Tithe an Oireachtais
Houses of the Oireachtas

AN COMHCHOISTE UM SLÁINTE

An Dara Tuarascáil Eatramhach maidir leis na hImpleachtaí don Earnáil Sláinte in Éirinn de bharr an Ríocht Aontaithe do tharraingt siar as an Aontas Eorpach

Bealtaine 2019

JOINT COMMITTEE ON HEALTH

Second Interim Report on the Implications of the Withdrawal of the United Kingdom from the European Union for the Health Sector in Ireland

May 2019

[32H0026]

Contents

Chair's Foreword

Dr. Michael Harty T.D.
(Rural Independent Technical Group)

This is the Second Interim Report on the implications of the withdrawal of the United Kingdom from the European Union for the health sector in Ireland. The report provides an update on the preparation undertaken by the Department of Health and other associated bodies in mitigating the effects of the withdrawal on the health services of Ireland.

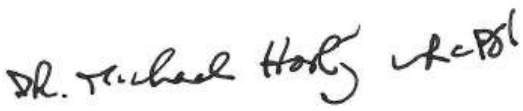
The United Kingdom's withdrawal from the European Union has generated much debate in the last couple of years. Such discussion and analysis primarily relate to political or economic consequences. However, the UK's departure will also have consequences for state bodies, health providers and citizens accessing health services throughout the country.

There are many health services which operate across the borders of Ireland and the United Kingdom. The framework for such co-operation is provided through international agreements, national legislation, service-level agreements, memorandums of understanding and other formal and informal arrangements. It is essential that these frameworks are re-examined and strengthened to ensure continuity of the services in the aftermath of the UK's withdrawal.

The Joint Committee on Health have now examined this topic on three occasions. The most recent meeting occurred on the 30 January 2019 and was attended by officials from the Department of Health and representatives of the Health Service Executive and the Health Products Regulatory Authority.

The Committee are reassured by the commitment and intensive efforts made by the Department and its associated bodies in preparing the health sector for the UK's exit from the European Union. The Committee also acknowledges the close collaboration between public and private health sector stakeholders. The Committee welcomes the co-operation between the various bodies associated with the health sector in the United Kingdom and their reassurance and commitment in continuing access to health services across both jurisdictions.

The United Kingdom's withdrawal from the European Union is an unprecedented event that brings many unique challenges. The Committee are cognisant that challenges remain and that many further matters may arise. The Committee considers that the best approach to confront these challenges is through continued co-operation and understanding of all stakeholders. The objective of these preparations is to ensure the continued access of health services throughout Ireland, including those services that operate across borders.



_____

Dr. Michael Harty, T.D.
Chair
Joint Committee on Health
29 May 2019

Executive Summary

On 23 June 2016, the United Kingdom voted by referendum to withdraw from the European Union. On 29 March 2017, the United Kingdom invoked Article 50 of the Treaty of European Union, which formally notified the European Commission of its intention to withdraw from the EU. This action also set a two year deadline for the UK and the EU to negotiate a withdrawal agreement by 29 March 2019.

However, the terms of the withdrawal remain ambiguous. The United Kingdom and the European Union have undertaken two years of negotiations but are yet to formally sign off on a withdrawal agreement. The date of the UK's withdrawal has been extended until 31 October 2019 and the final withdrawal agreement remains unresolved.

This uncertainty has presented a complex environment for health service providers. There are several potential scenarios which may occur following the UK's withdrawal and each scenario presents a unique challenge to the health sector. It is, therefore, necessary to plan for and mitigate against these risks.

This report is the second interim report of the Oireachtas Joint Committee on Health. The purpose of the report is to further examine the implications of the UK's withdrawal on the health sector in Ireland and to assess the preparation undertaken by the Department.

The Oireachtas Joint Committee on Health met with officials from the Department of Health, representatives of the Health Service Executive (HSE) and representatives of the Health Products Regulatory Authority (HRPA) on 30 January 2019. The Committee have also discussed the topic at previous meetings on February 2018 and March 2017.

The Committee was informed of the work undertaken by the Department and its associated bodies to mitigate against the potential effects of the UK's withdrawal from the EU. Much of this work involves co-operation with the United Kingdom and, in particular, with the health sector of Northern Ireland.

There are a number of specific areas within the Irish health sector which will be particularly vulnerable in the aftermath of the UK's withdrawal from the European Union. Firstly, there is a risk to citizens accessing cross-border health services. Many citizens from Ireland and the UK have benefited from their ability to access health services across jurisdictions.

It is required that sufficient provisions are made to ensure the continuity of access for individuals from both jurisdictions.

Secondly, there is a risk to medical supplies that originate from or transition through the United Kingdom to Ireland. A number of imports from the UK into Ireland are likely to be subject to custom checks. These inspections may result in delivery delays and medicines with a short-shelf life, refrigerated medicines and those which are critical to public health are particularly vulnerable.

Thirdly, there are a number of consequences should the United Kingdom diverge from EU regulations and standards. This may affect a number of areas such as regulatory activities, recognition of qualifications and food controls.

The Department of Health reassured the Committee "that there are no immediate risks to the health of the population because of Brexit". There has been intensive discussion and analysis to identify and understand these risks. There has also been significant preparation by the Department to abate these risks in the aftermath of the UK's withdrawal.

However, there are still a number of ongoing potential risks that require continuous monitoring. As such, the health sector must remain vigilant of the dynamic environment in which the withdrawal agreement is being undertaken and the potential fallout from some of the agreement.

In the report, the Committee makes a number of recommendations which are intended to further assist the Department's preparations and to highlight areas of particular risk. The Committee has a deep interest in the continuing of health services in Ireland, including those operating across borders.

Observations and Conclusions

1. The Committee welcomes the enactment of legislation that will establish the necessary provisions to facilitate continued access for Irish citizens to health services in the United Kingdoms and Ireland, following the United Kingdom's withdrawal from the European Union.
2. The Committee acknowledges the provisions of the Common Travel Area and in particular the rights of citizens in the Ireland and the United Kingdom to move live, travel, work and study freely within the CTA. The Committee also specifically notes that citizens can enjoy the right to access healthcare in both jurisdictions and that the rights of citizens under the Common Travel Area agreement are not dependent on the European Union or the continuing EU membership of the United Kingdom or Ireland.
3. The Committee supports the work of the Department and its associated bodies in ensuring that the UK's withdrawal from the European Union does not negatively impact upon the rights established by the Common Travel Area agreement.
4. The Committee acknowledges the importance of the Cross Border Directive and the Treatment Abroad Scheme in providing for access to health services in both jurisdictions. The Committee commends the work undertaken by the Department of Health and its associated bodies with their attempts to ensure the continuity of the Schemes.
5. The Committee strongly advocates for the continuation of services provided for under the Cooperation and Working Together (CAWT) scheme. The Committee is cognisant of the value that the CAWT provides to cross-border health services and to citizens in both Ireland and the United Kingdom.
6. The Committee acknowledges the increasingly significant role in which biological agents are utilised by consultants to control a variety of symptoms. Consequently, the Committee recommends that biological agents be considered as a critical medicine and that significant efforts be made to ensure that the United Kingdom's withdrawal from the European Union does not negatively impact the supply and access of biological agents across the Irish health sector.
7. The Committee welcomes the Department's reassurances that there are no expected disruptions with regard to vaccinations. However, the Committee recommends that further consideration be given to travel vaccinations to ensure that effective supply

chains are not contingent on the UK's status following its withdrawal from the EU.

8. The Committee is cognisant that any future deviation by the UK from EU regulations and standards will cause difficulties with a number of activities including marketing authorisation and labelling. The Committee recommends that specific attention is given to this area and that contingency planning is continuously undertaken to mitigate the effects of such an event.
9. The Committee recognises the benefits of the mutual recognition of health professional qualifications between Ireland and the UK. The Committee recommends that arrangements are provided for to ensure the continuity of this practice in the aftermath of the UK's withdrawal from the EU.
10. The Committee recommends that the Department and its associated bodies develop measures to provide for the availability of appropriate food controls, in the event that the United Kingdom withdraws from the European Union without ratifying a withdrawal agreement. The Committee is supportive of the Department's aims to ensure that appropriate food controls are conducted from a public health perspective, while being cognisant of the implications for trade.
11. The Committee recommends that communication relating to the UK's withdrawal from the EU and its effects on the Irish health sector is regular, consistent and appropriate. The Committee also recommends that all health service providers should receive adequate support to ensure that they can effectively advise patients.
12. The Committee acknowledges that General Practitioners, pharmacists and other front-line health providers have an important role in informing the public on the potential health sector implications following United Kingdom's withdrawal from the European Union. However, the Committee recommends that responsibility should remain with the Department of Health and the Health Service Executive.

1. Background

The likely withdrawal of the United Kingdom from the European Union will impact all Members States of the European Union. However, there will be a significant bearing on Ireland that will affect a wide range of social, economic and legislative factors.

The health sector must also confront a number of specific challenges. Over the last two years the Department of Health has worked closely with other state bodies, such as the Department of Foreign Affairs and the Office of the Taoiseach, in order to identify, prepare and mitigate against any such risks.

Irish state bodies, including the Health Service Executive, the Health Products Regulatory Authority (HPRA) and the Food Safety Authority of Ireland (FSAI) have also collaborated with the UK Department of Health and its associated bodies, to ensure continued access to health products and services across jurisdictions.

In May 2017, this Committee published its first interim report[1] following a meeting with the Department of Health and the Health Service Executive. In the report, the Committee made a number of recommendations which advised further consideration in a number of key areas.

On 24 January 2018, the Committee met again with officials who provided an update as to their response to the recommendations as outlined in the Committee's first interim report.

On 30 January 2019, the Committee held a further meeting as the final stages of the UK's withdrawal were being negotiated. The officials provided further detail as to their preparations and of emerging challenges.

This report provides an update on the meeting of the 30 January 2019.

[1] https://data.oireachtas.ie/ie/oireachtas/committee/dail/32/joint_committee_on_health/reports/2017/2017-05-25_report-on-the-implications-of-the-withdrawal-of-the-united-kingdom-from-the-european-union-for-the-health-sector-in-ireland_en.pdf

2. Legislation

The officials from the Department of Health informed the Committee that both 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.

In preparation of the UK's exit from the European Union, the Government has prepared the General Scheme of the Miscellaneous Provisions (Withdrawal of the United Kingdom from the European Union on 29 March 2019) Bill 2019[2]. The Bill will be enacted in the event that the United Kingdom leaves the European Union without a withdrawal agreement. Part 2 of the Bill considers Health Sector arrangements.

The draft heads of the proposed legislation seek to put in place an appropriate legal framework in Ireland to ensure the continuation of the Common Travel Area arrangement.

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, where treatments are not provided under our own healthcare systems or for an Irish person who becomes ill while on a visit to the UK and needs immediate health care there.[3]

The legislation also makes provision to preserve existing eligibility for healthcare in Ireland for a range of different cohorts of people including UK pensioners residing in Ireland, frontier workers and UK residents on a temporary visit to Ireland.[4]

1. The Committee welcomes the enactment of legislation that will establish the necessary provisions to facilitate continued access for Irish citizens to health services in the United Kingdom and Ireland, following the United Kingdom's withdrawal from the European Union.

[2] https://www.dfa.ie/media/dfa/eu/brexit/brexitnegotations/General-Scheme-of-Miscellaneous-Provisions.pdf
[3] IBID, Part 2, Section A, Head 5
[4] IBID, Part 2, Section A, Head 2

3. Usage by residents of Ireland of health services in the United Kingdom within Specific Schemes

One of the main challenges to the health sector, following the UK's relinquishing of its EU membership, is the provision of continued access to cross-border health services. Currently, there are a number of agreements and schemes which enable people from Ireland and the UK to access health services across the border.

The provisions required to ensure the continuation of the services will be mainly governed by service-level agreements although the Bill[5] includes provisions to ensure continuity of the cross border directive[6].

3.1 Common Travel Area

The Common Travel Area (CTA) agreement gives citizens of Ireland and the UK the right to live, travel, work and study freely throughout the Common Travel Area. Consequently, Irish and UK citizens can live in either country and enjoy associated rights and privileges, including access to healthcare.

The CTA is not dependent on the European Union or the continuing EU membership of the UK or Ireland. As such, the withdrawal of the UK from the EU should not curtail the freedom of movement between jurisdictions. However, some additional provisions are included in the General Scheme of the Miscellaneous Provisions (Withdrawal of the United Kingdom from the European Union) Bill 2019 to ensure continuity of healthcare access.

3.2 Cross Border Directive

The Cross Border Directive allows for treatment which can be received at home to be reimbursed, should a patient opt to receive it in another EU member state.

Officials from the Department told the Committee that they have agreed key principles with the UK to maintain bilateral health care co-operation. The proposed legislation will continue to allow Irish citizens obtaining healthcare in the UK to be reimbursed.

3.3 Treatment Abroad Scheme

The Treatment Abroad Scheme sets out to provide access to treatment in another EU/ EEA member state. The Scheme also provides for the cost of approved treatment in another EU

[5] General Scheme of the Miscellaneous Provisions (Withdrawal of the United Kingdom from the European Union on 29 March 2019) Bill 2019
[6] IBID, Part 2, Section A, Head 5

member state. In the context of UK, the scheme covers health services which are not available in Ireland and provides for Irish citizens to access healthcare in the UK.

Officials from the Department detailed to the Committee that the Treatment Abroad Scheme has created a close network between Ireland and the UK. Ireland has developed specialist links with the UK and Irish patients benefit in accessing such specialist services. Officials told the Committee that the UK is also keen to allow access for Irish patients to their services.

> "It is to their advantage that we form part of the catchment area for very highly specialist care and that we are able to feed in our patients to give them a critical mass of treatment within these islands. If they were to lose some of that critical mass it would undermine their services. They want to continue that relationship with us not only for altruistic reasons, which are very important, but also for the reputation of their units."

3.4 Cooperation And Working Together (CAWT)

Cooperation and Working Together (CAWT) is a partnership between the Health and Social Care Services in Northern Ireland and Republic of Ireland, which facilitates cross border collaborative working in health and social care. The scheme was established under the Ballyconnell agreement[7] in 1992 and is largely financed by European INTERREG funding.

Programmes and services provided by CAWT include GP out of hours services, acute services[8] and emergency services[9].

The representatives of the HSE confirmed that INTERREG funding for CAWT has been agreed up to 2021. Representatives also confirmed that both the UK and Ireland are committed in continuing this co-operation and that there is a recognition in Brussels of the importance of CAWT funds.

Representatives from the HSE told the Committee that

> "the focus of mitigation measures relating to continuity of care is on ensuring that service level agreements and memoranda of understanding are in place where necessary. This applies to specific services such as emergency cross-Border arrangements, cardiac and cancer services, treatment abroad placements and CAWT arrangements."

[7] http://www.cawt.com/wp-content/uploads/2018/02/The-Ballyconnell-Agreement-page-1.pdf
[8] http://www.cawt.com/projects/eu-interreg-va-programme-2014-2020/acute-hospital-services/
[9] http://www.cawt.com/projects/emergency-planning/

The representatives added that the national ambulance services in Northern Ireland and Ireland are liaising closely to ensure service continuity and agreement with regard to operating procedures. There are two key memorandum of understanding which provide for:

- the provision of assistance in the management and resourcing of emergency and urgent calls.
- mutual aid for declared major incidents.

2. The Committee acknowledges the provisions of the Common Travel Area and in particular the rights of citizens in the Ireland and the United Kingdom to move live, travel, work and study freely within the CTA. The Committee also specifically notes that citizens can enjoy the right to access healthcare in both jurisdictions and that the rights of citizens under the Common Travel Area agreement are not dependent on the European Union or the continuing EU membership of the United Kingdom or Ireland.
3. The Committee supports the work of the Department and its associated bodies in ensuring that the UK's withdrawal from the European Union does not negatively impact upon the rights established by the Common Travel Area agreement.
4. The Committee acknowledges the importance of the Cross Border Directive and the Treatment Abroad Scheme in providing for access to health services in both jurisdictions. The Committee commends the work undertaken by the Department of Health and its associated bodies with their attempts to ensure the continuity of the Schemes.
5. The Committee strongly advocates for the continuation of services provided for under the Cooperation and Working Together (CAWT) scheme. The Committee is cognisant of the value that the CAWT provides to cross-border health services and to citizens in both Ireland and the United Kingdom.

4. Medical Supplies

4.1 Importation of Medicines

In the aftermath of the UK's exit from the European Union, the UK will be considered as a third country. This status will have implications for goods entering into Ireland from the UK. Consequently, the importation of medicines requires special consideration, given its critical nature.

Officials told the Committee that up to 70% of medicines on the Irish market are manufactured in the UK or transit through the UK. The Committee were informed that there are approximately 11,000 pharmacies in Ireland which take, on average, 11 deliveries per week.

Specific UK imports will be liable for custom checks and these inspections have potential to delay deliveries. Medicines with a short shelf-life and refrigerated medicines are of particular risk.

Officials from the Department added that, as an additional safeguard, special consideration be given to categories of medicines which are considered most essential to public health. An expert group has been established to examine these categories of medicines and, where the supply chain indicates a risk of potential issues, are working with suppliers to verify that robust contingencies are in place.

The officials also detailed the work that had been undertaken in modifying supply chains and revising regulatory pathways to guard against disruption. There has been specific preparations to ensure continuity of health services and supply of medical products in the event of a no-deal withdrawal. The Department and its agencies are continuing to work closely with the pharmaceutical industry, to anticipate, in so far as is possible, potential vulnerabilities, risk assess these vulnerabilities and devise contingencies in order to minimise and address any risks to continuity of supply of medicines.

In summarising, officials stated that there has been no major supply issues identified through the preparedness and contingencies planning exercises.

4.2 Access to Medicine

Medicine Shortages

The Committee has observed numerous media reports in the UK which have highlighted the risk of medicine shortages in the immediate aftermath of the UK's exit from the EU. However, officials from the Department of Health reassured the Committee that Ireland is unlikely to face serious general medicines supply issues in the period immediately after the UK's withdrawal from the EU. There are a number of reasons for this.

- Additional stocks of medicines are already routinely built into the Irish medicine supply chain. Ireland utilises a different wholesaling model than that which operates in the UK. As a result, the HSE holds between 6-8 weeks of additional medicine stock.
- The pharmaceutical industry and wholesalers have provided assurance that they are confident that they will have sufficient stock to bridge any initial issues at ports, should they occur. Additional stock held by pharmaceutical companies in addition to stock held by the HSE, gives approximately a six-month supply of medicine.

Officials also advised that there was 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 of medicines for other patients.

The Committee noted the importance of the Department providing regular public information regarding this advice but also note the Departments concerns that increasing the publicity of such advice may have the contrary effect of increasing the numbers seeking additional prescriptions.

The Committee recognised that some individuals may wish to increase their stock of medicine regardless of advice and that the Department should be prepared should this situation actively deplete stocks. The Committee noted that strategies such as restricting prescriptions to a set limit could be considered in such an event.

The HPRA and HSE have requested that companies highlight any issues regarding the availability of specific products in the aftermath of the UK's withdrawal. Representatives of the HSE added that no major issues have been identified to date and any issues are managed through Medicines Shortages Framework.

The risk of medicine shortages are not particularly uncommon and an established framework is in place to manage such situations. There are, on average, approximately 45 such

potential shortages per month, however, fewer than 50% will develop a supply shortage. The representatives of the HSE reassured the Committee that such scenarios are always managed effectively and that there has yet to be a case of any patient being left without treatment for a particular condition.

Generic Medicine

Representatives of the HRPA alerted to the Committee that there is potential for future issues with generic medicines following the UK withdrawal from the EU. If there are divergence of standards between the EU and UK, further documentation may be required for generic medicines. Representatives of the HRPA told the Committee that they do not anticipate that there will be a major impact in the aftermath but that there may be, over time, a rationalisation by the industry of portfolios of medicines that are supplied into the Irish market. This may, potentially, impact upon the supply of generic medicines to the Irish market or result in an increase in the cost of generic medicine.

Biological Agents

The Committee noted the importance of biological agents which are increasingly used by consultants in order to initially control patient's symptoms. Consequently, the Committee is of the opinion that such medicines should also be considered as critical and monitored carefully by the Department and the HSE.

6. The Committee acknowledges the increasingly significant role in which biological agents are utilised by consultants to control a variety of symptoms. Consequently, the Committee recommends that biological agents be considered as a critical medicine and that significant efforts be made to ensure that the United Kingdom's withdrawal from the European Union does not negatively impact the supply and access of biological agents across the Irish health sector.

4.3 Vaccines

The officials from the Department reassured the Committee that there was no expected disruptions with regard to vaccines. They also noted that population health colleagues have tested supply chains for all immunisation programmes and that most vaccines imported to Ireland come directly to Ireland from Europe and do not transit through the UK.

The Committee queried whether travel vaccines would be impacted in any way and recommended that further examination is undertaken to ensure that no disruption occurs with regard to these medicines.

7. The Committee welcomes the Department's reassurances that there are no expected disruptions with regard to vaccinations. However, the Committee recommends that further consideration be given to travel vaccinations to ensure that effective supply chains are not contingent on the UK's status following its withdrawal from the EU.

5. Other Regulatory Activities and Labelling

The United Kingdom, as a EU member state, maintains the health standard and regulations of other EU states in a number of health service activities. The UK is expected to continue to utilise these standards after its withdrawal from the EU and representatives of the HRPA noted that it would contrary to the UK's interest to deviate from EU regulations and standards, as this would impact upon UK products accessing the EU market. They also noted that the UK has reaffirmed its intention to remain aligned within EU law.

However, the Department must be cognisant to the potential of any divergence of these standards and regulation with regard to a number of particular activities.

Regulatory Activities

Most marketing authorisations are authorised through the UK where the qualified person (QP) is domiciled in the UK. Representatives of the HPRA noted that work has been intensive in this area over the last two years and that the vast majority of companies have worked to transfer such activities into the other 27 EU member states. Accordingly, there are no current concerns regarding QPs.

Labelling

The HRPA have also examined potential issues with regard to joint labelling of medicines. Approximately 60% of medicines supplied in Ireland utilise joint labels with the UK. The HRPA confirmed that they would remain vigilant of this situation and that Ireland has discussed alternative labelling arrangements with other EU members and in particular with Scandinavian countries, should such a situation arise.

8. The Committee is cognisant that any future deviation by the UK from EU regulations and standards will cause difficulties with a number of activities including marketing authorisation and labelling. The Committee recommends that specific attention is given to this area and that contingency planning is continuously undertaken to mitigate the effects of such an event.

6. Recognition of Qualifications

Numerous health professionals from Ireland and the UK have studied and worked across both jurisdictions. This practice is facilitated by the mutual recognition of qualifications awarded in the UK and Ireland. However, any future divergence of UK standards and regulations in the aftermath of their withdrawal from the EU has potential to greatly curtail this practice.

In the short-term, there are no expected variance of alignments. 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. 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 draft regulations, which it intends to enact in the case of a no-deal Brexit. This legislation will enable Irish qualifications to be recognised in the UK.

In response, Irish health regulatory 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.

Officials from the Department stated that the Medical Council will be responsible for the recognition of qualifications, with other specific bodies, such as the Nursing and Midwifery Board of Ireland (NMBI) and CORU, responsible for recognising qualifications relating to their professions.

9. The Committee recognises the benefits of the mutual recognition of health professional qualifications between Ireland and the UK. The Committee recommends that arrangements are provided for to ensure the continuity of this practice in the aftermath of the UK's withdrawal from the EU.

7. Food controls

Additional food controls will be required on imports from the United Kingdom following its withdrawal from the European Union.

The Food Safety Authority is the central authority for official food controls. The Department of Health is largely responsible for the maintenance of safety standards for food imports of a non-animal origin from the UK and the Department of Agriculture, Food and Marine responsible for foods of animal origin.

Food controls of a non-animal origin from the UK will be managed specifically by the HSE environmental health service. The HSE has had an additional €6 million allocated to provide for an additional 61 additional environmental health officers.

Representatives of the HSE informed the Committee that preparations are ongoing. Arrangements are already in place for imports from third countries. Following the UK's withdrawal from the EU, many imports arriving in Dublin will do so as the first port of entry to the EU. This will require environmental health service personnel to go through products to ensure they are acceptable for supply to the Irish market. This will be done so on a risk basis, so that not every product will need to be examined.

The preparation of further food controls for UK imports has involved collaboration of a number of state bodies and agencies including the Department of Agriculture, Food and the Marine, the Revenue Commissioners and the Office of Public Works, OPW, with regard to the infrastructure and traffic management requirements at Dublin Port, Dublin Airport and Rosslare Europort. Officials from the Department conveyed to the Committee that the aim is to ensure that the appropriate food controls are conducted from a public health perspective, while being cognisant of the implications for trade.

10. The Committee recommends that the Department and its associated bodies develop measures to provide for the availability of appropriate food controls, in the event that the United Kingdom withdraws from the European Union without ratifying a withdrawal agreement. The Committee is supportive of the Department's aims to ensure that appropriate food controls are conducted from a public health perspective, while being cognisant of the implications for trade.

8. Communication

Officials from the Department of Health told the Committee that "an inter-agency communications group, chaired by the Department, had 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 number of items were highlighted as important with regard to communications. For example, officials from the Department noted that Ireland was unlikely to face serious general medical supply issues in the aftermath of the UK's withdrawal from the UK as additional stocks were available from both the HSE and pharmaceutical industry and wholesalers. The officials from the Department advised that there is no need for hospitals, pharmacists or patients to order extra quantities of medicines as doing so could disrupt existing stock levels of medicines for other patients. However, the officials voiced concern that increasing publicity of this advice may inadvertently increase demand for medicines.

The Committee are aware that many patients have already requested additional prescriptions. The Committee do not want General Practitioners, pharmacists and other front-line health service providers to be left with the responsibility for informing the public of this information.

The Committee is aware that the Department is actively considering their communications strategy and further information would be sent to GPs, pharmacists and other front-line workers to ensure that the correct information was available to them. The Committee recommends that this communication is regular, consistent and effective and that all health service providers should receive the appropriate support to ensure that they can advise patients. The Committee acknowledges that General Practitioners, pharmacists and other front-line health providers have an important role in supplying such information but that responsibility should remain with the Department of Health.

11. The Committee recommends that communication relating to the UK's withdrawal from the EU and its effects on the Irish health sector is regular, consistent and appropriate. The Committee also recommends that all health service providers should receive adequate support to ensure that they can effectively advise patients.

12. The Committee acknowledges that General Practitioners, pharmacists and other front-line health providers have an important role in informing the public on the potential health sector implications following the United Kingdom's withdrawal from the European Union. However, the Committee recommends that responsibility should remain with the Department of Health and the Health Service Executive.

Appendices

Appendix 1: Membership of the Joint Committee on Health

Deputies:

- Stephen Donnelly (Fianna Fáil)
- Bernard Durkan (Fine Gael)
- Dr. Michael Harty [Chairman] (Rural Independent Technical Group)
- Alan Kelly (Labour)
- Kate O'Connell (Fine Gael)
- Margaret Murphy O'Mahony (Fianna Fáil)
- Louise O'Reilly (Sinn Féin)

Senators:

- Colm Burke (Fine Gael)
- John Dolan (Civil Engagement Technical Group)
- Rónán Mullen (Independent)
- Dr. Keith Swanick (Fianna Fáil)

Appendix 2: Stakeholders and Transcripts

Stakeholders

The Joint Committee on Health held a hearing on 30 January 2019 to engage with relevant stakeholders to discuss the Implications of the Withdrawal of the United Kingdom from the European Union for the health sector in Ireland. The table below identifies all stakeholders who attended the Committee.

- Mr. Jim Breslin - Secretary General, Department of Health
- Mr. Fergal Goodman – Assist Secretary, Department of Health
- Mr. Kieran Smyth – Principal Officer, International Unit, Department of Health

- Mr. John Hennessy - National Director, Acute Strategy and Planning, HSE
- Ms. Paula Keon -Assistant National Director, EU & North/South Unit, HSE
- Mr. John Swords - National Director for Procurement, HSE

- Dr. Lorraine Nolan - Chief Executive, Health Products Regulatory Authority
- Ms. Rita Purcell - Deputy CEO, Health Products Regulatory Authority
- Dr. Caitríona Fisher - Health Products Regulatory Authority

Transcripts

The transcript of the meeting on the 30 January 2019 is available online[10].

The opening statement of the Department of Health[11] and the Health Service Executive[12] are also available online.

[10] https://data.oireachtas.ie/ie/oireachtas/debateRecord/joint_committee_on_health/2019-01-30/debate/mul@/main.pdf

[11] https://data.oireachtas.ie/ie/oireachtas/committee/dail/32/joint_committee_on_health/submissions/2019/2019-01-30_opening-statement-jim-breslin-secretary-general-department-of-health_en.pdf

[12] https://data.oireachtas.ie/ie/oireachtas/committee/dail/32/joint_committee_on_health/submissions/2019/2019-01-30_opening-statement-john-hennessy-national-director-acute-strategy-and-planning-hse_en.pdf

Appendix 3: Terms of Reference of Committee

A*)* Functions of the Committee [derived from Standing Orders – DSO 84A and SSO 70A]

(1) The Committee shall consider and report to the relevant House(s) on-

(*a*) such aspects of the expenditure, administration and policy of a Government Department or Departments and associated public bodies as the Committee may select, and

(*b*) European Union matters within the remit of the relevant Department or Departments.

(2) The Select Committee appointed by Dáil Éireann is joined with a Select Committee appointed by Seanad Éireann (to form a Joint Committee) for the purposes of the functions set out in this Standing Order, other than at paragraph (3), and to report thereon to both Houses of the Oireachtas.

(3) Without prejudice to the generality of paragraph (1), the Select Committee shall consider, in respect of the relevant Department or Departments, such—

(*a*) Bills,

(*b*) proposals contained in any motion, including any motion within the meaning of DSO 187,

(*c*) Estimates for Public Services, and

(*d*) other matters

as shall be referred to the Select Committee by the Dáil, and

(*e*) Annual Output Statements including performance, efficiency and effectiveness in the use of public moneys, and

(*f*) such Value for Money and Policy Reviews as the Select Committee may select.

(4) Without prejudice to the generality of paragraph (1), the Joint Committee may consider the following matters in respect of the relevant Department or Departments and associated public bodies:

(*a*) matters of policy and governance for which the Minister is officially responsible,

(*b*) public affairs administered by the Department,

(*c*) policy issues arising from Value for Money and Policy Reviews conducted or commissioned by the Department,

(*d*) Government policy and governance in respect of bodies under the aegis of the Department,

(*e*) policy and governance issues concerning bodies which are partly or wholly funded by the State or which are established or appointed by a member of the Government or the Oireachtas,

(*f*) the general scheme or draft heads of any Bill

(*g*) any post-enactment report laid before either House or both Houses by a member of the Government or Minister of State on any Bill enacted by the Houses of the Oireachtas,

(*h*) statutory instruments, including those laid or laid in draft before either House or both Houses and those made under the European Communities Acts 1972 to 2009,

(*i*) strategy statements laid before either or both Houses of the Oireachtas pursuant to the Public Service Management Act 1997,

(*j*) annual reports or annual reports and accounts, required by law, and laid before either or both Houses of the Oireachtas, of the Department or bodies referred to in subparagraphs (*d*) and (*e*) and the overall performance and operational results, statements of strategy and corporate plans of such bodies, and

(*k*) such other matters as may be referred to it by the Dáil from time to time.

(5) Without prejudice to the generality of paragraph (1), the Joint Committee shall consider, in respect of the relevant Department or Departments—

(*a*) EU draft legislative acts standing referred to the Committee under DSO 114 and SSO 107, including the compliance of such acts with the principle of subsidiarity,

(*b*) other proposals for EU legislation and related policy issues, including programmes and guidelines prepared by the European Commission as a basis of possible legislative action,

(*c*) non-legislative documents published by any EU institution in relation to EU policy matters, and

(*d*) matters listed for consideration on the agenda for meetings of the relevant EU Council of Ministers and the outcome of such meetings.

(6) Where the Select Committee appointed by Dáil Éireann has been joined with a Select Committee appointed by Seanad Éireann, the Chairman of the Dáil Select Committee shall also be the Chairman of the Joint Committee.

(7) The following may attend meetings of the Joint Committee, for the purposes of the functions set out in paragraph (5) and may take part in proceedings without having a right to vote or to move motions and amendments:

(*a*) members of the European Parliament elected from constituencies in Ireland, including Northern Ireland,

(*b*) members of the Irish delegation to the Parliamentary Assembly of the Council of Europe, and

(*c*) at the invitation of the Committee, other members of the European Parliament.

(8) The Joint Committee may, in respect of any Ombudsman charged with oversight of public services within the policy remit of the relevant Department or Departments, consider—

(*a*) such motions relating to the appointment of an Ombudsman as may be referred to the Committee, and

(*b*) such Ombudsman reports laid before either or both Houses of the Oireachtas as the Committee may select: Provided that the provisions of DSO 111F apply where the Committee has not considered the Ombudsman report, or a portion or portions thereof, within two months (excluding Christmas, Easter or summer recess periods) of the report being laid before either or both Houses of the Oireachtas.

B) Powers of the Committee [derived from Standing Orders – DSO 85, 114 and 116 and SSO 71, 107 and 109]

The Joint Committee has:-

(1) power to take oral and written evidence and to print and publish from time to time minutes of such evidence taken in public before the Committee together with such related documents as the Committee thinks fit;

(2) power to invite and accept oral presentations and written submissions from interested persons or bodies;

(3) power to appoint sub-Committees and to refer to such sub-Committees any matter comprehended by its orders of reference and to delegate any of its powers to such sub-Committees, including power to report directly to the Dáil and to the Seanad;

(4) power to draft recommendations for legislative change and for new legislation;

(4A) power to examine any statutory instrument, including those laid or laid in draft before either House or both Houses and those made under the European Communities Acts 1972 to 2009, and to recommend, where it considers that such action is warranted, whether the instrument should be annulled or amended;

(4B) for the purposes of paragraph (4A), power to require any Government Department or instrument-making authority concerned to submit a Memorandum to the Committee explaining any statutory instrument under consideration or to attend a meeting of the Committee for the purpose of explaining any such statutory instrument: Provided that such Department or authority may decline to attend for stated reasons given in writing to the Committee, which may report thereon to the Dáil;

(5) power to require that a member of the Government or Minister of State shall attend before the Committee to discuss policy for which he or she is officially responsible: Provided that a member of the Government or Minister of State may decline to attend for stated reasons given in writing to the Committee, which may report thereon to the Dáil and Seanad: and provided further that a member of the Government or Minister of State may request to attend a meeting of the Committee to enable him or her to discuss such policy;

(6) power to require that a member of the Government or Minister of State shall attend before the Committee to discuss proposed primary or secondary legislation (prior to

such legislation being published) for which he or she is officially responsible: Provided that a member of the Government or Minister of State may decline to attend for stated reasons given in writing to the Committee, which may report thereon to the Dáil and Seanad: and provided further that a member of the Government or Minister of State may request to attend a meeting of the Committee to enable him or her to discuss such proposed legislation;

(6A) power to require that a member of the Government or Minister of State shall attend before the Committee and provide, in private session if so requested by the member of the Government or Minister of State, oral briefings in advance of meetings of the relevant EU Council of Ministers to enable the Committee to make known its views: Provided that the Committee may also require such attendance following such meetings;

(6B) power to require that the Chairperson designate of a body or agency under the aegis of a Department shall, prior to his or her appointment, attend before the Committee to discuss his or her strategic priorities for the role;

(6C) power to require that a member of the Government or Minister of State who is officially responsible for the implementation of an Act shall attend before a Committee in relation to the consideration of a report under DSO 164A and SSO 157A;

(7) subject to any constraints otherwise prescribed by law, power to require that principal office-holders in bodies in the State which are partly or wholly funded by the State or which are established or appointed by members of the Government or by the Oireachtas shall attend meetings of the Committee, as appropriate, to discuss issues for which they are officially responsible: Provided that such an office-holder may decline to attend for stated reasons given in writing to the Committee, which may report thereon to the relevant House(s);

(8) power to engage, subject to the consent of the Houses of the Oireachtas Commission, the services of persons with specialist or technical knowledge, to assist it or any of its sub-Committees in considering particular matters; and

(9) power to undertake travel, subject to—

(*a*) such recommendations as may be made by the Working Group of Committee Chairmen under DSO 108(4)(*a*) and SSO 104(2) (*a)*; and

(b) the consent of the Houses of the Oireachtas Commission, and normal accounting *procedures.*

In accordance with Articles 6 and 8 of Protocol No. 2 to the Treaty on European Union and the Treaty on the Functioning of the European Union (*Protocol on the Application of the Principles of Subsidiarity and Proportionality*) as applied by sections 7(3) and 7(4) of the European Union Act 2009, the Committee has the power-

(a) to consider whether any act of an institution of the European Union infringes the principle of subsidiarity [DSO 116; SSO 109]; and

(b) to form a reasoned opinion that a draft legislative act (within the meaning of Article 3 of the said Protocol) does not comply with the principle of subsidiarity [DSO 114 and SSO 107].

C: **Scope and context of activities of the Committee**

In addition to the powers and functions that are given to Committees when they are established, all Oireachtas Committees must operate within the scope and context of activities in Dáil Standing Order 84 and Seanad Standing Order 70 as set out below.

- A Committee may only consider such matters, engage in such activities, exercise such powers and discharge such functions as are specifically authorised under its orders of reference and under Standing Orders;

- Such matters, activities, powers and functions shall be relevant to, and shall arise only in the context of, the preparation of a report to the relevant House(s).

- A Committee shall not consider any matter which is being considered, or of which notice has been given of a proposal to consider, by the Committee of Public Accounts pursuant to DSO 186 and/or the Comptroller and Auditor General (Amendment) Act 1993;

- A Committee shall not consider any matter which is being considered, or of which notice has been given of a proposal to consider, by the Joint Committee on Public Petitions in the exercise of its functions under DSO 111A(1); and

- A Committee shall refrain from inquiring into in public session or publishing confidential information regarding any matter if so requested, for stated reasons given in writing, by—

    (i) a member of the Government or a Minister of State, or

    (ii) the principal office-holder of a body under the aegis of a Department or which is partly or wholly funded by the State or established or appointed by a member of the Government or by the Oireachtas:

    Provided that the Chairman may appeal any such request made to the Ceann Comhairle, whose decision shall be final.