JOINT COMMITTEE ON HEALTH

Report on Scrutiny of the Medical Practitioners (Amendment) Bill 2017 (PMB)

February 2018
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1. Introduction

In accordance with Dáil Standing Orders 84a (3)(a) and 141, a Private Members Bill must be referred to the relevant Select Committee for detailed scrutiny following successful passage through the second stage. However, under Standing Order 141(3), a Joint Committee may instead undertake detailed scrutiny and report to both Houses, prior to Committee Stage consideration of the Bill by the Select Committee. In this instance the relevant Committee is the Joint Committee on Health. The Bill was referred to the Joint Committee on 19 October 2017 and detailed scrutiny took place on the 6 December 2017. The Bill does not require a money message.

2. Purpose of the Bill

The Medical Practitioners (Amendment) Bill 2017 (PMB) was taken for Second Stage in the Dáil on 28 March 2017. Introducing the Bill, the sponsor Mr. Billy Kelleher, T.D. stated:¹

“Its purpose is to make it a legislative requirement that there be a statutory declaration by consultants, clinicians and other medical practitioners who receive gifts or donations from pharmaceutical and other companies involved in the health care sector. These could include medical devices and other technologies. The purpose is to bring transparency...As we know, in the years ahead there will be major changes and advances in technologies and medicines, including fourth-generation medicines and orphan drugs. There will be a major increase in the State's requirement to fund these. Of course, with that comes a need to ensure full openness in how we assess and prescribe medicines across the health care sector...There needs to be full accountability and a proper register established whereby people who receive a gift or another service from a company would have to declare it on a statutory basis, as with Oireachtas Members and others.

A key objective of the Bill is to improve transparency between medical practitioners and commercial entities, such as medical equipment suppliers and pharmaceutical companies. In the USA and the EU, the push for greater transparency between healthcare workers and industry is driven by a concern that conflicts of interest may arise where gifts and/or income given to healthcare workers is not declared. In addition, medical practitioners and healthcare workers risk reputational damage in the event of any improper conduct.

The European Commission initiative on Ethics & Transparency in the pharmaceutical sector,\(^2\) led to a multi-stakeholders’ platform which resulted in a “List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector.”\(^3\) Section 3.3 of these Guidelines state:

“Transparency concerning relations between health professionals and companies is necessary in order to avoid any conflict of interest. Conflict of interest can be direct (e.g. employment with a company, consultancy for a company, strategic advisory role for a company, financial interests, ownership of a patent) or indirect (e.g. principal investigator, investigator, individual’s institution / organisation receiving a grant or other funding.”

\(^2\) European Commission. (Terms of reference (Platform on Ethics & Transparency).
\(^3\) EFPIA. (2016). European Federation of Pharmaceutical Industries and Associations (EFPIA) HCP/HCO Disclosure Transparency Requirements.
3. Procedural basis for Scrutiny

Private Members Bills referred to Select Committee are subject to the provisions of Standing Order 141(2) [Dáil] which provides that a Select Committee “shall undertake detailed scrutiny of the provisions of such Bills....and shall report thereon to the Dáil prior to Committee stage consideration....” unless the Committee decides in relation to a particular Bill that detailed scrutiny is not necessary.

Paragraph (3) of Standing Order 141 permits scrutiny of the Bill in Joint Committee, viz. “Nothing in this Standing Order shall preclude a Joint Committee from undertaking detailed scrutiny as set out in paragraph (2) and reporting thereon to both Houses prior to Committee Stage consideration of the Bill by the Select Committee.”
4. Detailed Scrutiny

The Joint Committee on Health undertook detailed scrutiny of the Medical Practitioners (Amendment) Bill 2017 on 06 December 2017\(^4\). The sponsor of the Bill, Mr. Billy Kelleher T.D., was accompanied by Dr. Jean O’Sullivan, consultant in emergency medicine at Tallaght hospital. Officials from the Department of Health were also present, to provide the Department’s views on the Bill.

The Committee are broadly supportive of Deputy Kelleher’s Bill. The Department affirmed that they and the Minister also agreed with the general principles of the Bill and stated that;

“the Bill gives the opportunity to address a gap in legislation which many other European States are also in the process of addressing”.

The following issues were highlighted during the Committee’s consideration of the Bill.

4.1 Requirement for statutory regulation

With the introduction of any new statutory regulation, the Committee considered if existing regulations are sufficient and whether or not the Code of the European Federation of Pharmaceutical Industries and Associations (EFPIA) disclosure code, combined with Medical Council guidelines, provides sufficient transparency between pharmaceutical/medical device companies and medical practitioners.

As stated by the Minister of State at the Department of Health, Ms. Catherine Byrne T.D., during the second stage debate of this legislation, the fact that individual healthcare professionals can avoid having their details published “does not provide transparency.”

The Committee noted that other countries have implemented similar legislation in an effort to improve transparency, while other countries have no regulation

beyond the EFPIA code. Where sunshine laws have been introduced they are relatively recent and evaluating their success is therefore difficult.

**Regulations currently in place in Ireland**

(i) **Medical Council Guidelines**

Section 62.3 of the Medical Council’s *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (2016), under Managing conflicts of interests, states:

> “You should not accept gifts (including hospitality) from pharmaceutical, medical devices or other commercial enterprises. This does not prevent you attending educational meetings or receiving payment of reasonable fees for professional services to commercial enterprises. You should be aware that even low-value promotional materials can influence prescribing and treatment decisions.”

The Medical Council state that this advice is given because:

> “…of the risk that the doctor’s professional judgement might be affected by accepting gifts or hospitality. Doctors have a professional obligation to obey the Medical Council’s guidance.”

(ii) **Code of the European Federation of Pharmaceutical Industries and Associations (EFPIA)**

The European Federation of Pharmaceutical Industries and Associations (EFPIA) require that member companies disclose individual transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations. The Irish Pharmaceutical Healthcare Association has adopted a transfers-of-value voluntary pharmaceutical code. Since 1 January 2016 this code obliges members to make publicly available information relating to donations, grants and sponsorships to healthcare organisations and healthcare professionals.

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6 EFPIA. (2014). *Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations.*
The Irish Pharmaceutical Healthcare Association (IPHA) considers the code to be “an appropriate” step in assuring the public that they can trust their doctor to administer care “based solely on clinical evidence.”

However, under data protection rules, individual healthcare professionals can avoid having their names disclosed, unless they consent. Without consent, only an aggregate figure for unnamed healthcare professionals will be disclosed. In Ireland 55% of healthcare professionals, that received payments from the pharmaceutical industry, consented to having their names listed in the database.

### 4.2 Scope of the Bill to go beyond medical practitioners

During the Committee’s scrutiny of the Bill it was suggested that the scope of the Bill could be broadened to include nurses, pharmacists and other health professionals. Another option which was put forward, is to include healthcare organisations within the scope of the legislation.

The officials from the Department believe that the scope of the Bill may be too narrow to achieve the overall objective of transparency, as it limits transparency to doctors only, while other health professionals are also involved.

### 4.3 Responsibility for populating the register

Under the Bill, as published, medical practitioners will have responsibility for reporting transfers of value to the Medical Council. An alternative option is for pharmaceutical and medical device companies to be given the responsibility for populating the register.

The Bill, if enacted, is likely to have resource implications for the Medical Council who will be charged with maintaining and publishing the register.

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7 Irish Pharmaceutical Healthcare Association (IPHA) - [ToV - your questions answered.](#)

8 Ibid.

9 [Irish Medical Times.](#) Higher consent over payments will emerge.
The legislation may also lead to more complaints. The internal mechanisms for dealing with such complaints will have to be considered.

4.4 Threshold for declarable income

In the Bill “declarable income” is defined as any money or other form of payment with a value of more than €600. There is some concern that this value will make it possible for companies to circumvent the legislation by making a number of smaller payments, if each was worth less than €600?

4.5 Definition of “gift”

Some Members also queried whether a gift, as defined in the Bill, should also cover the funding of a medical unit or personnel, or foreign travel.

The Bill defines a gift as:

“…any voluntary transfer of money, grant for research, bursary, service or property without compensation above the value of €600.”

During the Committee’s scrutiny some Members asked whether the term gift would cover foreign travel, such as to conferences. In reply to this Dr. Jean O’Sullivan said:

“If doctors have to declare that they were sponsored in going to a conference or to a meeting, it would probably take the pressure off them to feel in any way conflicted to support that particular drug or that particular treatment.”

Some Members also queried whether or not the definition of gift should also cover the funding, by medical device companies, of a medical unit or personnel. In answer to this, the Sponsor Mr. Billy Kelleher, T.D. stated:

“The medical device industry funding equipment, a unit or personnel would not be covered by this particular Bill unless the doctor is making personal gains from it. If he or she is working within the unit, there is no material benefit. However, if he or she is charging people to use that facility, that would be seen as a gift because there would be a gain to the health care professional in that circumstance. If a nurse is being funded by a
pharmaceutical company and is in a hospital, there is no material gain to an
individual clinician if he or she is working in the same unit and just doing
his or her job. If there was a direct transfer to that clinician because that
nurse was being paid by the pharmaceutical industry it would have to be
seen as a gift or a transfer of value under this legislation. That would
require more thorough scrutiny on Committee Stage.”

4.6 Other Definitions

The officials from the Department stated that a number of definitions and
terminology in the Bill require amendment in order that it is consistent with
existing Irish and European Pharmaceutical and medical device legislation. These
are listed below.

- The officials stated that defining “Declarable Income” as “money or
other form of payment” is too narrow. They suggested a broader
definition such as “transfer of value” with a specific definition of
what this entails.

- The term “Medical Equipment” and “Supplier” are not recognised
terms under the EU and Irish legislation. The term Medical Device,
which is used in existing legislation, includes medical equipment.

- There is no definition of Pharmaceutical Company in EU medicines
legislation. EU legislation refers to marketing authorisation and
companies are known as “market authorisation holders”, where the
company or other legal entity is granted approval to market a
medicine in one, several or all EU Member States.

4.7 Public expenditure of pharmaceuticals

Some commentators argue that sunshine laws result in doctors prescribing fewer
expensive branded drugs, where generic alternatives are available. The research
evidence behind this appears to be mixed however.
Some exponents of sunshine laws believe that doctors will be less likely to prescribe expensive branded drugs, where generic alternatives are available, if there is transparency regarding their interaction with pharmaceutical companies. A study of prescribing patterns in Maine and West Virginia found: “...a limited effect on prescribing and on expenditures.” However, another study in Massachusetts found that doctors did prescribe fewer drugs and that this was: “...likely a consequence of increased self-monitoring among physicians to curb over-diagnosis.”

Another U.S. study, which examined the effects of payments or items of value received by physicians from drug, medical device, and biological agent manufacturers, found:

“...strong evidence of association between physician payments from industry and their prescribing patterns across specialties.”

The Department of Public Expenditure and Reform (DPER) published a Spending Review 2017: Future Sustainability of Pharmaceutical Expenditure. The report looked at pharmaceuticals as a component of health care expenditure and found that public expenditure on pharmaceuticals (ingredient cost) totalled €2 billion in 2016, across Acute Hospitals, Primary Care Reimbursement Service (PCRS) and Local Schemes. DPER compared expenditure in Ireland with a number of select countries and found that expenditure per capita in Ireland ranked highly, only below Greece, Switzerland and Germany.

4.8 Data protection considerations

The provisions of the Bill will result in individual medical practitioners’ names being published on a searchable register. This has not proven possible under the EFPIA code, unless consent is given. The Data Protection Commissioner may be

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able to give an opinion on the feasibility of introducing the provision outlined in s. 2 of the Bill. It is worth noting that a similar register is maintained by the Standards in Public Office Commission (SIPO). SIPO also monitor compliance and investigate breaches of legal requirements where necessary.

4.9 Existing regulations and voluntary codes?

As stated by the Minister of State at the Department of Health, Ms. Catherine Byrne T.D., during the second stage debate of this legislation, the provisions of this Bill, if enacted should work alongside other regulations such as the Medicinal Products (Control of Advertising) Regulations 2007, which deal with the advertising of medicinal products.

The Bill also refers to the Statutory Declarations Act 1938 as the means by which doctors would declare gifts and supports received. The officials from the Department stated that this requires further consideration and they noted that a statutory declaration under this legislation involves a person making such a declaration in front of a notary, a commissioner for oaths or a peace commissioner.

4.10 What measures can be taken to ensure compliance?

One aspect of enforcing the provisions of the Bill, may involve educating medical practitioners about their obligations under the legislation, so that compliance is more likely.

4.11 Capacity of the Medical Council to take on new responsibilities

The Bill, if enacted, is likely to have resource implications for the Medical Council who will be charged with maintaining and publishing the register. The legislation may also lead to more complaints. The internal mechanisms for dealing with such complaints will have to be considered.
5. Observations of the Minister and the Department Of Health

The Government supports the objectives of the legislation, however the Minister for Health, Mr. Simon Harris T.D. told the Dáil on 19 October 2017 that he has the following reservations/suggestions:

- the Bill needs to be clearer in its language – for instance does “medical equipment” mean “medical devices” or is it broader than this?
- the Bill is limited to medical practitioners, however dentists and some nurses prescribe medicines, while pharmacists play a key role in the delivery of healthcare. If the scope of the legislation is to be broadened to other healthcare professionals, then logistics and cost will have to be assessed.
- the Bill should also deal with healthcare organisations as they also receive funding and support from industry.

The Minster has stated that he will work with Deputy Kelleher to achieve the best legislation.

An official from the Department of Health proposed to the Committee, a number of alternative approaches which regard to the scope of the Bill and the responsibility of the register. The official listed five options:

- The option as proposed in the Bill as published, in which the Medical Council is the holder of the register.
- A register to be established elsewhere (but which would apply only to doctors) that is populated by commercial interests.
- Another option would be to extend the scope of the Bill to all health care professionals, including nurses, pharmacists, dentists and allied health professionals.
- Extend the scope of Bill to cover all health care professionals and health care organisations in the public system.
- Extend the scope of the Bill to cover all health care professionals and health care providers in both the public and private health care systems.
Further to these options the Department official asked if the Health Information and Quality Authority (HIQA) should hold the register, or should it be the Health Products Regulatory Authority (HPRA), which already has responsibility for regulation of pharmaceuticals and medical devices?

The official also suggested a “stepwise” approach which worked well in the Netherlands, whereby legislation commenced which covered only pharmaceuticals at first (i.e. medical devices were not included). The Department consider that such an approach would allow for testing the “workability” of the system before extending the scope to medical devices.
6. Recommendation to the Dáil

Based on its considerations, as outlined above, the Committee has determined that the Bill has technical issues and implementation difficulties.

The Committee recommends that further consideration be given to the key issues listed below, prior to the Bill moving to Committee Stage.

1. Assessment of whether or not the current European Federation of Pharmaceutical Industries and Associates (EFPIA) disclosure code, combined with the Medical Council guidelines, provide sufficient transparency between pharmaceutical/medical device companies and medical practitioners.

2. Perhaps it might be appropriate to broaden the scope of the Bill to include nurses, pharmacists and other health professionals. If that was to happen consideration would have to be where the register would be located.

3. Further consideration should be given to as to whether responsibility for populating the register would remain with medical practitioners or be given to pharmaceutical and medical device companies.

4. Is the current suggested threshold of €600 appropriate, particularly as companies could circumvent the legislation by making a number of smaller payments.

5. Should the definition of a “gift” also cover the funding of a medical unit or personnel, or foreign travel.

6. While the research evidence is mixed as to whether sunshine laws result in doctors prescribing fewer expensive branded drugs, where generic alternatives are available. Is it envisaged that the Bill would lead to reduced public expenditure on pharmaceuticals.

7. The provisions contained in the Bill will result in the names of individual medical practitioners being published on a searchable register and may give rise to data protection considerations. This has not proven possible under the EFPIA code, unless consent is given so perhaps this issue might be further considered.
8. Will the provisions in the Bill impact on the self-regulation (Under EFPIA code) and other regulations around the advertising of medicinal products

Measures to ensure compliance

9. In relation to enforcement of the provisions of the Bill, perhaps consideration should be given to educating medical practitioners about their obligations under the legislation in order to better ensure compliance.

10. Has the Medical Council the resources to maintain and publish the register, particularly as the Bill may lead to more complaints.

Dr. Michael Harty T.D.
Chair
Joint Committee on Health
28 February 2018
Appendix 1 – Membership of the Joint Committee on Health

Deputies:

Bernard Durkan (Fine Gael)
Dr. Michael Harty [Chairman] (Rural Independent Technical Group)
Billy Kelleher (Fianna Fáil)
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 - 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.