An Comhchoiste um Sláinte

Cion Polaitiúil maidir le
COM (2018) 51

Togra le haghaidh Rialachán ó Pharlaimint na hEorpa agus ón gComhairle maidir le measúnacht teicneolaíochta sláinte agus lena leasaítear Treoir 2011/24/AE

Aibreán 2018

Joint Committee on Health

Political Contribution on
COM (2018) 51

Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

April 2018

[32H019]

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1 Introduction

The Joint Committee on Health considers COM(2018)51: Proposal for a Regulation of the European Parliament and of the Council on Health Technology Assessment and Amending Directive 2011/24/EU to be significantly important to Ireland and the EU.

2 Scrutiny by the Joint Committee

The Joint Committee on Health (hereinafter referred to as "the Committee") scrutinised this proposal at two meetings on 21 March and 28 March 2018.

2.1 At its meeting of 21 March the Committee agreed that COM(2018)51 warranted further scrutiny and agreed to invite officials from the Department of Health to further discuss the technical aspects of the proposals. The Committee also agreed to invite representatives of the Health Information and Quality Authority (HIQA) and the National Centre for Pharmacoeconomics (NCPE) to discuss the impact of the proposal on Ireland's current assessment process.

2.2 The relevant witnesses attended the Committee meeting on 28 March. Following the Committee's consideration of these matters, it agreed that a Political Contribution be made.

3 Decision of the Joint Committee

3.1 At its meeting on 18 April the Committee agreed that a copy of this Political Contribution be forwarded to Mr Jean Claude-Juncker, President of the European Commission, Mr Antonio Tajani MEP, President of the European Parliament, and Mr Donald Tusk, President of the European Council. The Committee also agree to forward a copy to Mr Simon Harris T.D., Minister for Health.

3.2 The Joint Committee further agreed that, in the interests of inter-parliamentary cooperation on EU matters, a copy of this report be forwarded to the appropriate Committee in the National Parliament of each EU Member State and each of Ireland's MEPs.

4 Opinion of the Joint Committee

Having considered the proposal in detail, the Committee makes the following observations.

4.1 The Committee welcomes the proposal and supports the objectives of reducing duplication of efforts for Health Technology Assessment (HTA) bodies and industry, promoting convergence in HTA procedures and methodologies, and improving co-operation between Member States.

4.2 The Committee also supports the potential benefits of the proposal which include reduced costs for HTAs, increased efficiency and standardisation of HTA protocols. The Committee recommends that the standardisation of any methods and processes regarding HTAs must be to the highest quality and aligned to international best practice.

4.3 The Committee recommends that the Commission consider whether it will be mandatory for pharmaceutical companies to submit evidence as part of this assessment process. As much of the relevant clinical evidence is held by the companies, their participation in this assessment process is considered to be critical.

4.4 The Committee recommends further consideration of the coordination of the publication of the joint clinical assessments and the product launch date in Ireland. Product launches and reimbursement applications are often made in Ireland some time after receipt of EU marketing authorisation. Efficiency gains may be lost if a product launch is later than the date of marketing authorisation, and reassessment is required, due to the availability of new clinical evidence.

4.5 The Committee recommends that any joint assessment reports must be translated into all official languages of the European Union immediately to ensure that all efficiency gains are realised.

4.6 The Committee also recommends that the following aspects of the General Provisions of the proposal[1] are addressed or clarified before it enters into force:

a) **Article 5 (1)(c)**: the potential that in vitro diagnostic devices classified as class C can be added to the scope for joint clinical assessments as these technologies (including self-testing diagnostics) are becoming increasingly important;
b) **Article 6(2)**: in the case that a health technology developer refuses to comply with a request to submit information and documentation (relating to a health technology that is to undergo joint clinical assessment) the cause of action or next steps to be undertaken by the HTA;
c) **Article 7(1)** provides that the Commission shall publish joint clinical assessment reports where it considers that the report complies with the substantive and procedural requirements of the regulation. Any assessment of the substantive nature of a HTA report should be conducted by HTA agency experts.
d) **Article 7(2)** makes provision for notification to the Commission within 30 days of the completion of a HTA on a health technology that has been subject to a joint clinical assessment. Details of the outcome should be notified e.g. the recommendations of the national HTA and the investment decision taken should be specified;
e) **Article 21(1)** specifies that the Commission will publish the summary reports of all clinical assessments carried out as part of national HTAs outside the scope of the regulation, thereby facilitating access to work undertaken in other Member States. It is not clear if these summary reports will be subject to a quality assessment prior to publication, or indeed if they will be published into all official languages of the EU.

[1] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU, p 22-38

Meeting both these criteria would facilitate the re-use of information to Member States;

f) **Article 34 (3)** allows Member States to carry out a clinical assessment using means other than those set out in the regulation on the grounds of public health protection, following approval by the Commission, within three months of notification of intent by the Member State. This seems an unnecessarily long response time by the Commission in the context of the rare circumstance of a potential public health emergency.

5 Members of the Joint Committee on Health

Deputies:

Bernard Durkan (FG)
Michael Harty (RITG) **[Chair]**
Billy Kelleher (FF)
Alan Kelly (LAB)
Kate O'Connell (FG)
Margaret Murphy O'Mahony (FF)
Louise O'Reilly (SF) **[Vice-Chair]**

Senators:

Colm Burke (FG)
John Dolan (CETG)
Rónán Mullen (IND)
Keith Swanick (FF)

6 Orders of Reference of the Joint Committee on Health

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.