Department of Health & Social Care

Edward Argar MP
Minister of State for Health

39 Victoria Street
London
SW1H 0EU

020 7210 4850

Lord Teverson
Chair, European Union Environment Sub-Committee
House of Lords
London
SW1A 0PW

Dear Lord Teverson,

10th November 2020

Supply of pharmaceuticals to Northern Ireland

Further to your letter on 28 October I want to reassure you that your concerns are duly noted and I hope that my response will provide assurance that the Government is taking the necessary steps to help ensure that medicines supply into Northern Ireland continues to flow in January 2021.

The UK Government is taking a robust and flexible multi-layered UK-wide approach to help prepare for the end of the transition period. This approach includes re-routing supply chains away from the short straights, being 'trader ready' and stockpiling. In addition to the UK-wide programme we are also taking specific steps with regards to the Northern Ireland Protocol, working collaboratively with Trade Associations, industry and the Northern Ireland Civil Service to understand the issues faced by industry and to develop mitigations collectively.

Requirements – under the Northern Ireland Protocol medicines will have to comply with the EU medicines acquis. If moving from or through GB (outside of the Common Transit Convention) this includes the 'safety features' under the EU's Falsified Medicines Directive (FMD) which primarily impacts prescription- only medicines; the need to be batch tested in an EU Member State (or for the Protocol purposes, NI); the need to be certified by a Qualified Person (QP); to undergo independent testing through the EU's Official Control Authority Batch Release process for biological medicines; and to possess a Manufacturing / Importation Authorisation (MIA).

Preparations – industry have been clear that they will need time to implement changes, that they will require significant investment and would be extremely challenging ahead of January 2021. My officials are working with their counterparts in negotiation teams and Northern Ireland, and with industry colleagues to discuss the consequences of the Northern Ireland Protocol, in particular the issue of FMD and regulatory requirements.

In June 2020 we made the case to the Ireland/Northern Ireland Specialised Committee, setting out the need for a 12-month grace period. This would grant industry additional time

to fully implement the requirements above. This was done following intensive discussion with industry.

I am pleased to say these conversations have been successful and the Commission agreed to a pragmatic approach to implementation, announced by the Government in the INISC statement of 5 November [https://www.gov.uk/government/news/irelandnorthern-ireland-specialised-committee-05-november-2020]. The Committee noted that an agreed approach had been reached on a phased process for implementing medicines regulation in Northern Ireland up to 31 December 2021, providing the additional time needed for businesses to prepare in relation to batch testing, importation and FMD requirements. Further guidance will follow and we will work closely with industry to ensure they have the clarity and assurance needed.

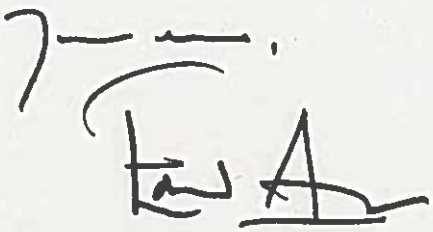
Buffer stocks – as part of our end of transition period contingency planning for the UK we encourage companies to make stockpiling a key part of contingency plans, and ask industry, where possible, to stockpile to a target level of 6 weeks' total stock on UK soil. DHSC stands ready to support companies with their plans if required and understands that a flexible approach to preparedness may be required that considers a mixture of stockpiling and rerouting plans as necessary. Further to this, the MHRA has published guidance (Article 41) relating to the placement of 'goods on the market' prior to 11:00pm, 31 December, so as to ease the short-term flow into Northern Ireland without further regulatory checks. The guidance is available here: https://www.gov.uk/guidance/supplying-medicines-to-northern-ireland-from-1-january-2021.

Mitigations – my officials continue to work alongside industry and Northern Ireland officials on the specific arrangements that will be required longer-term. We will continue our work at pace to help industry prepare to implement the Protocol in January 2022. As you mention, options include the Common Transit Convention and the use of bonded warehouses, , re-routing and regulatory flexibilities in addition to stockpiling and trader readiness.

Guidance – specific guidance has been published on Northern Ireland setting out the requirements that industry will have to meet to move goods from GB to Northern Ireland and vice versa, available here: https://www.gov.uk/government/publications/moving-goods-under-the-northern-ireland-protocol/moving-goods-under-the-northern-ireland-protocol-section-two-moving-goods-from-great-britain-to-northern-ireland. We continue to work closely with industry to signpost to guidance and ensure it is easily found; as well as to refine guidance and address remaining queries.

We continue to seek a free trade agreement with the EU and a mutual recognition agreement on Good Manufacturing Practice and Batch Testing remain critical components of these negotiations. However, it must be stressed that there will still remain regulatory requirements for EU products moving from/through GB to Northern Ireland unless moving from an EU27 country under the Common Transit Convention. Therefore, we continue to work with the EU in the Joint Committee to resolve outstanding issues with the NI Protocol – that is our overriding priority.

The Government, Northern Ireland Executive, pharmaceutical industry and NHS will continue to work together to help ensure patients right across the UK have access to the medicines and treatments they need.



EDWARD ARGAR MP