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AN COMHCHOISTE UM SLÁINTE

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Bealtaine 2018

JOINT COMMITTEE ON HEALTH

Report on Foetal Anti-Convulsant Syndrome

May 2018

[32H021]

Contents

Chair's Foreword

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

Foetal Anti-Convulsant Syndrome (FACS) describes a number of conditions which can affect children in the womb when they are exposed to valproate medicines.

Valproate medicines are most commonly prescribed to prevent epileptic seizures but can also be prescribed for bi-polar disorders. However, when taken by women in pregnancy, they greatly increases the risk of congenital malformations.

There is also evidence that exposure to the medicines can cause a number of developmental delays in children. Those affected by FACS will often display more than one malformation or developmental delay.

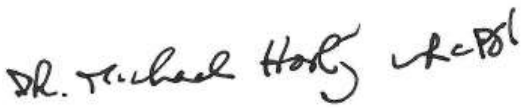
The Oireachtas Joint Committee on Health met with the FACS Forum, the Health Products Regulation Authority and the Health Service Executive to discuss FACS. The Committee welcomes the opportunity to discuss this matter and to highlight the impact FACS has had on individuals and families. I would like to thank those who addressed the Committee and their contributions to the debate.

The Committee wishes to emphasise its support for those affected by FACS and acknowledges their concerns as advocated by the FACS Forum. This report makes a number of recommendations which are intended to address some of these concerns.

A lack of appropriate preventative measures resulted in numerous cases of FACS in Ireland. It will take time and resources to examine these areas. However, the Committee are anxious that some areas are addressed as a matter of urgency.

The Committee urges that prompt access to adequate services is made available to families affected by FACS. The Committee also recommends that all stakeholders collaborate to ensure these families receive this support. It is noted that individuals with FACS are not affected by chance but by the failure to adequately inform and counsel women who were prescribed valproate medicines.

Further examination is required to establish liability but regardless of the causes, the Committee is of the opinion that the State has responsibility to assist all those affected by FACS.



Dr. Michael Harty, T.D.
Chair
Joint Committee on Health
30 May 2018

Executive Summary

Sodium Valproate, also known as Epilim, is an anti-epileptic drug (AED) that has been prescribed in Ireland since 1973. It is also used for the treatment of bi-polar disorder and for the prevention of migraines. However, when children in utero are exposed to valproate, there is a greater risk of Foetal Anti-Convulsant Syndrome (FACS), which can result in a congenital malformations and developmental disorders.

Since it's availability in the 1970's, product information to doctors has warned of the risk of birth defects when taking Epilim during pregnancy. In spite of this warning, adequate information was not disseminated to users of Epilim. As a result, there have been numerous cases of FACS in Ireland.

The purpose of this report is to examine the use of valproate since it was first licensed in Ireland. The report also examines some of the ongoing issues regarding FACS such as registers, access to support service and implementing measures to reduce the risk of FACS.

The Oireachtas Joint Committee on Health, hereinafter referred to as the Committee, met with officials from the Health Products Regulatory Authority (HPRA) and the Health Service Executive (HSE). It also met with representatives of the Foetal Anti-Convulsant Syndrome (FACS) Forum, an umbrella group of organisations that advocate for families and children affected by FACS.

This report makes a number of recommendations which address the main themes and concerns discussed in the meeting. Such recommendations are intended to provide support to those affected by FACS and to establish a platform to investigate historical decisions and procedures that failed to prevent FACS. For example, the recommendation for the establishment of a register is imperative to allow a central point of reference for patients and to allow further examination of the effects of valproate.

Chapters 1 and 2 of the report examine the link between Sodium Valproate and FACS. Chapter 3 addresses the European Medicines Agency's review and recommendations of 2014 and 2018, as well as the implementation of these recommendations in Ireland. Chapter 4 examines ongoing issues related to FACS.

Summary of Recommendations

1. The Committee recommends that all of the EMAs measures regarding FACS, outlined in Chapter 3 of this report, are implemented without delay.
2. The Committee supports the additional recommendations put forward by the FACS Forum and recommends that close collaboration between the HSE, HRPA and the FACS Forum continue with a view to implementing such measures as quickly as possible.
3. The Committee recommends that all measures are reviewed regularly to ensure that they are effective in reducing the risk of FACS.
4. The Committee recommends that a register is established to record individuals who were prescribed valproate medicines during pregnancy and all individuals affected by FACS.
5. The Committee recommends that such a register should be supported and resourced by the HSE or HPRA or a collaboration of these two bodies.
6. The Committee recommends that high priority be given to the establishment of a central point of reference for those affected by FACS.
7. The Committee recommends that responsibility for this central point of reference be delegated to either the HSE Valproate Response team or the HPRA-led stakeholder group.
8. The Committee recommends that children exposed by to valproate are assessed to examine whether valproate has impacted negatively on them. Such a diagnosis should be coordinated by either the HSE Valproate Response team or the HPRA-led stakeholder group.
9. The Committee recommends that a HSE liaison officer would engage with families affected by FACS and that a full suite of services would be agreed with families within 8 weeks of the publication of this report.
10. The Committee recommends that representatives of the HSE would report back to the Committee on progress in establishing those support services within 12 weeks of the publication of this report.
11. The Committee recommends the establishment of an independent investigation to examine the historical use of valproate medicines in Ireland and into the ongoing effects of valproate medicines.
12. The Committee recommends that further consideration and examination is undertaken with regard to compensating FACS patients.

1. Sodium Valproate

Sodium Valproate is an anti-epileptic drug (AED) which is used for the prevention of epileptic seizures and for the treatment of psychiatric patients with bi-polar disorder. It has been in use in the EU since the 1960's and, in Ireland, under the brand name Epilim since 1975.

For some people, Epilim may be the only effective AED and it is particularly useful for some disorders such as Juvenile Myoclonus Epilepsy.

Officials from the HSE discussed the risks of seizure in epilepsy, especially when patients stop taking AEDs. This is particularly applicable to pregnancy and the HSE stated that in the last tri-annual report for the UK and Ireland, there were 14 deaths from epilepsy in pregnancy.

However, it should be noted that there are health risks in switching a prescription from Sodium Valproate to another AED. Officials from the HSE stated that such a process takes time and must be conducted by a specialist.

2. Foetal Anti-Convulsant Syndrome

Foetal Anti-Convulsant Syndrome (FACS) describes a condition that occurs in children exposed to valproate in utero.

Children exposed to valproate while in utero have an 11% chance of congenital malformations compared to 2% in the general population.

Such malformations include:

- malformations of the limbs, heart and kidneys;
- facial and skull malformations, such as cleft lip and palate;
- spina bifida.

Valproate can also have adverse effects on the mental and physical development of children.

Evidence shows that 30-40% of children exposed to valproate while in the womb, will develop neurodevelopmental disorders. Children exposed to valproate are three times

more likely to develop autistic spectrum disorder and five times as likely to develop childhood autism, compared to children not exposed to the drug.

There is also evidence that the Intelligence Quotient (IQ) of children exposed to valproate may be affected.

Initial studies have also revealed that exposure to valproate greatly increases the likelihood of developing symptoms of attention deficit hyperactivity disorder (ADHD)[1].

2.1 FACS in Ireland

Sodium Valproate has been available in Ireland since 1975. Product information for doctors regarding the adverse effects of Sodium Valproate on the foetus was included.

Teratogenic evidence (evidence of an agent disrupting the development of an embryo) of valproate was first reported in the 1980's and these effects have been widely accepted since the 1990's.

Despite knowledge of these risks, many patients were prescribed valproate without warning of the risks if taken during pregnancy and risk-reduction measures were not put in place.

There is currently no verifiable data available which details the total numbers affected by FACS in Ireland but the FACS Forum estimate that approximately 400 may be affected. The genetics department in Our Lady's Hospital for Sick Children, Crumlin has diagnosed 43 cases of FACS.

1 http://www.ema.europa.eu/ema/index.jsp%3Fcurl%3Dpages/medicines/human/referrals/Valproate_and_related_substances/human_referral_prac_000032.jsp%26mid%3DWC0b01ac05805c516f

3. European Medicines Agency

Because of increasing evidence of the risks of valproate medicines, the Pharmacovigilance and Risk Assessment Committee (PRAC) at the European Medicines Agency (EMA) conducted a review of valproate medicines in 2014.
The PRAC is responsible for assessing and monitoring safety issues for human medicines.

Following this review, the PRAC recommended new measures to address the low levels of awareness of the effects of Valproate. The EMA recommended that

> "Valproate should not be used to treat epilepsy or bipolar disorder in girls and woman who are pregnant or who can become pregnant unless other treatments are ineffective or not tolerated".

It also recommended that:

> "doctors who prescribe valproate provide women with full information to ensure understanding of the risks and to support their decisions".[2]

In 2017, the EMA commenced a second review to re-examine "the effectiveness of the measures and to consider whether further EU-wide action should be recommended to minimise the risks in women who are pregnant or of childbearing age".

In 2018, the EMA recommended further measures[3] which included the following recommendations:

- valproate medicines are now contraindicated; i.e. must not be used, in girls and women who are able to have children unless the terms of a special prevention programme are followed;
- changes to product information to reflect these new conditions and also to be incorporated into the packaging of the medicine including a visual warning in the form of a boxed text.

[2] http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Valproate_and_related_substances_31/Recommendation_provided_by_Pharmacovigilance_Risk_Assessment_Committee/WC500175214.pdf

[3] http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Valproate_2017_31/Position_provided_by_CMDh/WC500246350.pdf

- educational materials in the form of guides for patients and doctors will also be updated to reflect the current situation and provide age-appropriate advice. In addition there will be a patient alert card attached to the packaging so that pharmacists can go through it with the patient when the medicine is dispensed.
- healthcare professionals will receive further information at national level in due course as the recommendations are implemented.

3.1 Response in Ireland

A number of new measures were introduced in Ireland following the EMA's 2014 recommendations. These include:

- updating prescribing information and package leaflet for patients with new recommendations around the supervision of treatment by a specialist;
- the importance of using effective contraception;
- the need for regular treatment reviews.

Following the EMA recommendations in February 2018, the HPRA mandated that the outer packaging of all valproate medicines must include a visual symbol warning about the risks in pregnancy in addition to the boxed text that is already approved.

Various stakeholders including the FACS Forum, HPRA, the HSE, and the Department of Health have met to discuss implementation of the measures in Ireland.

Recommendations have been proposed including:

- establishment of HPRA-led Stakeholder group and a HSE Response Group to drive implementation, both of which include representatives from the Forum
- proposed visual warning symbols on boxes and safety information on blister packs
- updated and accessible information resources (online & print) for patients and professionals
- the use of the brand name Epilim on all patient materials
- commitments to end practice of medications being dispensed in plastic bags without Patient Information Leaflets (PILS)
- mandatory use of PILs and reminder cards by pharmacies, and a greater role for pharmacists in communicating with patients and prescribers.
- proposed communication from the HSE to all GPs on a named-patient basis

- new drug safety communications with prescribers and pharmacists including instructions on the new Pregnancy Prevention Programme.

However, there is still a concern that the risks of valproate medicines are not being communicated to women susceptible to FACS.

The FACS Forum is also calling for the following additional actions to further reduce the future risk associated with valproate:

- a commitment from HPRA, HSE and Pharmaceutical Society of Ireland (PSI) that the impact of all new initiatives will be independently measured and evaluated and additional action taken if necessary
- a commitment by the HSE that all women currently prescribed valproate, especially those under GP-only care, be given priority referrals in 2018 to a specialist for urgent treatment review.
- the setting up of a nationally maintained register for women prescribed Valproate.
- the mandatory use/ recording of information materials and risk acknowledgement forms.
- the use of "point of care alerts" in primary practice and pharmacy dispensing software
- investment in targeted public awareness campaigns.

The Committee is supportive of these measures and recommends that all stakeholders, including the HSE and HRPA, work closely in order to implement.

Recommendations

1. The Committee recommends that all of the EMAs measures regarding FACS, outlined in Chapter 3 of this report, are implemented without delay.
2. The Committee supports the additional recommendations put forward by the FACS Forum and recommends that close collaboration between the HSE, HRPA and the FACS Forum continue with a view to implementing such measures as quickly as possible.

4. Ongoing Issues

4.1 Information and Prevention

The failure to prevent cases of FACS can be directly associated with the failure to adequately communicate the risks of valproate medicines to patients and those prescribing the medicine. Since Valproate was first prescribed in Ireland there has been knowledge of the risks if taken during pregnancy. However, despite this, adequate information regarding these risks was not communicated.

In 2014, new measures were introduced following the EMA review of FACS and Valproate. However, in 2017 the EMA admitted that these measures were not having a significant impact in reducing the risk of FACS.

The 2018 EMA recommendations aim to better inform women about these risks and to discourage the use of valproate in girls and women unless there are no alternatives. However, there is still concern that some may be unaware of the risks.

Officials from the HPRA stated that:

> "In terms of moving forward, we have a more robust approach now to communication, at least from the perspective of what we are accountable for, which is the regulation of the product".

It is vital that the EMA's 2018 measures reduce the risk of children being born with FACS and prevention of such conditions is dependent on effective communication of information.

The Committee welcome the fact that stakeholders in Ireland have already met to discuss implementation of new measures and urge that these measures are implemented without delay.

It also recommends that, following agreement and implementation of these measures, regular reviews are carried out to ensure that such information is being acted upon by health professionals.

Recommendations

3. The Committee recommends that all measures are reviewed regularly to ensure that they are effective in reducing the risk of FACS.

4.2 Register

Currently, there is no register available in Ireland that can detail the numbers affected by FACS. Officials from the HPRA and HSE discussed a number of difficulties with setting up such a register. However, officials also discussed a number of possible options which could be explored.

The establishment of a register is essential as:

- it would allow investigation into how decisions were previously made and how women in pregnancy were continually prescribed valproate medicines;
- it would allow for a central point of reference to be established. Such a group would allow effective communication to and from those affected by FACS;
- It would allow for a central point of reference where those affected by FACS could apply for services.
- It should include all women prescribed Epilim during pregnancies and should monitor those not affected by FACS, and whether or not later symptoms are displayed.

Recommendations

4. The Committee recommends that a register is established to record individuals who were prescribed valproate medicines during pregnancy and all individuals affected by FACS.
5. The Committee recommends that such a register should be supported and resourced by the HSE or HPRA or a collaboration of these two bodies.

4.3 Access to Services

The effects of FACS include a variety of congenital malformations and developmental delays and therefore, can be complex, wide-ranging and individual.

Representatives of the FACS Forum stated that obtaining a diagnosis is difficult and lengthy, and treatment will involve attending many unconnected and un-coordinated specialist services.

The FACS Forum discussed the need to streamline diagnosis pathways. There is currently no package available to those affected by FACS.

The Committee recommends that those affected by FACS should be provided with access to support services without delay and that effective pathways are available to patients.

Recommendations

6. The Committee recommends that high priority be given to the establishment of a central point of reference for those affected by FACS.
7. The Committee recommends that responsibility for this central point of reference be delegated to either the HSE Valproate Response team or the HPRA-led stakeholder group.
8. The Committee recommends that children exposed to valproate are assessed to examine whether valproate has impacted negatively on them. Such a diagnosis should be coordinated by either the HSE Valproate Response team or the HPRA-led stakeholder group.
9. The Committee recommends that a HSE liaison officer engages with families affected by FACS and that a full suite of services are agreed with families within 8 weeks of the publishing of this report.
10. The Committee recommends that following this agreement, officials from the HSE report back to the Committee on its progress, with a view of establishing support services within 12 weeks of the publishing of this report.

4.4 Further Investigation

The representatives of the FACS Forum requested further examination into how valproate was prescribed to women in pregnancy. The representatives added that the number of individual FACS cases is still unknown and there are many FACS cases still undiagnosed.

4.4.1 Audit of Numbers Affected

Representatives of the FACS forum highlighted the need for an audit of women who have taken Epilim while pregnant and of the numbers affected by FACS.

Such information would allow greater understanding as to the scale of the numbers affected. It would also allow for better service to those already affected by FACS.

Representatives of FACS Forum and officials from the HSE discussed a register at Beaumont Hospital which gathers information on women when they were pregnant and what medications they were on. There was debate on whether this register can be updated to be more specific to the needs of this audit. It was also noted that this register is funded by pharmaceutical companies.

4.4.2 Investigation into Historical Use of Valproate

The Committee recommends that further examination is required to look at previous policy decisions which contributed to valproate being prescribed to pregnant women. The Committee also recommends that such an examination is independent and specifically examines the following areas:

- How valproate medicines were made available to pregnant women despite the known risks to children in utero;
- How many women were prescribed valproate from 2014, after the EMA's recommended measures, and how did these measures fail to prevent such action occurring?
- Did information provided in Ireland regarding Epilim reflect international knowledge of the drug? The Committee acknowledges that in March 2001 the Irish Medicines Board approved the inclusion of information restricting use of valproate in women of childbearing age to severe case or for women resistant to other treatment until 2012.

4.4.3 Investigation into effects of FACS and the link with valproate

Officials from the HSE and HPRA stated that proving a link between valproate usage and FACS can be difficult.

As congenital defects are visible from early in a child's life, such FACS cases are usually identified early on. However, neurodevelopmental disorders are more subtle and may take time to link with valproate exposure in utero. Such disorders are on a spectrum and some patients may be more severely affected than others.

Officials also stated that there is a requirement to exclude any other possible underlying causes that may affect a child's health. It is possible to make a reasonable assumption based on evidence, but genetic testing or chromosome analysis such as microarray or other modern tests provide a more comprehensive link. However, such examinations require further resources such as appointing geneticists.

Representatives from the HSE stated that such a process is ongoing in the UK and is required in Ireland to ensure diagnoses are correct and to examine whether other problems are present.

It notes that reasonable assumption can be made when it is known that a child, exposed to valproate, displays effects often associated with FACS. However, doses of valproate may have differed between individuals and further analysis is required to clarify a diagnosis of FACS.

However, the Committee affirms that regardless of the causes of the conditions, the State has responsibility to assist those children and their families.

Recommendations

11. The Committee recommends the establishment of an independent investigation to examine the historical use of valproate medicines in Ireland and into the ongoing effects of valproate medicines.

4.5 Compensation and Liability

The representatives of the FACS Forum called for a system of redress to be established to "meet lifelong care needs of children and to address the impact of diagnosis on families".

The Committee acknowledges concerns of liability with those affected by FACS, particularly in cases where children were exposed to valproate after the EMA's 2014 recommendations.

The establishment of a compensation package would be beneficial as it would avoid the need for legal solutions, which would be an additional burden on families affected by FACS;

There is also debate required regarding the liability of pharmaceutical companies.

The prescription of valproate medicines to pregnant woman is a concern worldwide and particularly in the EU. France and the UK have both examined the issue of compensation.

France

In France, there has been continuous debate on use of valproate medicines and the role of pharmaceutical companies.

In 2016, a health authorities report estimated that 425 to 450 children were affected by valproate from 2006 to 2014. Following the report changes were made to the labelling.

In August 2016, the French government announced that they would be responsible for all medical costs of those diagnosed with FACS in cases, where they are not compensated by the pharmaceutical companies.

In 2017, the Government approved an initial €10m to a compensation fund.

The French medicines regulator ANSM (L'Agence Nationale de Sécurité du Médicament et des Produits de Santé) requested that the EMA re-address the safety of valproate in 2017.

United Kingdom

As of yet, the UK has not set up a compensation fund for those affected by FACS. However, the 2014 Children and Families Act 2014 introduced a statutory framework for local authorities and clinical commissioning groups to secure various services, including health and social care services, for young people up to the age of 25 years.

The FACS Forum stated that there is an estimated 20,000 children affected by FACS in the UK. The Forum also stated that there is an ongoing investigation into a number of drugs, including valproate, examining whether the State reacted adequately to safety issues regarding these drugs.

In terms of genetic testing of individuals to examine a link between Epilim and FACS, the HSE reported that the UK have processed and analysed over 100 cases.

Recommendations

12. The Committee recommends that further consideration and examination is undertaken with regard to compensating FACS patients.

5. Summary

The effects of valproate medicines on children while in the womb are wide ranging and complex but no less devastating to each individual.

Valproate medicines are now contraindicated in girls and woman who are able to have children. However, the prescription of valproate to those most vulnerable to its effects was a failing of appropriate policy.

The Committee welcomes the ongoing collaboration between the various FACS stakeholders to implement new measures which intend to greatly reduce the risk of FACS.

Such collaboration is vital and, with Government support, is necessary to respond accordingly in the following areas:

- To provide adequate support to those affected by FACS;
- To ensure measures are implemented to avoid future cases of FACS;
- To investigate the historical use of valproate and how inaction resulted in cases of FACS.

In order to address the matter comprehensively, time and resources will be required.

However, the Committee notes that some of the outstanding concerns require immediate action and should be considered as high priority.

The Committee requests that the observations and recommendations in this report are taken into consideration by all relevant authorities.

6. 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

The Joint Committee on Health held a hearing on 25 April 2018 to engage with relevant stakeholders to discuss Foetal Anti-Convulsant Syndrome. The table below identifies all stakeholders who made presentations to the Committee.

24 April 2018

Ms Joan O'Donnell, Foetal Anti-Convulsant Syndrome Forum, FACS

- Ms Karen Keely, Foetal Anti-Convulsant Syndrome Forum, FACS
- Mr Peter Murphy, Foetal Anti-Convulsant Syndrome Forum, FACS
- Dr Joan Gilvarry, Health Products Regulatory Authority
- Dr Almath Spooner, Health Products Regulatory Authority
- Mr Kilian McGrath, Health Service Executive, HSE
- Dr John Murphy, Health Service Executive, HSE
- Dr Peter McKenna, Health Service Executive, HSE
- MS Cora Flynn, Health Service Executive, HSE

The transcript of the meeting of 25 April 2018 is available online[4].

[4] https://beta.oireachtas.ie/en/debates/debate/joint_committee_on_health/2018-04-25/3/

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.