



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Director General

Brussels,
SANCO/C/C2/DH,
sanco.ddg1.c.2(2014)3854092

Dear Mr Kane,

Subject: Your application for access to documents – Ref GESTDEM 2014/4650

~~I refer to your e-mail dated 09/10/2014 in which you make a request for access to documents, registered on 09/10/2014 under the above-mentioned reference number.~~

Your application concerns the following documents:

- 1) The terms of Reference re. EU Scientific Committee on Emerging and Newly Identified Health Risks that is considering the Safety of surgical meshes used in urogynecological surgery
- 2) A list of all members who are in that Review
- 3) A Register of Interests for the Review
- 4) A list of meetings that the Review has conducted and a list of prospective meetings
- 5) Any note or minutes of any meeting that has taken place
- 6) A list of interviews that the Review has conducted
- 7) Correspondence between the Review and the MHRA in London and the Scottish Government in Edinburgh

Concerning point 4), please note the following information:

- 1st meeting of the Working Group on Surgical Meshes – 12 March 2014
- 2nd meeting of the Working Group on Surgical Meshes – 14 April 2014

Tommy Kane,
C/O 4 Northfield Court,
West Calder, West Lothian
Scotland, UK EH55 8DS

- 3rd meeting of the Working Group on Surgical Meshes – 26 June 2014
- 4th meeting of the Working Group on Surgical Meshes – 30 June 2014
- 5th meeting of the Working Group on Surgical Meshes – 15 September 2014
- SCENIHR Request for a scientific opinion

Next meetings of this working group will be held on 4 November and 2 December.

In response to your request, annexes are attached corresponding to points 1), 4) and 5). However, please note that all these documents are publicly available on the Scientific Committees website at:

http://ec.europa.eu/health/scientific_committees/index_en.htm

For point 6), the description given in your application does not enable us to identify concrete documents which would correspond to your request. We therefore invite you, pursuant to Article 6(2) of Regulation (EC) No 1049/2001 regarding public access to documents, to provide us with more detailed information on the documents which you seek to obtain, such as references, dates or periods during which the documents would have been produced, persons or bodies who drafted the documents etc. The 15 working days time limit for handling this part of your application will start running when we receive the requested clarifications.

Regarding point 7), i.e. correspondence with Medicines and Healthcare products Regulatory Agency (MHRA), please be informed that the Secretariat of the Scientific Committees did not have any contacts with this institution regarding the opinion on the safety of surgical meshes used in urogynecological surgery. As regards the correspondence with the Scottish Government in Edinburgh, please find the correspondence via e-mail attached. This correspondence has been expunged of personal data, in compliance with Article 4(1)(b) of Regulation (EC) No 1049/2001, referenced below.

As for points 2) and 3), you request information or documents which are or contain personal data.

According to point 34 of the Rules of Procedure of the Scientific Committees *'the requests for access to Committee documents shall be handled under Regulation 1049/2001'*. However, when considering the exceptions listed in Article 4 of that Regulation, account shall be taken of the need to preserve the integrity and the independence of the scientific advice, which supports the decision making process of the Union. Integrity and independence of the scientific advice is ensured, inter alia, by protecting the names and declarations of interest of members of a Committee's working group while work is ongoing.

However, names of members of the working group and their declarations of interests will be publicly available by publication on the Scientific Committee website at the time of the publication of the preliminary opinion, as laid down by point 36 of the Rules of Procedure "Names of Members, Advisors and external experts appointed to Working Groups as well as their declarations of interest shall be published after the adoption of the opinion to which they have contributed". We expect to publish the preliminary opinion in early 2015.

We consider that the necessity of disclosing to you the aforementioned personal data as requested under 2) and 3) cannot be established at this time. These documents are therefore entirely covered by the exception provided for in Article 4(1)(b) of Regulation 1049/2001, according to which:

"The institutions shall refuse access to a document where disclosure would undermine the protection of: ...privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data."

In accordance with Article 7(2) of Regulation 1049/2001, you are entitled to make a confirmatory application requesting the Commission to review this position.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretary-General of the Commission at the following address:

European Commission

Secretary-General

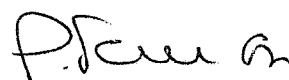
Transparency unit SG-B-5

BERL 5/327

B-1049 Brussels

or by email to: sg-acc-doc@ec.europa.eu

Yours sincerely,



Paola Testori Coggi

Enclosures: Minutes of 1st meeting of the Working Group of Surgical Meshes –
12 March 2014
Minutes of 2nd meeting of the Working Group on Surgical Meshes –
14 April 2014
Minutes of 3rd meeting of the Working Group on Surgical Meshes –
26 June 2014
Minutes of 4th meeting of the Working Group on Surgical Meshes –

30 June 2014

Minutes of 5th meeting of the Working Group on Surgical Meshes –

15 September 2014

SCENIHR Request for a scientific opinion

Correspondence with the Scottish Government in Edinburgh (partial)

List of all members who are in that Review (no access)

Register of Interests for the Review (no access)