Healthcare Distribution Association (HDA UK) – written evidence, dated 17 January 2022

HDA response to the EU proposals published in December 2021 regarding the Northern Ireland Protocol

The EU proposals which allow for medicines tested and released in Great Britain to be distributed in Northern Ireland are very welcome indeed. Similarly, the EU indication that they will allow medicines to be licensed UK-wide also removes many of the concerns of the wholesale distribution sector since this allows for the continuity of the existing medicines supply chain. The responsibility is now with the MHRA and UK Government to make these positive proposals work in regulatory and operational terms.

HDA believes that there are still 3 major issues for our sector that remain to be addressed in the current negotiations at a technical level. The remaining concerns centre around products with an existing 'GB only' Product Licence (PLGB) and the EU's Falsified Medicines Directive (FMD) requirements which are still in place in NI, plus the ongoing issues of importation declarations when supplying NI from GB.

1) **PLGB licensing issue**

   Around 2500 products which previously had an EU-wide licence have been granted PLGB (GB-only) licences, technically these products cannot be supplied in NI, however, *currently wholesalers have no viable way of identifying the licence status of these products,* especially as manufacturers have a 3-year grace period in which to update their packaging to reflect the new licence status of the products. In this fluid and impractical situation, and for the sake of supply continuity, wholesalers are continuing to supply all types of licensed products to the NI market, in order that there are no patient safety impacts.

   The UK Government has very recently mandated a back-up regulatory process to try and keep medicines supplies flowing, called NIMAR (Northern Ireland MHRA Approved Route) see:
   https://questions-statements.parliament.uk/written-statements/detail/2021-12- 16/hcws507
   An SI has been laid in the UK Parliament to mandate this, and NIMAR is designed to provide a route for the lawful supply of prescription-only medicines that are unlicensed in NI where no alternative is available.

   HDA believes that the NIMAR process set up to allow supply of GB-licensed medicines in NI does not address this wider PLGB-licensing issue.

HDA believes that early and rapid MHRA guidance allowing and recommending that medicines Marketing Authorisation Holders (MAHs) can change PLGB licenses to PLUK (UK-wide) licenses would remedy this solution quickly and easily, and would seem to be under UK jurisdiction to enact given the recent EU announcement.

2) **FMD**

The 3-year derogation agreed by EU and UK has been proposed in order to allow manufacturers to not to have to decommission prescription medicines moving from the EU to the UK, thus protecting NI (and some small EU Member States) access to UK medicines, as all medicines in NI have to comply with the FMD, and the UK currently unilaterally recognises EU-regulated medicines.

· Wholesalers and all end-user dispensing points in NI are still bound by the requirements of the EU's FMD. This means that, in order to comply with the FMD, MAHs regardless of the licence status of their product, *must* continue to apply the EU FMD safety features to their products when supplying NI. *In addition*, MAHs must upload the Unique Identifier (UI) pack data to the European Medicines Verification System (EMVS) if they are supplying NI.

There is no obligation for MAHs to maintain FMD Safety Features on their products and upload the UI data. MAHs can currently just supply GB if they choose – but if they select this route, they are legally obliged to give six months' notice to the Department of Health & Social Care.

This may be further complicated if the UK decides to introduce its own version of the FMD in due course.

3) **Importation requirements for medicines supplied from GB to NI via wholesale distributors**

The Healthcare Distribution Association (HDA) is concerned that implementation of the Northern Ireland Protocol *could* eventually lead to a reduction in the range of medicines and medical products available to patients in Northern Ireland. This is because the extra importation and regulatory requirements needed to enter the EU Single Market regime *could* eventually become prohibitive for a market as small as Northern Ireland. Even with the EU's latest proposals for the medicines' regulatory regime, which are very welcome, but not operationally clear yet, HDA believe that smaller UK wholesalers and distributors will be reviewing the viability of their own distribution routes to Northern Ireland.

This is because of the extra burdens already being put on their companies by customs declarations and the full implementation of the EU's Sanitary and Phytosanitary (SPS) regime – the latter is currently expected from July 2022. Anecdotally, the HDA understands that several small wholesale businesses have ceased to supply Northern Ireland already. If true, this, when taken together with longer term cost increases for the larger companies' operations in Northern Ireland, will inevitably reduce efficiency and the choice available for the NHS in Northern Ireland when compared to the rest of the United Kingdom.

Medical Devices

The unintended consequences of the EU Medical Device Regulations (MDR) particularly around the 'importer' requirements where stock is moved or bought from GB-NI are another cause for concern. There is a letter of comfort from the MHRA allowing stock to continue to be supplied from GB to NI, but the requirements on importers (GB-NI is designated as importation) are onerous (for example certificates of compliance for ~8000skus must be collected and updated).

Concluding Points

In summary, HDA and its members are concerned that without some guidance being issued to the supply chain stakeholders very shortly, misunderstandings and lack of communication will result in inefficiencies, wasted resources and medicines being distributed incorrectly. The PLGB- created vacuum is one we want to shorten at all costs. In fact, it is only the MAH holder who can identify what type of licence a particular pack of medicines has on it - perhaps the communication to other players in the supply chain should begin there, whilst this vacuum exists?

Communication and clear signposting will be helpful to support our member companies, so they are not bombarded with requests and questions from many different interests, that they may not be able to respond to with any certainty yet.

In addition, it is worth reporting that our member companies believe that there is already confusion apparent and contradiction across the supply chain, including amongst many MAHs, who simply believe that the EU announcements have now overcome all regulatory issues, and this will include those that market PLGB licences and quote official Ministerial statements such as *'the trade in medicines to NI will continue on the same basis as it does now'.*

In the absence of absolute regulatory and legal clarity, rather than taking decisions to stop or block supply, HDA and its members will work with all industry stakeholders to seek the clarity needed to prevent this from happening and will maintain supply to patients across primary care & secondary care in NI.

Please be reassured that all HDA companies will protect and maintain supply to all patients in NI who order all existing products. Our collective position, in the absence of clear guidance, is to continue supply to NI, as we did pre-Brexit, for the sake of continuity of supply and patient safety.

Footnote
To aid understanding, HDA thought it might be helpful to describe a typical HDA member company operation as follows:

- a typical HDA member company is a 'full-line wholesale distributor of medicinal products' (controlled drugs, prescription medicines, cold chain products, OTC medicines, medical devices and medicinal foods, along with a small range of sundries) which delivers to customers in NI, including pharmacies, hospitals, GP practices and other healthcare settings

- the wholesale distributor delivers twice daily to their customers in NI - orders placed night before for next morning (6pm cut off for next am delivery from a Belfast warehouse and GB mainland hub stocks) or on the morning of the delivery for that afternoon delivery (12pm cut off for same day pm delivery from NI locally-stocked lines only). They hold approximately 8,500 Stock Keeping Units (SKUs) in a Belfast warehouse and 14,000 additional SKUs in their GB hub depot. This is a typical arrangement for supply of medicinal products to NI, operated by all of the leading HDA wholesale distributors

- for context and to provide a sense of scale, a community pharmacy will usually have a stock range of about 1800 SKUs - meaning they rely on wholesale distributors for prompt deliveries of non-stocked lines

HDA
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