HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Oireachtas Joint Committee on Health: 25 September 2019

Opening Statement from the Health Products Regulatory Authority

Good morning Chairman and members of the Committee.

My name is Lorraine Nolan, Chief Executive of the Health Products Regulatory Authority (HPRA). I am joined by my colleagues Rita Purcell, Deputy Chief Executive and Larry O'Dwyer, Scientific Manager.

The HPRA, as the regulator of medicines and medical devices, has been engaged in preparing for the UK's exit from the EU since article 50 was invoked. Since the beginning of this year our preparations and engagement with stakeholders have intensified and have been based on the worst-case scenario associated with a disorderly Brexit.

At a high level there are three major strands to our current work. We have been working with companies since Brexit was announced to ensure that they understand their obligations to be in regulatory compliance by 31 October. We have also been working intensively and proactively with the Department of Health and the HSE on the supply of medicines deemed critical to patient care and we have been assisting the HSE in its review of the supply of medical devices. This has been supported through our work with primary wholesalers, who introduce stock to the market, to review their capacity to hold stock in the event of a disorderly Brexit. I will speak more about these shortly. Within the HPRA, we have detailed plans to not only address the immediacy of a hard Brexit, but also to continue the HPRA's participation as a key European regulatory agency in the aftermath of Brexit.

The final area of focus has been supporting the Department of Health in engaging with the many relevant stakeholders to ensure a common understanding of the issues and a co-ordinated approach to interaction and communication.

In all our work to date, our aim is to ensure, to the fullest extent possible, that the necessary preparations are completed in time so as to mitigate any potential adverse impacts on patient care. I will now provide an update on specific elements of our preparations for a no-deal scenario.

The Committee will be aware from your meeting on 30 January that the HPRA has been engaged in an extensive industry engagement exercise with the Department of Health and the HSE, focussed on the supply of critical medicines. These are medicines with a short shelf life, refrigerated supply chains, time-critical logistics or compounded for specific patients or patient groups. However, through working with the HSE, this exercise has also been able to review supply arrangements for all prescription medicines regardless of criticality. The review involves liaising directly with hospitals, companies and distributors to identify supply routes and ensure companies have contingency plans in place if their supply routes have been from, or through, the UK. This exercise was first conducted in quarter 1 this year and work has remained ongoing since that time. In advance of the 31 October deadline we are again repeating this coordinated outreach to companies to seek final reassurances of their supply arrangements and contingencies for 31 October in the event of a disorderly Brexit. This work is continuing at this time.

As an example of this work for the Committee, I can point to radiopharmaceuticals which have a short shelf life and very specialised transport and storage requirements. Some do not transit the UK; however, the majority are flown from continental Europe to Ireland via East Midlands airport by the one logistics company. Companies who use this route have previously received assurances from their logistics provider that it will continue to operate these supply routes post-Brexit as it does currently. We have been in contact with the companies who supply these products to the Irish market who have confirmed their intention and plans to continue the supply to Ireland post Brexit. We have also requested written assurances from the logistics provider involved. Separately there is ongoing direct engagement with the logistics provider in question to ensure that their service can be relied upon and if necessary consider alternative solutions that may be required. Currently all the responses we have received indicate that all parties believe that they can continue to supply the Irish market and all parties are actively considering contingency plans. However, this is a good example of the complexity and the many players that are involved in getting product to Ireland. In this case as the product is intended for both Ireland and the UK (and there is effectively only one carrier for the product) it must stop first at East Midlands airport which introduces an element outside the control of all the parties. While there is no indication that this will cause a problem, it is indicative generally that with multiple independent players in the supply chain one cannot fully rule out all risks, but the HPRA and the HSE plan to actively monitor this situation and manage as necessary.

Another example for the Committee relates to insulins which are critical medicines for diabetic patients and which need to be refrigerated during transportation and storage. We have engaged with the three suppliers of insulins to Ireland who have all provided assurances that they will have a minimum of 8-10 weeks' stock of all insulins in Irish wholesalers on 31 October. In addition, all suppliers have taken steps to ensure that they are in a position to replenish these stocks post-Brexit, including the use of alternative transport routes which do not involve supply from or via the UK.

A key part of our Brexit planning is to ensure that there is sufficient stock in Ireland so that temporary delays during transportation will not significantly affect access by patients to medicines. We have contacted all the primary wholesalers who have provided assurances that for the vast majority of medicines they will hold between 8 to 10 weeks of stock. This level of stock holding will allow Ireland manage short-term disruptions to the supply of medicines. We have also, as part of our engagement with companies supplying the market, requested them to confirm that they will have sufficient stock

levels (8 to 10 weeks) at 31 October and can maintain these levels post-Brexit period by appropriate replenishment procedures. We have also continuously stressed to companies the need to be aware of, and comply with, customs procedures and requirements and have issued individual letters, follow up calls and a check list to that effect.

For medicines where stock levels are less than this, we are actively working with the wholesale sector on addressing potential Brexit impacts, and ensuring that cases where continuity of patient care could be compromised are in so far as possible addressed. This includes the ability if possible to build additional stock levels and the development of contingency arrangements to ensure a sustained process of stock replenishment. The work remains ongoing.

In relation to the supply of medicines post-Brexit, it needs to be recognised that some products will still either come from the UK by air or sea or by necessity be transported across the UK. The assurances received from companies are based on the continued operation of these transport routes combined with the maintenance of sufficient stocks levels (depending on shelf life) in Ireland. However, significant and prolonged delays anywhere along these routes could potentially interrupt supply to the Irish market. While our preparations are focused on ensuring that such impacts are prevented or minimised, there are no absolute guarantees.

No major supply concerns for continuity of patient care have been identified to date, and we have, through our shortages protocol, plans in place to address issues should they arise. This framework predates Brexit as medicines shortages can occur, for various reasons, on an ongoing basis.

I would like to emphasise that there is no need for hospitals, healthcare professionals or patients to order extra quantities of medicines ahead of Brexit. To do so could disrupt existing stock levels and hamper the supply of medicines for other patients.

Marketing authorisations for medicines place a number of regulatory obligations on the holder. These include that the holder must be based in the EU, and each batch of product imported from a non EU country must be retested and released in an EU member state.

Regulatory compliance among companies has been improving steadily as affected operations have moved from the UK to an EU27 country. In a repeat of the exercise conducted in quarter 1 of this year, we issued a list of questions in August to those companies which potentially might not be in regulatory compliance at 31 October, or 31 December if they availed of a Commission-approved temporary waiver of retesting requirements on importation into the EU.

A medicine which is non-compliant as of 31 October does not automatically present an immediate risk to supply and we will work to ensure that regulatory issues associated with Brexit will not hinder the supply of medicines in the immediate aftermath. We are continuing to engage with companies to ensure that they address outstanding regulatory actions in a timely manner.

Medical devices, unlike medicines, are not authorised by the HPRA. Each medical device on the market requires a CE mark to demonstrate conformity with the regulatory framework and for medium to high risk devices, a CE certificate issued by a Notified Body located in any EU Member State. The HSE as the

main procurer of medical devices for the Irish health system, has engaged in an in-depth exercise of analysing medical devices for exposure to the UK (land-bridge or manufacturing) and for certification from a UK Notified Body.

The HPRA is participating in the HSE-led Criticality Assessment Group for medical devices and is sharing information with the HSE to assist them in their risk assessment of critical medical devices supplied to and used in the health services.

The HPRA has communicated with manufacturers and authorised representatives at national level a number of times to ensure appropriate awareness of the implications of a disorderly Brexit for medical devices. We have also led on EU work with other competent authorities to promote awareness and to prevent adverse impacts on medical devices used in Ireland.

From our engagement, we know that larger manufacturers have measures in place to transition their UK medical device certificates to an EU 27 Notified Body, while many small and medium sized manufacturers have indicated that their main challenge is in securing an EU27 Notified Body to issue new certificates. As such it remains the case that a significant number of UK certificates have not transitioned to an EU member state.

There are a number of factors contributing to this. Historically there has been a high dependency on UK Notified Bodies for medical device certification activities. This is due to the broad ranging designation scope which the UK bodies have to conduct such activities and to their size. Notified Bodies throughout Europe are also preparing for new EU Regulations which apply from May 2020, a factor which is impacting on their ability to take on additional certification activities.

The HSE is reviewing the impact of this on medical devices on the Irish market. The situation is not unique to Ireland, though our market is likely to be more impacted. The HPRA and other EU authorities are working together to develop and agree with the EU Commission, a European approach to manage UK certificates that have not transitioned by the deadline.

If such an approach is not agreed the HPRA has developed contingencies to manage this. Given that a medical device which becomes non-compliant with regulatory requirements after the 31 October does not present an immediate risk, we will work to ensure continuity of care for patients whilst ensuring that products return to compliance as quickly as possible.

As government public communications have recognised, any Brexit outcome that does not include regulatory alignment will mean change as the UK and Irish markets adjust over time. Brexit will bring change across all areas and in the dynamics of the supply chain and model in Ireland for both medicines and medical devices. The issues we see in the longer term may be quite different to those in the immediate aftermath.

It is realistic to expect that companies may after a period of time make commercial decisions with respect to the continued viability of supply of certain products to our market. We have stressed to companies that, in advance of making any such decisions, they should let us know of their plans as soon as possible. The earlier we have this information, the better we can plan for change, including

working with HSE colleagues. Alternatively, we may be able to help in identifying a course of action to prevent such an outcome.

In closing, Chairman, I would like to assure the Committee of the strenuous efforts being made by HPRA staff in relation to protecting the supply of medicines to Irish patients post Brexit. I also wish to acknowledge the huge collective efforts of our colleagues in the Department of Health and the HSE and the substantial engagement by industry and healthcare professionals. It is this open and cooperative approach among all stakeholders across the health products sector that will help to ensure we effectively and collectively manage the potential impact of Brexit on supply and availability.

Thank you Chairman, and we will be happy to address any questions.