



Brexit contingency and preparedness update



At the time of going to print, the process of ratifying the Withdrawal Agreement and Political Declaration continued at Westminster, and the Irish Government continued its no-deal Brexit contingency planning. Four Memos were brought to Government on legislation required in a no-deal scenario; an approach to no-deal Brexit legislation no-deal Brexit legislation; the Common Travel Area; Medicines and Transport Connectivity.

Department of Foreign Affairs & Trade: Contingency and preparedness update

Legislation required in a no-deal Brexit scenario

The Government had a detailed discussion on its approach to legislation to mitigate some of the most damaging effects of a no-deal Brexit. An outline approach was published, based on a full review of Irish legislative provision, in the No-Deal Contingency Action Plan on 19 December*.

Government agreed that, aside from the European Parliament Elections (Amendment) Bill 2018 and the Regulated Professions (Health and Social Care) (Amendment) Bill, legislation across different sectors be grouped into one omnibus Bill, in order to assist with the speed of passage through the Houses. The Bill, comprising 17 Parts, will focus on the broad themes of protecting the citizen, and supporting the economy, enterprise and jobs. There will also be 20 Statutory Instruments covering a range of matters to mitigate a no-deal Brexit.

Update on Common Travel Area (CTA)

The CTA is a long-standing arrangement between Ireland and the UK, which means Irish citizens can move freely to live, work, and study in the UK on the same basis as UK citizens and vice versa. It provides for associated rights and privileges including access to employment, healthcare, education, and social benefits, as well as the right to vote in certain elections. Considerable progress has been achieved bilaterally with the UK over the past year, involving several Departments in what has been a whole-of-Government exercise.

The CTA is an arrangement that is valued on both islands. Both the Government of Ireland and the UK Government have committed that the CTA will be maintained in all circumstances. The CTA pre-dates Irish and UK membership of the EU and is not dependent on it. The CTA is recognised in Protocol

20 to the EU Treaties, which acknowledges that Ireland and the UK may continue to make arrangements between themselves relating to the CTA, while fully respecting the free movement and other rights of EU citizens and their dependents. Protocol 20 will continue to apply to Ireland after Brexit.

Detailed bilateral work with the UK has continued, including in the social security, health and education sectors. Arrangements relating to immigration continue to be led by the Minister for Justice and Equality, through long-established structures. Ireland's shared aim with the UK throughout has been to ensure that the necessary arrangements are made in both countries so that the CTA continues to function effectively after the UK leaves the EU – irrespective of whether there is an orderly Brexit, or a no-deal scenario. Neither Irish citizens in the UK nor British citizens in Ireland are required to take any action to protect their status and rights associated with the CTA. After the UK leaves the EU, both Irish citizens in the UK and British citizens in Ireland will continue to enjoy these rights. Both Governments have committed to undertaking all the work necessary, including through legislative provision, to ensure that the agreed CTA rights and privileges are protected.

Medicines

As part of a whole-of-Government response to Brexit, Minister for Health Simon Harris TD has outlined a comprehensive and coordinated set of preparations to ensure the continuity of health services and supply of medical products in the event of a no-deal Brexit. This work involves the Department of Health, the HSE, the Health Products Regulatory Authority (HPRA) and other agencies engaging in intensive Brexit preparedness and contingency planning.

Minister Harris outlined the fact that a wide range of issues are being examined with contingency planning for a range of eventualities underway. A key consideration is to ensure, as far as possible,

minimum disruption to health services and that essential services are maintained on a cross-border, all-island and Ireland-UK basis.

In relation to the continuity of supply of medicines in the event of a no-deal Brexit, significant work has already been undertaken by the Department of Health, the HSE, and the HPRA, together with industry, to minimise and address any risks to continuity of supply. The supply chain for medicines is complex, and shortages are an increasing feature of the global medicines landscape faced by all countries on an ongoing basis, irrespective of Brexit.

In 2018, the HPRA developed and launched a multi-stakeholder Medicine Shortages Framework to mitigate the impact of medicine shortages when they occur. This framework is used to manage and address an average of 45 shortage notifications a month. The health system is therefore well placed to anticipate and respond to any additional shortages, should they arise because of Brexit.

There are approximately 4,000 medicines marketed in Ireland, of which 60% – 70% come from, or transit through, the UK. The HSE and HPRA have advised that the supply of a small number of these products may be vulnerable for reasons such as their short shelf life, special storage and transportation requirements, and single supplier reliance. The HSE and HPRA are progressing contingency plans including those involved in the supply of critical medicines, verifying contingency planning to date and, where necessary, identifying clinically appropriate alternatives to these small number of vulnerable products.

Industry, including pharmaceutical companies and wholesalers, has been engaging in extensive planning for Brexit for some time and advanced arrangements are in place to ensure continuity of supply. Both the HPRA and HSE are working closely with companies to highlight any issues regarding the availability of specific products associated with Brexit. To date, no major issues have been identified

through this process.

The Department of Health, HSE and HPRA do not anticipate an immediate impact on medicine supplies should there be a no-deal Brexit on 29 March. There are already additional stocks of medicines routinely built into the Irish medicine supply chain, and these additional stocks, together with planning by Revenue to allow the fast-tracking of essential drugs into Ireland, will help deal with any delays and shortages that may arise.

It is important to note that the Department has said that there is no need for hospitals, pharmacists or patients to order extra quantities of medicines, as doing so could disrupt existing stock levels and hamper the supply of medicines for other patients.

Transport connectivity

Currently, trade between the UK and Ireland is relatively frictionless as it is all within the Single Market. With the UK potentially becoming a third country from 29 March 2019, substantial additional customs, agriculture, health controls will be required at ports and airports that involve trade with the UK. The main pinch-points are likely to emerge in Irish, UK and French ports – in particular, Dublin, Rosslare and Dover-Calais.

The Department of Agriculture, Food and the Marine, the Department of Health and the Revenue Commissioners are already preparing by developing the necessary plans within Dublin and Rosslare Ports and Dublin airport to allow for these controls. The scale of the checks required will likely result in delays for goods moving through the ports but there is a focus on preventing congestion through the provision of appropriate measures.

The Minister for Transport, Tourism and Sport has assessed the maritime capacity for direct sailings between Ireland and continental EU ports as a potential alternative for trade that currently takes place using the Landbridge. Based on consultations with the shipping sector and wider stakeholders, the Minister's preliminary assessment is

that sufficient capacity will be available on direct routes to continental ports from end of March 2019, and should demand for further capacity arise, the shipping sector can respond quickly to meet such demands.

The Minister also raised a number of other potential risks to transport connectivity from a no-deal Brexit and notes the temporary mitigation measures proposed by the European Commission in a no-deal scenario to ensure basic connectivity for flights between the EU and UK, as well as its proposals to facilitate the continuation of international road haulage between the EU and UK.

**The text of the Government's Contingency Action Plan Preparing for the withdrawal of the United Kingdom from the European Union on 29 March 2019 can be viewed on the DFA website, www.dfa.ie.*

Health Products Regulatory Authority (HPRA)

Following the UK's triggering of Article 50 to leave the European Union, the HPRA, together with medicines agencies in Europe, is making preparations to ensure that they continue to deliver on their patient and animal health remit, even if the UK fully exits the current systems on 29 March 2019. There are potential implications for the European network as a whole

and particularly for Ireland with its shared marketplace.

The HPRA is actively involved in the ongoing planning to ensure the continued supply of medicines after Brexit and this includes working with the Department of Health and the HSE, as well as engagement with wholesalers, pharmaceutical companies and industry representative groups to ask them to review their supply chains in the light of a potential disorderly Brexit. The HPRA has an existing Medicine Shortages Framework in place, the aim of which is to help avert potential shortages from occurring and to reduce the impact of shortages on patients by co-ordinating the management of potential, or actual, shortages as they arise. This framework is used to manage and address an average of 45 shortage notifications a month. The HPRA's current list of resolved shortages (for the past six-month period) contains a list of 24 medicines and can be viewed on www.hpra.ie.

The key risk to medicines supply, presented by a disorderly Brexit, is due to potential delays at customs. The HSE and HPRA have advised that the supply of a small number of products may be vulnerable, with particular consideration being given to radioisotopes, medicines subject to cold storage and products that require specialised manufacturing processes.

The HSE and HPRA are contacting the associated suppliers to ensure contingency plans are in place for Brexit. In addition, they are working with the Revenue Commissioners to ensure that any delays at customs are minimised. Regardless, their distribution system already holds sufficient stocks to help absorb any short-term delays that may arise.

Furthermore, as an additional safeguard, consideration is being given to those categories of medicines which

are considered most essential in the clinical setting. While the HPRA is responsible for the authorisation of medicines, decision making in respect of treatment options is part of healthcare provision, and as such is outside of the remit of the HPRA. The role of the HPRA is focused on contacting suppliers of those categories of medicines identified and to seek assurances in respect of their continued supply in the event of a disorderly Brexit. Work on this iterative process is ongoing and will continue for the foreseeable future. To date, the HPRA has not been informed of any potential shortages due to Brexit. Should any potential issue be identified, they will then utilise their existing shortages framework, outlined above.

During the past two years, the HPRA has proactively engaged with key stakeholders to identify issues affecting UK-based supply chains and to support pragmatic or innovative solutions to potential regulatory barriers. Additionally, during this time their detailed Brexit planning has included:

- Participating in the ongoing discussions at European level for Brexit preparedness and seeking to ensure that the specific needs of the Irish market are recognised and addressed;
- Working with the pharmaceutical and medical device industries to ensure the timely implementation of any regulatory changes for health products arising due to the UK withdrawal. This has included the provision of significant levels of advice on how best to approach the challenges associated with Brexit;
- Increasing their commitment to the assessment of applications for market medicines within the European regulatory network;
- Exploring opportunities for joint labelled packaging with other European markets; and

- Working with UK regulators to help maintain, if needed, joint labelling for products that are on both the UK and Irish markets.

All of the Brexit planning to date by the HPRA has involved proactive actions to facilitate the continued supply of health products and to minimise the impact on patients and healthcare professionals.

NOTE: While the HPRA regulates the distribution of medicines in Ireland, the supply routes for medicines are a matter for individual companies provided that compliance with regulatory requirements is ensured.

The HPRA has no role in the procuring, pricing or selection of medicines within the health service in Ireland.

Irish Pharmacy Union (IPU)

The IPU is working closely with the Department of Health, the HSE, the HPRA and all stakeholders involved in the supply chain of medicines, to plan for any potential disruptions to medicine supplies as a result of Brexit.

The Department of Health, the HSE and the HPRA, are facilitating ongoing engagement with everyone involved in the medicine supply chain, including manufacturers, wholesalers and pharmacists, to identify any potential issues that could affect the supply of medicines and to develop solutions to protect medicine supplies to Irish pharmacies and patients.

We have received assurances that everything that can be done is being done to anticipate, plan for, and mitigate against any potential problems that may arise, and to develop solutions to protect medicine supplies to Irish pharmacies and patients, with a particular focus on the supply of those that have been identified as critical medicines. The IPU is working with the Department of Health, the HSE and the HPRA on ensuring that supplies of such critical medicines are protected.

