONSENT MOTION

I wish to advise you about a Legislative Consent Motion asking the Assembly to agree a number of provisions that deal with transferred matters within the Medicines and Medical Devices Bill which was introduced in Parliament on 13 February 2020. A copy of the Bill as introduced in Parliament is available from:

https://publications.parliament.uk/pa/bills/cbill/58-01/0090/20090.pdf.

The aspects of the Bill that will require a Legislative Consent Motion relate to the clauses that fall under Parts 1, 2, 4 and 5.

Background
A large proportion of the legal framework for medicines and medical devices in the UK derives from EU Directives and has been implemented into domestic legislation through section 2(2) of the European Communities Act 1972 ("the 1972 Act"). This enables EU Directives to be transposed into UK law through secondary legislation and has been used to create a body of regulations that include the:

- Human Medicines Regulations 2012;
- Medicines for Human Use (Clinical Trials) Regulations 2004;
- Veterinary Medicines Regulations 2013; and,
- Medical Devices Regulations 2002.

At the end of the Transition Period, the European Union (Withdrawal) Act 2018 will have preserved these frameworks as "retained EU Law". The 1972 Act, however, will no longer

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be available to the UK to amend the regulations. There is no other 'general power' for updating these regulations, except through the introduction of primary legislation.
The Bill does three things:

i. introduces targeted delegated powers in the fields of human medicines, veterinary medicines and medical devices to enable the existing regulatory frameworks to be updated following the UK's exit from the EU;
ii. consolidates the enforcement provisions for medical devices and introduces sanctions; and,
iii. provides an information gateway to enable the sharing of information held by the Secretary of State about medical devices, for example to warn members of the public about safety concerns.

The regulatory gap is addressed by proving delegated powers to replace section 2(2) of the 1972 Act, supported by an exhaustive list of purposes for which those powers can be used. These powers will enable updates to be made to the Human Medicines Regulations 2012, Medicines for Human Use (Clinical Trials) Regulations 2004, the Medical Devices Regulations 2002 and Veterinary Medicines Regulations 2013. These powers are necessary to prevent stasis and enable the UK to remain at the forefront of the global life sciences industry.

The Bill will also enable government to support its regulators (i.e. the Medicines and Healthcare Products Regulatory Agency (MHRA) and Veterinary Medicines Directorate (VMD)) to go even further in developing innovative regulation. The effective regulation of human and veterinary medicines and medical devices is necessary to benefit industry and people in all regions and nations of the UK and help to ensure that the right balance is achieved between having robust safeguards to protect patient safety and encouraging innovation in the health system. In particular, the Bill consolidates the enforcement regime for medical devices and provides the Secretary of State with the ability to impose civil sanctions – as an alternative to criminal prosecution – for breaches of the medical device regime.

The Department of Health and Social Care (DHSC) has advised that the majority of the Bill's provisions will commence two months after it receives Royal Assent. The only exception to this will be those measures relating to events that could pose serious harm to human health which will be commenced immediately, and certain medical devices enforcement measures which will be by commencement order.

The Bill deals with policies that fall under the remit of the Department of Health (DoH) and 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.

A copy of the Bill has been shared with the Departmental Solicitor's Office (DSO) with a request for a legal perspective on those provisions dealing with human medicines. I am aware, however, that they are under considerable pressures providing advice in response to the Covid-19 pandemic.

I will, of course, continue to keep you apprised of all developments with the Bill and I look forward to working with the Health Committee on this issue.

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

Appendix 2 - Legislative Consent Memorandum

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 as introduced to Parliament on 13 February 2020 dealing with human medicines and veterinary medicines."***

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 13 February 2020. The latest version of the Bill can be found at:

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

Summary of the Bill and its policy objectives

3. 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 relating to human medicines and veterinary medicines.

4. The Medicines and Medical Devices Bill provides for the Secretary of State, in respect of England, Scotland and Wales, and for relevant Northern

Ireland departments in respect of Northern Ireland, to make regulations relating to human medicines and veterinary medicines.

5. 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.

6. 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.

7. 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 and Part 5 deals with commencement and includes a power for the relevant Northern Ireland department to make transitional provision in connection with commencement.

P**rovisions which deal with a Devolution Matter**

8. The subject matter of human and veterinary medicines (including clinical trials of human medicines) is reserved in relation to Scotland and Wales but is 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 relation to 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.

9. The subject matter of medical devices is reserved in relation to Scotland, Wales or 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.

Reasons for making the Provisions

10. The regulation of medicines, medical devices, clinical trials and veterinary medicines has been a matter of EU competence since the UK joined the EU. The legislative frameworks are in the Human Medicines Regulations 2012, the Veterinary Medicines Regulations 2013, the Medical Devices Regulations 2002 and the Medicines for Human Use (Clinical Trials) Regulations 2004.

11. At the end of the transition period, the EU Withdrawal Act 2018 will have preserved these frameworks as "retained EU law" and supporting legislation will ensure they can operate effectively after the UK leaves the EU. However, the EU Withdrawal Act 2018 will repeal the legislation allowing these frameworks to be amended. Without these delegated powers, the UK would have to rely on primary legislation to make changes to these regulatory frameworks.

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

12. 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.

13. 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.

14. New primary legislation is, therefore, needed to replace the broad regulation-making power currently available in section 2 (2) of the European Communities Act 1972. The Medicines and Medical Devices Bill will provide these powers to ensure that the UK can use subordinate/secondary legislation to bring forward any necessary amendments to the regulatory regime for human medicines and veterinary medicines.

Consultation

15. After the end of the transition period, section 2 (2) of the European Communities Act 1972 will no longer be available to update the regulatory schemes for human medicines, clinical trials of human medicines , or veterinary medicines through subordinate legislation.

    The Medicines and Medical Devices Bill simply seeks to provide targeted delegated powers in the field of human medicines, veterinary medicines and medical devices to enable the existing regulatory frameworks to be updated following the UK's departure from the EU.

16. 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 40 in relation to the powers in clauses 1(1), 8(1) and 12(1) and paragraph 9 of Schedule 1. The only exception to this requirement is where regulations contain only provision made in reliance on clause 6(1) (disapplication of provisions relating to human medicines where there is a risk of serious harm to health), or clause 15(1) (disapplication of provisions relating to medical devices where there is a risk of serious harm to health) and if they contain a declaration that they need to be made urgently. This will enable the power to be exercised urgently to protect the public from an imminent threat of serious harm to health, when there may not be time for consultation.

Human Rights and Equality

17. 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

18. Existing regulations which govern human medicines, veterinary medicines and medical devices will become retained EU law at the end of the transition period by virtue of the European Withdrawal Act. The Bill introduces powers to enable changes domestic legislation to be made. There a no immediate financial implications arising from the delegated powers in the Bill.

Summary of Regulatory Impact

19. The Department of Health and Social Care (England) published an Impact Assessment which is available from

https://publications.parliament.uk/pa/bills/cbill/58-01/0090/20200210_Bill_IA_latest.pdf

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

20. The Department of Health and Social Care (England) has indicated that the provisions relating to human medicines and veterinary medicines 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

21. The Health Committee was informed on 2 April 2020 of the Minister Health's intention to seek Executive agreement to a Legislative Consent Motion in relation to the Medicines and Medical Devices Bill.

Conclusion

22. 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

May 2020

Appendix 3 – AERA Committee report on the LCM

Medicines and Medical Devices Bill
Committee for Agriculture, Environment and Rural Affair
Consideration of Part 2 Veterinary Medicines

Background

1. At its meeting 5th March, the Committee considered a letter from the Minister of Agriculture, Environment and Rural Affairs regarding the Medicines and Medical Devices Bill. That letter noted that this is a UK Government Bill making its passage through Westminster, that it is predominantly focused on human medicines and medical devices with one section dealing with veterinary medicines. The letter noted that the Bill had a number of provisions that dealt with transferred matters and that the legislative consent of the Assembly would be required.

2. On the 27th May 2020, the Minister of Health tabled a Legislative Consent Memorandum in the NI Assembly on this Bill. It was referred to the Committee for Health for consideration under Standing Orders 42A. On the 2nd June the Committee for Health asked the Committee for Agriculture, Environment and Rural Affairs to consider and comment on the Legislative Consent Memorandum as it related to Part 2 Veterinary Medicines. The Committee for Health explained that the deadline for response was extremely tight, requested comment by 10th June and that the legislative consent debate in the Assembly was anticipated to be on 16th June.

3. The Committee for Agriculture, Environment and Rural Affairs considered the four clauses that make up Part 2 Veterinary Medicines. It received written briefings and took oral evidence from DAERA on Thursday 11th June. The written evidence is attached at Appendix A. The Committee agreed its report on Friday 12th June.

4. Due to the complexity of the Bill, its technical nature and the limited time available to scrutinise it, the Committee wishes to be clear that it has not had the opportunity to explore in full the implications of the clauses for this jurisdiction. The time constraints have not allowed it to consult with relevant stakeholders. The Committee did however ask and received assurances that after the enactment of the Bill, the existing regime would remain largely the same.

The Bill and provisions for Veterinary Medicines

5. The Medicines and Medical Devices Bill has two main purposes. First, it seeks to provide a mechanism for strengthening and maintaining the regulatory system for both human and veterinary medicines, clinical trials and medical devices after the UK leaves the EU. Secondly, the Bill aims to consolidate the enforcement framework relating to medical devices and to

introduce a new civil sanction regime. The Explanatory Notes that accompany the Bill explains the existing regulatory regime for veterinary medicines as follows: -

"*Veterinary medicines are currently regulated by the Veterinary Medicines Regulations 2013 (SI 2013/2033) which implement various pieces of EU legislation. These regulations help ensure animal welfare, and protect the safety of treated animals, people handling the medicines, consumers of produce from treated animals, and the environment. They do this by regulating the authorisation, manufacture, classification, distribution and administration of veterinary medicinal products.*"

6. The provisions of the Bill that deal with veterinary medicines are transferred, and as such, would fall within the legislative competence of the Northern Ireland Assembly. Veterinary medicines are not devolved in the other jurisdictions.

7. The Bill will also enable support the veterinary medicines regulator - Veterinary Medicines Directorate (VMD) to developing innovative regulation.

8. Part 2 of the Bill covers Veterinary Medicines and the following clauses are relevant
   - Clause 8: Power to make regulations about veterinary medicines
   - Clause 9: Manufacture, marketing, supply and field trials
   - Clause 10: Fees, offences, powers of inspectors, costs
   - Clause 11: Interpretation of Part 2 and supplementary provision

9. Part 4 of the Bill covers Regulations made under Part 2 and therefore, is also relevant. It has the following clauses
   - Clause 38 Power to make consequential etc. provisions
   - Clause 39 Scope of powers of Northern Ireland departments
   - Clause 40 Consultation
   - Clause 41 Procedure

10. The EU Veterinary Medicines Regulations 2013 were made on a UK wide basis. They will be transposed into UK law. After the transition period, the Bill will allow DAERA to amend the Veterinary Medicines Regulations 2013 in relation to this jurisdiction. Members noted that DAERA can also amend the provisions acting jointly with the relevant UK Minister. The written briefing from DAERA explained

"The Bill provides a power to amend or supplement the Veterinary Medicines Regulations 2013 (the 2013 Regulations). It provides that any change to the 2013 Regulations in relation to NI can be made by DAERA acting alone or DAERA and the Secretary of State for the Environment, Food and Rural Affairs acting jointly. ***The Bill provides that any changes relating to Northern Ireland must be subject to the scrutiny of the Northern Ireland Assembly irrespective of how they are made (see Clause 41).*** *Most changes are subject to the affirmative resolution procedure (i.e. they require the approval of the NI Assembly),*

although there are a few changes which are subject to the negative resolution procedure before the Assembly.

11. DAERA explained that this is essentially an enabling Bill, that it does nothing in itself, but enables amendments to be made by secondary legislation and that it is considered appropriate to retain this flexibility going forward.

12. The Committee discussed clause 9(2) with DAERA officials. Under the Protocol, this administration must remain aligned with EU Regulations on Veterinary Medicines. However, the Explanatory Note to the Bill states that Clause 9(2)
"provides the means for making corresponding or similar provision to the new EU Regulations as the UK sees fit."

13. DAERA officials noted that this refers mainly to new EU Regulations coming forward in 2022. Because this jurisdiction must adhere to the Protocol and remain aligned with the EU, this provision in clause 9(2) was unnecessary. It was a dormant power. DAERA had indicated to DEFRA that they would prefer that it was not included, had asked for it to be removed but accepted that this was unlikely to happen and indicated that they could "live with it".

14. Further consideration of this issue by the Committee yielded that the only circumstances in which the provision in clause 9(2) might be used were if the NI Assembly voted, in four years, to remove the Protocol. However, DAERA officials noted that even in this scenario, it was difficult to see how this power would be exercised, because at that point, the 2022 EU Regulations would have been incorporated into the veterinary medicine regime.

15. Written briefing from DAERA referred to a Common Framework that is being developed to maintain a consistent and common approach between all four jurisdictions in the area of animal health and welfare issues. It is expected that this will include the regulation of veterinary medicines post transition i.e. after 31st December 2020. The Committee noted that it had not yet considered this Common Framework and that this left a gap in knowledge that it was unable to address due to a lack of time.

16. Members took note of clause 8(2)(c) (see below) and questioned the meaning of the word "attractiveness". DAERA officials agreed to provide further clarity on this as a matter of urgency.

(2) *In making regulations under subsection (1), the appropriate authority must have regard to—*
(a) the safety of veterinary medicines in relation to animals, humans and the environment;
(b) the availability of veterinary medicines;
(c) the attractiveness of the relevant part of the United Kingdom as a place in which to develop or supply veterinary medicines.

17. The duty to consult was discussed with officials. Clause 40 provides that DAERA, as the appropriate authority for veterinary medicines, must consult with such persons, as it considers appropriate when making regulation using the powers in this Bill.

18. **At its meeting on 11th June 2020, the Committee discussed and agreed that it content with the Legislative Consent Motion as it related to the veterinary medicine provisions in the Bill**. However, it does ask that DAERA

- ensures that the Committee is consulted in advance of its intention to make regulations acting jointly with a UK Minister**;**
- informed the Committee of new veterinary medicines to be introduced under the term of the Protocol, but not introduced into GB and vice versus;
- provides detailed briefing on the Common Framework for Animal Health as soon as possible.

APPENDIX 1

Central Service and Contingency Planning Group
Central Management Branch

Department of Agriculture, Environment and Rural Affairs
www.daera-ni.gov.uk

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5 June 2020

Dear Stella

RE: Medicines and Medical Devices Bill – Legislative Consent Motion

The purpose of this letter is to ask the Committee to consider the Legislative Consent Motion (LCM) (**Appendix A**) for the Medicines and Medical Devices Bill (the Bill) (**Appendix B**), a UK Bill which is currently making its way through Westminster.

The Department of Health (DoH) is the lead Northern Ireland (NI) Department on the Bill and most of its provisions relate to matters which fall within its auspices. The Bill does, however, contain some technical provision on veteterinay medicines. Veterinary medicines is a matter which falls within the remit of the Department and you will recall that I previously wrote to you on 25 February 2020 to inform you of the Minister for Health's intention to lay a LCM on the Bill. The LCM was laid with the Assembly Business Office on 27 May and requires the Committee's consideration to proceed to debate.

Background

The Bill was introduced in the House of Commons on 13 February 2020. Its main purposes are to;

- provide a mechanism for strengthening and maintaining the regulatory system for medicines (both human and veterinary), clinical trials and medical devices after the UK leaves the EU; and
- consolidate the enforcement framework relating to medical devices and introduce a new civil sanction regime.

Relevant provision
There is a body of EU law regulating veterinary which is supported by domestic legislation in the UK, namely by the Veterinary Medicines Regulations 2013 which are UK wide. The Bill creates powers to amend or supplement the 2013 Regulations (see Clause 8 of the Bill). The powers are needed because existing legislative powers under section 2(2) of the European Communities Act 1974 are to be repealed at the end of the transition period. The Bill provides similar powers in respect of domestic legislation relating to human medicines.

The Bill allows the Department to amend the 2013 Regulations in relation to Northern Ireland. The 2013 Regulations were made on a UK wide basis and it is considered appropriate to retain this flexibility going forward. The Bill also, therefore, provides that the Department can amend them acting jointly with the relevant UK Minister.

Need for a LCM
Human medicines and veterinary medicines are transferred matters and, as such, the Bill requires a LCM. The relevant LCM was agreed by the Executive meeting on 22 April 2020. Prior to that meeting, issues were raised by both Minister Poots and Minister Dodds regarding how certain provisions in the Bill sat with the NI Protocol.

There is provision in the Bill which provides that the Department, acting alone or jointly with the relevant UK Minister, can make legislation that corresponds or is similar to an EU Regulation on veterinary medicines (see Clause 9(2) of the Bill). Under the NI Protocol, the relevant EU Regulation will automatically apply to NI and there will be a requirement for NI to fully align with it. This provision was considered potentially unnecessary and arguably out with the spirit of NI Protocol. A similar issue arises in respect of provision in the Bill on human medicines.

Since the Executive meeting, Department officials have engaged with colleagues in Departmental Solicitors Office, DoH and the UK Department of Health and Social Care (DHSC) (which leads on the Bill) on the matter. Unfortunately, the DHSC is not minded to amend the Bill as it is of the view that the powers conferred in it can be exercised compatibly with the NI Protocol. The Minister for Health has accepted that the need to bring forward the legislation at this stage is paramount and has advised Ministerial colleagues that he has laid the LCM for the Bill in the Assembly on the basis of the DHSC advice. The NI provisions are needed to ensure that there are no gaps in the powers to make legislation on veterinary medicines in the future. On balance, the Department considers that it can accept that any issues regarding potential compatibility in the NI Protocol would, in practice, only arise if the Department were to exercise the relevant power conferred by the Bill and the need to comply with the Protocol would prevent it from exercising the power in any event.

Timing

The Bill passed its Second Reading in the House of Commons on 2 March 2020 and it is expected that the Reporting stage will take place there on week commencing 22 June 2020. It is necessary to have the Assembly's approval prior to then and, subject to the Committee's views, the LCM is expected to be debated before the Assembly very shortly.

I, therefore, ask the Committee to agree the Memorandum to allow the DoH to progress the LCM through the NI Assembly.

Yours sincerely

Michael Oliver
Departmental Assembly Liaison Officer

Sent: 09 June 2020 11:13

To: McArdle, Stella <Stella.McArdle@niassembly.gov.uk>

Cc: Callaghan, Naomi <Naomi.Callaghan@daera-ni.gov.uk>; Oliver, Michael <Michael.Oliver@daera-ni.gov.uk>

Subject: FW: Medicines and Medical Devices Bill – Legislative Consent Motion

Hi Stella,

Further to our telephone conversations please see the information below.

1. **Will new veterinary drugs with UK approvals be unavailable for use in NI unless there is also an EU approval?**

Marketing Authorisation approvals granted in UK or EU before the end of the transition period will remain valid in NI after 31 December 2020. For market authorisations to apply in NI after the transition period, these will have to be authorised centrally in the EU (from applicant based in EU member state), or be authorised in UK for NI under the requirements of the EU Medicines Directive.

2. **Will consent/approval be sought from the NI Assembly in cases where either is seeking amendments to the veterinary medicines legislation for market authorisations etc or DAERA is seeking amendments acting jointly with the Secretary of State for the Environment, Food and Rural Affairs?**

The Bill provides a power to amend or supplement the Veterinary Medicines Regulations 2013 (the 2013 Regulations). It provides that any change to the 2013 Regulations in relation to NI can be made by DAERA acting alone or DAERA and the Secretary of State for the Environment, Food and Rural Affairs acting jointly. **The Bill provides that any changes relating to Northern Ireland must be subject to the scrutiny of the Northern Ireland Assembly irrespective of how they are made (see Clause 41).** Most changes are subject to the affirmative resolution procedure (i.e. they require the approval of the NI Assembly), although there are a few changes which are subject to the negative resolution procedure before the Assembly.

3. **Is the issue of Veterinary Medicines included in any of the Common Framework Agreements being drafted for use by UK at the end of the transition period to ensure consistency and a common approach by Defra and the devolved Administrations in respect of devolved matters?**

Yes. In conjunction with the Devolved Administrations, Defra is developing a Common Framework to maintain a collaborative approach to animal health and welfare issues, including the regulation of veterinary medicines, post transition.

I hope this answers all of your questions sufficiently and apologies for the time it took me to ensure I was giving you accurate information (as explained it is a new area of work for me). Your understanding was very much appreciated.

Regards

Alastair

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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