PROCESS PROTOCOL

Contributing to the Review

1. In February 2018, the Secretary of State for Health and Social Care, the Rt Hon Jeremy Hunt MP, announced a review into how the health system responds to reports from patients about harmful side effects from medicines and medical devices, namely the Independent Medicines and Medical Devices Safety Review ('the Review'). The announcement in the House of Commons followed patient-led campaigns on the use of the hormone pregnancy test Primodos, anti-epileptic drug sodium valproate and pelvic mesh. The Review is chaired by Baroness Julia Cumberlege and is independent of the Government, NHS, regulatory and other public bodies, and the pharmaceutical and medical devices industries. Its Terms of Reference can be found on the Review's website at www.immdsreview.org.uk

2. The principle of independence is fundamental to the work of the Review and will be adhered to throughout its work. As a contributing organisation, the Department of Health and Social Care will be treated in exactly the same way as all other contributors.

3. All those who can offer evidence of their experience of using or having been affected by the hormone pregnancy test Primodos, the anti-epileptic drug sodium valproate (when taken by women of child bearing age), or have been treated with mesh implants in pelvic abdominal and vaginal procedures, are encouraged to contact the Review. This includes not only clinicians and patients, but also families and carers. The Review will be assisted by hearing from anyone affected by the three interventions, whether their experiences were positive, negative, or mixed.

4. In addition, the Review will issue a specific call for evidence to all those involved in bringing the three interventions to market and in their subsequent post-marketing surveillance, regulation and prescribing guidance and practice. This will include the manufacturers and suppliers, the regulators, NHS and other public bodies, private healthcare providers, the clinical professions as well as the Department for Health and Social Care given its oversight of the whole. This call for evidence will be based on a series of focussed questions arising directly from the Review's Terms of Reference.

5. Initial contact can be made with the Review in the following ways:

    a. By email: reviewteam@kcl.ac.uk
    b. Through the Review's website: www.immdsreview.org.uk
    c. By telephone: 020 7848 6386

    d. By post: Independent Medicines and Medical Devices Safety Review

    King's College, London
    Shepherd's House
    Room 3.25b
    London SE1 1UL

6. The Review will comply with the requirements of the General Data Protection Regulations and the Data Protection Act 2018 and is registered with the Information Commissioner's Office as a data controller. Please refer to our 'How we will handle the information you provide to the Review-Data Protection and Privacy Information' document.

7. This Review process protocol is a living document and will be revised and refreshed as the Review progresses.

Our findings and "families first"

8. The principle of 'families first' will be a guiding principle for the Review's work. The Review will disclose its Report fully to individuals and families on the day of publication but in advance of the Report becoming available to any other person or to the media or to the general public. To the best of the Review's ability, the same will apply to any other interim statement or announcements.

The Review's approach to taking evidence

9. The Review embraces a transparent way of working and evidence gathering. Any information, statements or other evidence provided to the Review will be made available on the Review's website after the deadline for the call for evidence has expired and prior to the start of the oral hearing sessions, subject to the application of the Review's Anonymity and Redaction Framework and the time needed to determine any issues arising under it. This publication will not, however, include the personal

testimonies of patients and their families.

10. Individuals and organisations who have submitted information and material prior to the call for evidence being issued will have an opportunity to say via the webform template posted on the Review's internet page or otherwise in writing whether they wish that material to be treated as part of the formal evidence gathering. If they do so, it will be handled and subsequently published in line with the Review's information handling and process protocols. If they do not, it will not be considered further as part of the Review's work.

11. The Review's evidence will be gathered in the following ways:

Patients and Families and Patient Groups

12. The Review will hold a series of patient engagement events throughout the life of the Review at which the personal testimonies from individuals affected and their families and the patient groups may be given orally and/or submitted in writing. The dates, times and locations of these meetings are advertised on our website.

13. Those unable to attend one of these engagement events, or who prefer not to provide evidence orally, and have not already submitted their personal stories to the Review team, are encouraged to submit their testimony using the evidence gathering webform that will be posted on the Review's website at www.immdsreview.org.uk or by email or in writing to the above address. There is an opportunity in the webform to attach documents, including information in pre-completed formats. Those unable to attend or submit information online can contact the Review to submit their evidence by another means.

Manufacturers, distributors/suppliers, clinicians, professional bodies, patient groups, regulators, Government Departments and other bodies

14. The wider stakeholder group and persons of interest to the Review will receive a call for evidence. A template to assist with this evidence gathering will also be made available on the Review's website. The evidence submitted may be in the form of statements, as well as relevant documents, letters and reports, newspaper articles, emails, electronic documents, paper records and any other media.

15. Based on the evidence provided by the manufacturers, distributors/suppliers, clinicians, regulatory, NHS and other public bodies and persons of interest, individuals representing any one of these may be invited to attend one or more of a series of oral evidence gathering sessions to be held in central London, on a date to be notified to them well in advance. These oral sessions will not be open to the public to attend, but will be video recorded.

General

16. All those asked to submit evidence in writing and/or orally will be asked to sign a declaration detailing the extent of any financial/ commercial/ legal relationship with the pharmaceutical and medical devices industries or other bodies of interest to the Review.

17. Organisations and individuals must ensure that they retain original versions of all documents submitted to the Review and that any information relevant to the Review's work is not destroyed before the Review has completed its work.

18. Please note we are unable to accept information that is submitted on electronic external devices such as CDs and USBs. Electronic documents should be submitted via the web template.

Expert evidence

19. As necessary, the Review will appoint experts to assist in the interpretation and analysis of any of the evidence received either in written submissions or in oral hearing sessions. The list of persons so appointed will be published on the website during the course of the Review.

Publication of Evidence

20. The following will be published on the Review's website:

    a. All written evidence obtained from manufacturers, distributors/suppliers, clinicians, professional bodies, regulators, Government Departments, NHS and other bodies and groups or persons of interest which arise from the Review's Terms of Reference (subject to intellectual property rights or other necessary

redactions, see the Review's Anonymity and Redaction Framework);

b. the list of manufacturers, distributors/suppliers, clinicians, professional bodies, charities and patient groups, regulators, Government Departments, NHS and other bodies and groups or persons of interest invited to submit evidence to the Review; and
c. the lines of enquiry which contributors to the Review have been asked to address; and
d. the written assessments of any evidence that experts appointed to the Review have been asked to consider and comment upon.

21. In addition, the oral hearing sessions will be video-recorded. The video recording will appear on the Review's website as soon as possible thereafter, usually within 5 working days from the date of the hearing. A transcript of the audio recording will also be posted on the website at a later stage, but prior to publication of the report.

22. Publication as set out above will be subject to any redaction required under the Review's Anonymity and Redaction Framework. Requests to redact confidential information from the version of a document to be published must be made to the Review and will be decided by the Chair of the Review.

23. Use of any part of the personal testimonies submitted by those affected by any of the three interventions in the Review's Report or elsewhere will be anonymized unless explicit consent is given to do otherwise.

Confidentiality and Information Sharing

24. Issues raised by any of the evidence received may be used to question other individuals as part of a line of enquiry. Identifiable details will only be used if the source of the relevant information has explicitly agreed that it may used for this purpose.

25. A request for disclosure of information that is held by the Review might be made under the Freedom of Information Act (FOIA). If such a request is made, it will be handled as set out in paragraphs 36 – 40 below.

26. It may be that the Review will wish to draw on information contained in documents provided in accordance with this protocol when producing its final (and any interim) Report. It may also wish to evidence observations,

findings and conclusions in any report by referring to the documentation on which these observations are based.

27. In the event that the Review is required to engage with any external regulators or other bodies which hold statutory powers, this may entitle them to access the confidential notes/ testimonies relating to this Review.

28. The Review also may also consider that it is necessary to share information with others, in the event that information is received which gives rise to concerns which could constitute professional misconduct or are of a potentially criminal nature, or the information discloses a risk of serious harm to any person. See further the Review's 'How we handle the Information you provide to the Review- Data Protection and Privacy Information'.

Support for those wishing to give evidence to the Review

29. An individual who has any particular needs (as a result of ill health, for example) which may affect the arrangements for attending a patient engagement meeting, or an oral hearing or who wishes to be supported by a friend or relative, should advise the Review in advance.

30. In addition, the Review has put in place an off-site remote counselling service to which individuals affected by one of the three interventions and who wish to be supported to engage with the Review process can be referred. Details of this support and how to access it are to be found on the Review's website.

Further Oral hearing sessions/statements

31. If new matters relevant to the evidence of a particular person or organisation come to light after the initial receipt of their evidence, that person or organisation may be asked about, or given the opportunity of, commenting on those matters. Such a request may take the form of inviting the individual or organisation to a further oral session, or a request for a written statement.

Checks for factual accuracy and possible Warning Letters

32. The Review team will consider circulating to those organisations named in its report extracts from its findings of fact inviting them to check for factual accuracy and to make any amendments in writing within a specified period

of time.

33. The Review team will also consider sending a warning letter to any organisation or person who may be subject to criticism in the Review's report. If a person or organisation receiving a warning letter wishes to respond to the points it raises, he or she must do so in writing, again within a specified period of time.

34. Such warning letters will set out the criticism or proposed criticism and the basis on which that criticism is made. No significant or explicit criticism of a person or organisation will be made without the individual or organisation affected having been given time to consider and respond to that criticism during the course of the Review.

35. Any such warning letter will be treated as subject to an obligation of confidence which extends to the fact of the letter's existence and to its contents. That obligation is owed by the recipient of the warning letter to the Review Team and by each member of that team and any legal adviser involved. The obligation of confidence ends when the Report is published.

Freedom of Information Act 2000 and the General Data Protection Regulations

36. The Review has set out its policy towards material to be published by it in paragraphs 20-24 above. The observations below relate to material which is not intended for publication by the Review, and which it would therefore regard as confidential or personal in nature.

37. Subject to the operation of the Freedom of Information Act 2000 ("FOIA") and of the General Data Protection Regulations, the personal testimonies, supporting documents and any other written statements received in evidence will remain confidential, except as described above.

38. If a request for access to an individual's statement, or documentary or other information held by the Review is made by any other person, whether under the Freedom of Information Act 2000 (FOIA) or otherwise, the Review will seek legal advice on whether or not it is subject to disclosure obligations under FOIA or under any other legal enactment.

39. Certain documents in the possession of the Review would generally be regarded by the Review as exempt from disclosure under FOIA, by virtue

of the confidential setting in which the information was given and received, and also by virtue of the fact that the content is likely to amount to the 'personal data' of the individual or others, under the General Data Protection Regulations and Data Protection Act 2018. In addition, when patients are interviewed, or the care of a living patient is discussed, information about care or treatment will amount to "special category" data (i.e., sensitive data) under these legal provisions. As a result, and subject to any legal advice that may be taken on individual cases, the Review believes that it would generally be in the public interest to resist requests for disclosure of the information to third parties. If the circumstances of a particular case or legal advice received suggest that an exception to that approach might be appropriate, affected individuals would be asked for their views.

40. The Review notes, however, that decisions which it may reach on disclosing or withholding information are subject to rights of appeal and to decisions by the Information Commissioner, courts or tribunals service; these bodies may reach decisions concerning the application of FOIA and the General Data Protection Regulations which will bind the Review.

14.09.18