## **Appendix – Questions** (DoH answers in Red)

- Can you expand on the work you are undertaking to understand the interaction between these proposals and the Windsor Framework / Regulation 2023/1182 and Directive 2022/642?
- As part of this, have you engaged with stakeholders?
- What are the specific areas of concern or uncertainty?
- When will you complete your assessment of the proposals?

**A: The Department of Health (DoH) works closely with the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA) to analyse the impact of EU proposals on the UK and Northern Ireland (NI). Stakeholder engagement also continues to be an important element of this work, including the partnership meetings that occur between the MHRA and industry.**

**At this stage, DoH understands the two EU amendments will continue to apply in NI and wants to reassure the Committee that these amendments will continue to support the long-term supply of medicines into NI. Whilst aspects of the interaction between the proposals and amendments are known, DoH continues to support the MHRA as the MHRA continues its ongoing work on the technical details of the reforms to understand other aspects that require further clarification, including the reclassification of antimicrobials as prescription only medicines.**

**As the current EU draft proposals are not finalised, and the MHRA are continuing to work on the technical details, an assessment date cannot be provided at this stage.**

*The assessment of impact states, "Department of Health policy officials have been liaising with their DHSC policy counterparts and colleagues from the MHRA to determine what actions are required and what possible impacts the proposals may have. This work will continue as EU proposals become clearer."*

- At this stage, have any actions been identified?
- Have you identified any potential negative impacts?
- What are the possible impacts of **not** applying the proposals in Northern Ireland?
- Have you identified any benefits of applying the proposals in Northern Ireland?

**A: DoH continues to work with DHSC and the MHRA to identify if there are any aspects of the proposals that require further clarification or actions to be taken. As stated above, this includes the reclassification of antimicrobials as prescription only medicines. If antimicrobials medicines are to be classified as prescription only medicines, this would mean products currently licensed as General Sale List or Pharmacy only medicines could no longer be supplied or sold under their current provisions, and they would need to be supplied or sold under provisions as prescription only medicines.**

**The non-application of these proposals would remove dual market access for NI manufacturers.**

*Regarding paediatric medicines, the assessment of impact states, "There is now a better understanding that most regulatory submissions that trigger paediatric requirements will be products that [are] within the scope of the EU's centralised authorisation procedure and therefore, these medicines can be regulated under UK legislation."*

- How many regulatory submissions that trigger paediatric requirements are products that are **not** within the scope of the EU centralised authorisation procedure?
- Is this still an area of concern?

**A: It would not be possible to provide the number of applications that would trigger paediatric requirements that are not within the scope of the EU centralised authorisation procedure, but such applications would be considered rare. In these rare instances, the marketing authorisation holder would only be able to apply for a UK-wide or NI only licence, therefore, DoH does not currently have concerns in this area.**

*The assessment of impact states, "There may be financial implications for the medicinal products industry to meet some of the requirements placed on them to ensure security of supply; detailed financial impacts are not known at this stage".*

- Have you engaged with stakeholders on this potential impact?
- Are there any other potential issues arising for manufacturers of medicines in Northern Ireland?

**A: No stakeholder engagement on potential financial implications has been carried out, at this stage.**

*The assessment of impact states, "the EU and UK Government intend to raise any questions or concerns at meetings between joint bodies, with the Joint Consultative Working Group potentially providing the exchange of views on future legislation regarding goods of relevance to the operation of the Windsor Framework".*

- Have any issues or concerns related to this legislative package been discussed at joint EU-UK bodies?
- At the time of writing, the proposals are still being considered by the Council of the EU. Have any changes to the proposed legislation been suggested by the European Parliament which may have a negative impact in Northern Ireland?

**A: Any queries on potential discussions between the UK Government and the EU at joint bodies regarding the EU pharma legislative package should be directed to the UK Government.**

**In terms of potential changes to the initial draft proposals, DoH understands there are still ongoing discussions regarding some aspects of the proposed reforms within the EU, including the data market exclusivity period. However, changes to the data exclusivity period for novel and innovative products would not apply in NI due to Windsor Framework arrangements.**

- In respect of amendments to 726/2004 and the DSC concerns around Veterinary Medicine supplies, does this amendment take veterinary medicines out of scope of the new proposals? (Steve Aiken, MLA – 22/5/2025)

**A: When introduced, Regulation (EU) 726/2004 laid down the legal framework for medicinal products for human and veterinary use and established the European Medicines Agency (EMA).**

**However, it is the understanding of DoH that Regulation (EU) 2019/5 amended the EU pharmaceutical legal framework set out by Regulation (EU) 726/2004 and created a legal framework specific to veterinary products. The new veterinary provisions have applied since 28 January 2022, when Regulation (EU) 2019/6 replaced Directive 2001/82/EC.**

**This means the current consolidated version of Regulation (EU) 726/2004 relates only to the authorisation and supervision of medicinal products for human use and establishing the EMA. The new EU pharma proposals repeal Regulation (EU) 726/2004 meaning they only relate to medicinal products for human use and the establishment of the EMA and do not repeal the current veterinary provisions that apply under Regulation (EU) 2019/6.**