Introduction

Good morning Chairman and Committee members. I would like to thank the Committee for inviting the Department of Health, the HSE and the Health Products Regulatory Authority (HPRA) to assist you with your examination of issues arising from Brexit.

I am joined today by colleagues:-

Muiris O’Connor, Assistant Secretary General,

Eamonn Quinn, Pharmacist and

Colm O'Loughlin, Assistant Principal, Medicines Unit

I am also joined by colleagues from the HSE and the HPRA.

The Department, along with the HSE and the HPRA, last appeared before you on 30th January to update you in relation to the preparedness of the health sector for Brexit. A lot has happened in the intervening period, including two extensions to the withdrawal date and the election of a new British Prime Minister, so your invitation is timely as we finalise our preparations for the likely possibility of the withdrawal of the UK from the EU on 31st October.

I can assure the Committee that Brexit preparation continues to be a foremost priority for the Department and key health agencies and very significant further work has been undertaken since we last met. When we last discussed the subject,
I said that Brexit preparation was an exercise in “damage limitation” for Ireland generally and for the health sector specifically. Had we a choice all of us would instead much prefer to devote our intensive efforts to addressing the lots of positive opportunities that exist to improve the health of our population. However, while we all hope that negotiations will be successful in resolving the threat of a no deal Brexit, we must continue to work with industry and other stakeholders to protect public health against every eventuality.

This year we have committed over €10 million in funding to health sector Brexit preparations and, if Brexit proceeds on a no deal basis on the 31st October next, it will be necessary to incur further costs this year and on an ongoing basis. We could do much to improve our health services with this money but instead we must use these resources to mitigate any potential Brexit impact on population health.

Neither is Brexit a temporary or once-off adverse event – it represents permanent change in many aspects of daily life encompassing how we trade, import and regulate goods and services including health-related products.

**Health Sector Brexit Planning**

Previously I outlined to the Committee the structures we are using to prepare for Brexit. These structures remain in operation. In summary, we have a Heads of Agencies Group where I meet with the CEOs of the HSE, the HPRA and the Food Safety Authority of Ireland (FSAI) on a weekly basis to review progress on Brexit preparedness and to consider any new issues arising.

The Brexit Operations Team, which is chaired by a Deputy Secretary General in the Department and is comprised of senior officials from the Department and
Agencies, also meets weekly and works to resolve issues and to escalate them to the Heads of Agencies Group, if necessary.

The Operations Team has a number of groups active in addressing particular issues. Two multi-agency expert groups are working to verify the assurances and contingency planning in place in relation to the supply of medicines and medical devices respectively. These groups, which include clinical expertise, are working with suppliers to assess the vulnerability of products to supply disruption as a result of Brexit and making further preparations to ensure continuity of care for patients.

A communications group, chaired by the Department, is leading communications with relevant stakeholders and, as part of Government’s overall communications strategy, with the public.

As I said at my last appearance before this Committee our greatest protection against Brexit is our membership of the EU. The Department and the HPRA continues to work very closely with the Commission and with other Member States to mitigate the worst effects of Brexit and will continue to do so. The additional time granted by the extension to a possible Brexit on 31st October has been used to deepen our preparedness. We have reached out to all parts of the health sector including industry and suppliers, patients and healthcare professionals, to understand the challenges they face and to work together to resolve them. I would like to acknowledge the cooperation we have received across the sector in this work. We will provide detailed information to the Committee on this work throughout this session with a particular focus on the supply of medicines and the implications on the movement of health professionals between Ireland and the UK.
In this work our overriding concern is to ensure the protection of public health, the continuity in the provision of health services and the maintenance of existing services.

**Common Travel Area**

Our membership of the Common Travel Area (CTA) with the UK also provides certainty to Irish and British citizens resident in the other jurisdiction in relation to access to healthcare.

The Irish and British Governments have committed to the shared objective of maintaining the CTA arrangements which have long facilitated Irish and UK residents in accessing health services in each other’s jurisdictions.

Provision has been made to ensure the arrangements necessary to maintain health service cooperation after Brexit. Part 2 of the Withdrawal of the UK from the European Union Act 2019 will underpin continuity in the provision of healthcare in the event of a ‘no deal’ Brexit.

This will see the maintenance of current arrangements for access to routine, planned and emergency health services for UK/Irish residents and visitors in the other jurisdiction. It also includes North South and East West health co-operation on access to specialist health services in the other jurisdiction.

**North South Health Cooperation**

We are committed to protecting the many areas of cooperation in the health sector on a North/South, cross border, basis. These well-established and widely supported arrangements make life easier for people living along the border and
allow for the best use of resources for both health systems. Examples include cancer care at Altnagelvin Hospital, Paediatric Cardiology Services in Crumlin and cross border ambulance services.

The Department of Health has been in regular contact with the Department of Health in Northern Ireland in relation to the commitment of both Governments to ensure the continuation of North South health service co-operation arrangements. These contacts build on many years of very positive cooperation. In all of our preparations we have been able to build upon this very strong spirit of collaboration in the interests of patient care, at clinical, hospital, administrative and political level.

The HSE has been tasked with addressing GDPR and any other issues arising at operational level with their counterparts. Northern Ireland Department of Health officials are due to visit the Department of Health for a further meeting in early October.

I am confident that all existing North South health cooperation will continue, including arrangements with Northern Ireland health service providers.

**Supply of Medicine and Medical Devices**

Safeguarding the supply of medicines and ensuring continuity of care for Irish patients is of utmost importance to the Department of Health and the Government.
The EU has a sophisticated regulatory framework for medicines and medical devices and detailed preparations are in place across industry and regulators as the UK leaves this system. Lorraine Nolan from the HPRA will outline this in more detail.

Ireland is at the end of a very sophisticated supply chain when it comes to the importation of medicine and medical devices. My colleagues from the HPRA and the HSE will provide detailed updates on the current position and contingency plans in relation to supply security. We are working closely with the pharmaceutical and med tech industries to modify supply arrangements and minimise potential disruption.

Ireland is unlikely to face general medicine shortages in the period immediately after the 31st October. Any emerging supply issues will, in the first instance, be dealt with from existing supplies held within the domestic distribution chain. This supply chain is different to that of some other markets, including the UK.

It is important to reiterate

- There are already additional stocks of medicines routinely built into the Irish medicine supply chain.
- This is different to the wholesaling model which operates in the UK.
- The pharmaceutical industry and wholesalers have provided assurances that they are confident that they will have sufficient stocks to bridge any initial issues at ports, should they occur.
- There is no need for hospitals, pharmacists or patients to order extra quantities of medicines, or for doctors to issue additional prescriptions,
as doing so could disrupt existing stock levels and hamper the supply of medicines for other patients. Patients should continue to fill their prescriptions as normal.

As I have said, strong general assurances have been received from industry but an expert group is also examining categories of medicine where it is deemed especially important to work directly with suppliers to verify that robust contingencies are in place.

Unfortunately, medicine shortages do arise from time to time and are a feature of health systems around the world. Ireland has an existing multi-stakeholder Medicine Shortages Framework in place, coordinated by the HPRA, to help prevent shortages from occurring and to reduce the impact on patients and healthcare professionals by co-ordinating the management of potential or actual shortages as they arise. The health system is, therefore, well placed to deal with any additional shortages as a consequence of Brexit, should they occur.

Brexit is likely to herald changes in our medicines market as we will be less integrated with the larger UK market. Therefore, our focus on this issue will continue well past any Brexit date and into the medium term. Work on the Medicines Shortages Framework and the involvement of clinicians in contingency planning give us an enhanced capacity to respond to any such developments and, for example, mean that should particular products no longer be available expert clinicians in the respective medical specialties concerned will have identified equally effective alternatives.
Recognition of Health Professional Qualifications

The Department of Education and Skills has coordinated work across Government to ensure that, as far as possible, arrangements will be in place to maintain recognition of UK professional qualifications post Brexit when the UK becomes a ‘third country’. The importance of this work as part of affirming the right to work under the Common Travel Agreement was acknowledged in the Memorandum of Understanding signed by both Governments in May 2019.

At the outset it is important to say that decisions on qualification recognition that have already been made under EU Directives will remain valid and existing recognised health professionals will be able to continue to practice in either jurisdiction, subject to compliance with all regulations within that profession.

In respect of new recognitions, the recognition of qualifications in the EEA is carried out through the implementation of an EU directive on the recognition of professional qualifications. The Directive also provides a mechanism for the exchange of information on professional misconduct. It applies to all regulated professions – not just those in the Health area.

When the UK leaves the EU (either after the transition period, if it occurs, or on the withdrawal date), UK qualifications and the qualifications of UK nationals will no longer fall within the scope of the Directive.

Instead, Irish health professional regulators each have “third country” recognition routes, which apply to qualifications which are obtained outside the EEA or which are held by non-EEA nationals. The regulators have considered these “third country” recognition routes with the objective of ensuring efficient routes for
recognition of UK qualifications, while ensuring that this is done in an objective and non-discriminatory way.

The Irish health professional regulators are satisfied that they can continue to recognise UK qualifications within approximately the same time frames and the same level of application fee as applies currently, but now under this different legal base.

Similarly, the UK has preparations in place in respect of the recognition of health and social care professions which will enable Irish qualifications to be recognised in the UK in the event of a no-deal Brexit.

Irish regulatory bodies have also been linking with their UK counterparts to develop protocols for transferring personal data in accordance with the General Data Protection Regulations (GDPR). Transfers of personal data by the Irish regulators to their UK counterparts may be required in the processing of recognition applications or in the conveyance of disciplinary information.

**Food Safety**

As part of the whole of Government preparations, the Department has worked in close partnership with the Food Safety Authority of Ireland (FSAI), the HSE, and with the Department of Agriculture, Food and the Marine on the issue of food safety in the context of the UK’s departure from the EU. Enhanced staffing and procedures will be in place at the ports to facilitate inspections.
In order to avoid unnecessary delays, it will also be vital that industry prepares as fully as possible. Businesses will need to familiarise themselves fully with all relevant customs procedures and ensure that all necessary documentation is properly completed and submitted in advance.

**Conclusion**

We have engaged extensively with suppliers both in their industry groupings and on an individual company basis in respect of products. We have stressed to them the importance of providing early information on any emerging issues and, for our part, we have assured them that we are in problem solving mode. We are focused on pre-empting or solving problems using pragmatic solutions and we will be there to trouble shoot with industry issues that arise in the days and weeks following Brexit.

In conclusion I am satisfied that the health sector is working well to prepare for Brexit. We are linking in with central Government to ensure that all cross sectoral issues are identified and resolved. We are working with industry including the pharmaceutical, med tech, food industries and private health service providers, as appropriate, to ensure that the health sector, our employees and citizens are well prepared and protected as far as possible from adverse effects of Brexit.

Thank you, Mr Chairman. I look forward to the views and questions of Members.