Opening Statement

Introduction

Thank you, Chairman. I would like to thank the Committee for inviting the Department of Health to engage with you in relation to the preparedness of the health sector for Brexit.

I am joined today by colleagues Fergal Goodman, Assistant Secretary General, with responsibility for Primary Care and Kieran Smyth, Principal Officer, International Unit in the Department. I am also joined by colleagues from the HSE and the Health Products Regulatory Authority.

At the outset I wish to assure the Committee that detailed planning for Brexit has been ongoing in the Department and its agencies for over two years. As part of the whole of Government work on Brexit preparation the Government is working to secure an orderly and agreed Brexit, but in view of the uncertainty in London and the increased risks of a no-deal Brexit, we will continue to intensify our preparations for any such outcome. Our number one protection from whatever Brexit brings will be our status as an EU member state, with all the stability, predictability and solidarity that brings. On the 19th of December, the Government published its Contingency Action Plan, which outlines the approach to no-deal Brexit planning and the Department of Health and its agencies are contributing in full to this. Brexit of any kind will mean change and will impact on all sectors, including health.
It is recognised that managing a no-deal Brexit would be an exercise in damage limitation and it would be impossible in a no-deal scenario to maintain the current seamless arrangements between the EU and UK across a full range of sectors, which are currently facilitated by our common EU membership.

Having said that, it is important to underline that certain measures will allow us to mitigate, as far as possible, the implications of a no deal Brexit. Both the Irish and British Governments are committed to maintaining the Common Travel Area in all circumstances, and have committed to undertaking all the work necessary, including through legislative provision to ensure that the Common Travel Area rights and privileges are protected. The Department has focussed attention on protecting the Common Travel Area in terms of access to health care and allowing the freedom of movement we currently have for Irish and UK citizens. Protecting and maintaining the Common Travel Area and the associated rights and privileges is a key part of our contingency planning and preparations. This is vital in the context of the Good Friday Agreement and the Northern Ireland Peace Process, as well as broader UK-Ireland relations.

The Department continues to work closely with other Government Departments and agencies on all aspects of Brexit planning particularly the Department of the Taoiseach and the Department of Foreign Affairs and Trade. The Department is represented at all relevant cross sectoral working groups and is cooperating fully with colleagues across Government.
The Department has also strengthened its internal capacity to plan for Brexit. I meet with the heads of the HSE, Health Products Regulatory Authority and the Food Safety Authority of Ireland weekly to review progress on Brexit preparedness and to consider any new challenges identified. I have also established a Brexit Operations Team, chaired by a Deputy Secretary General and comprised of senior officials from the Department, HSE, HPRA and the FSAI. This group works to resolve issues and to escalate them to the Heads of Agency group, which I chair, if necessary. An inter-agency communications group, chaired by my Department, has been established to plan for all aspects of a communications strategy to ensure that the public is fully informed of the health implications of either a central case Brexit or a no deal Brexit. A further working group is working to identify and monitor medicines that may be vulnerable to supply disruption as a result of Brexit.

The Department and its Agencies particularly the HPRA, FSAI and HSE have been in regular contact with stakeholders to assess the level of preparedness for a no deal Brexit. It is important to state that while the Department continues to monitor and seek assurances in a number of areas, our current analysis is that there are no immediate risks to the health of the population because of Brexit.

It is important also to note that cooperation on health care provision and the protection of public health on the island of Ireland and between Ireland and Britain has developed over many years to the mutual benefit of the all parties. Some of these arrangements are underpinned by EU regulations while others are on the basis of bilateral agreements or service to service arrangements. Both Governments have repeatedly stressed that they are anxious for these services to continue post Brexit and the Departments of Health continue to be in close contact to facilitate this.
I would now like to update you on progress and the current status of priority issues since the Department’s last appearance on this issue in January 2018.

**Preparation of legislation to allow for the continuation of existing health arrangements in the event of a no deal Brexit.**

In the event that the United Kingdom leaves the European Union on 29 March 2019 without a withdrawal agreement in place it will be necessary to put in place legislative provisions to enable necessary healthcare arrangements, including reimbursement arrangements, to be maintained between Ireland and the United Kingdom. The Irish and British Governments have committed to maintaining the Common Travel Area and its associated rights and privileges. These arrangements facilitate access to health services in the UK and Ireland, including access to emergency, routine and planned healthcare. The draft heads of the proposed legislation therefore seek to put in place an appropriate legal framework in Ireland to ensure the continuation of the Common Travel Area arrangements.

The Department, as part of the cross-government approach to contingency planning, has prepared heads of a bill which is consistent with our commitment to provide for the rights and privileges of the Common Travel Area. The proposed legislation would allow the Minister for Health and the HSE, as appropriate, to cover the cost of healthcare provided in the UK under the same conditions as currently e.g. where treatments are not provided under our own healthcare system or for an Irish person who becomes ill while on a visit to the UK and needs immediate health care there.
It also makes provision to preserve existing eligibility for healthcare in Ireland for a range of different cohorts of people including for example UK pensioners residing in Ireland, frontier workers and for UK residents on a temporary visit here.

As part of the Common Travel Area discussions key principles have been agreed at official level with the UK to maintain bilateral health care co-operation. There has been very good ongoing engagement with the UK on the technical work needed to ensure continuity of health care arrangements. Proposals are now being examined with a view to ensuring the maintenance of the status quo pending the finalisation of longer-term arrangements. This cooperation will support the objectives of the health care legislation proposed in the "no deal" Brexit Omnibus Bill. It is also important to state that this overall framework will build upon many years of very positive cooperation between the two jurisdictions. This is true of our administrative systems, but it is also true at a clinical level. There are very strong and well-established relationships at clinician to clinician level, indeed many of our respective clinicians have trained together. 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 supply of medicines that originates in, or transitions through, the UK**

The Department is working closely with the HPRA and the HSE in relation to the supply of medicine. Since the UK referendum industry has undertaken very significant work in modifying supply chains and revising regulatory pathways to guard against Brexit. This work is continuous and the Department, the HPRA and the HSE are continuing to work closely with suppliers.
As part of a whole-of-Government response to Brexit, Minister Harris recently outlined a comprehensive set of preparations to ensure 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 HPRA and other agencies engaging in intensive Brexit preparedness and contingency planning.

In relation to the supply of medicines and other medical goods, significant work has been undertaken by the Department of Health, the HSE, and the HPRA, together with the pharmaceutical industry, to anticipate - in so far as is possible - potential vulnerabilities, risk assess these and devise contingencies in order to minimise and address any risks to continuity of supply of medicines.

No major supply issues have been identified through the preparedness and contingency planning exercises.

Ireland is unlikely to face serious general medicines supply issues in the period immediately after 29th March. Any emerging supply issues will, in the first instance, be dealt with from existing supplies held within the domestic distribution chain.

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 wholesale providers have provided assurance 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.

As an additional safeguard, special consideration is being given to those categories of medicines which are considered most essential to public health. An expert group is examining these categories of medicine, and, where the supply chain indicates that Brexit could potentially cause issues, are working with suppliers to verify that robust contingencies are in place. Work on this process is ongoing and will continue for the foreseeable future.

Both the HPRA and HSE have requested that companies highlight any issues regarding the availability of specific products associated with Brexit - no major issues have been identified to date. If any potential issue is identified, it will be managed through the existing Medicine Shortages Framework.

Medicine shortages inevitably arise from time to time and are a feature of health systems around the world. The HPRA has an existing Medicine Shortages Framework in place to help prevent shortages from occurring and to reduce the impact of shortages on patients and healthcare professionals by co-ordinating the management of potential or actual shortages as they arise. This framework is already used to manage and address an average of 45 shortage notifications a month. There is no current shortage caused by Brexit.
The continued recognition, in Ireland of health care qualifications awarded by institutions in the UK.

The mutual recognition of qualifications has been considered in the context of the negotiations on the Withdrawal Agreement and on the Framework for the Future Relationship. Clearly an EU/UK agreement on the mutual recognition of qualifications, were that to be achieved, would address the issue in the best way possible.

The recognition of qualifications has been discussed as part of the engagement at official level between the UK and Ireland on the Common Travel Area and Associated Rights and Privileges for Irish and UK Citizens. Both the UK and Ireland are committed to ensuring measures are in place to allow for the recognition of qualifications within the parameters applying.

The UK has recently published its draft European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2018 which it is intended to enact in the case of a no-deal Brexit. This legislation will enable Irish qualifications to be recognised in the UK.

The Irish Health Professional Regulation bodies have been examining the mechanisms in place for the recognition of qualifications with the objective of ensuring efficient processes for recognition for those holding UK qualifications while ensuring that this is done in an objective and non-discriminatory way. The Irish bodies have been linking with their UK counterparts on this issue.
Ensuring official food controls are appropriately maintained.

The maintenance of food safety standards of food imports from the UK and the efficient flow of food through the ports is another issue which the Department is planning for. The withdrawal of the UK from the EU and its new status as a third country will have implications for the official food control system in Ireland. The Food Safety Authority of Ireland is the Central Competent Authority for official food controls; controls which are carried out by a range of ‘official agencies’. This includes the HSE’s Environmental Health Service which is largely responsible for foods of non-animal origin and the Department of Agriculture, Food & the Marine which is responsible for foods of animal origin and plants. Challenges ahead in this area include import and export issues as well as potential divergence with EU law over the longer term.

The importation of food is subject to EU legislation. Additional resources have been provided to conduct the appropriate checks where Ireland is the first point of entry to the EU. Preparations are also underway in the event that the UK should decide to require export certificates for certain food products.

To facilitate these preparations the Department is working closely with the relevant Agencies and has approved additional resources for Environmental Health Service staff, the Public Analyst Laboratory and the Food Safety Authority of Ireland.
It is also working with the Environmental Health Service, the Department of Agriculture, Food and the Marine, Revenue and OPW with regard to the infrastructure and traffic management requirements at Dublin Port, Dublin Airport and Rosslare Europort. The aim is to ensure that the appropriate food controls are conducted from a public health perspective while being cognisant of the implications on trade.

In conclusion, I wish to reiterate that the Department, Minister Harris and the relevant Agencies under the aegis of the Department, are fully engaged in Brexit planning to ensure, as far as is possible, that the health sector is prepared for any adverse impacts as a result of Brexit.

We recognise the valuable work of the Committee and I thank the members for the opportunity to be here today. I look forward to the views and questions of the members.