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LEGAL OPINION

15 October 2003

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To: **Maurice Wagner**

Re: **Reclassification of Medical Devices**

INTRODUCTION

1. This memorandum addresses related questions concerning the draft Commission Directive 'On the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices' ('the draft Directive').[1]

2. The background to these questions is set out in the documentation provided to us and which formed the basis of our preliminary discussions in conference on July 17.[2] The key facts are as set out in the following paragraphs.

3. By letter dated 5 November, 2002, the competent authorities in the UK and France jointly Requested that the Commission reclassify total joint replacements as class III medical devices ('the Request').[3]

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1 Reference 'ENTR PE 2002/297/G4', dated 7 July 2003.

2 These comprise, in addition to the draft Commission Directive (noted in footnote 1): (1) Eucomed Discussion paper on Reclassification; (2) Eucomed recommendations on reclassification of medical devices; (3) Eucomed letter dated 1 July to Mr. Connelis Brekelmans on 'Up-Classification of Hip Joints'; and (4) Request from UK and France for 'Reclassification of certain medical devices'.

3 The Request comprises 2 pages with no annexes or accompanying materials.

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4. The Request was made pursuant to Article 13(1)(b) of Council Directive 93/42/EEC ('the MDD'), which provides:

> 'Where a Member State considers that...a given device or family of devices should be classified, by way of derogation from the provisions of Annex IX, in another class...it shall submit a duly substantiated Request to the Commission and ask it to take the necessary measures. These measures shall be adopted in accordance with the procedure referred to in Article 7(2).' [Emphasis added.]

The procedure, set out in Article 7(2), for taking the decision is a committee procedure involving the 'Committee on Medical Devices' ('CMD').[4]

5. The Request cites a 'public health and safety rationale'. Its central concern is that the medical devices in question do not always 'work properly the first time' and that the risks associated with replacing them are 'particularly high in this area'. In raising the classification of the devices the Request aims to address this alleged problem because the new classification would 'ensure that the [relevant Member State] Notified Body examine[s] the detailed design dossier of the critical devices before they are placed on the market' - rather than carrying out only spot checks, as occurs under the current classification. The Request also cites the 'problems that have arisen' when 'manufacturers have made, what at first sight may appear to be relatively minor changes to the design and/or composition of previously trouble free joint replacements'.

6. The Request 'additionally' makes reference to, and endorses, the Report on the Functioning of the Medical Devices Directive (June, 2002) from the Medical Devices Expert Group ('the Report'), section 7.1.2. This refers to an apparent incoherence in classification rules and recommends that medical devices in

[4] Established by Article 6 (2) of Directive 90/385/EEC.

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contact with the central nervous system should be in class III because the 'risks associated' with contact 'do not diminish with duration of contact'. The Report recommends, in its list of actions, that Member States 'use the possibility to submit Requests for reclassification of individual medical devices and groups...based on article 13 MDD...' It is not clear that the Report necessarily forms part of the reasoning for the Request but at any rate this issue is not referred to in the draft Directive.

7. The draft Directive consequently proposes reclassifications applying to hip, knee and shoulder joint replacements. It adopts the same public safety rationale as set out in the Request. It cites, amongst other things, the risk of failure of these joints once installed - associated with their 'particular complexity'[5] - and the problems which can be caused by minor changes in the products made after they are placed on the market.

8. Eucomed takes issue with the reasoning underlying the Request and the draft Directive:

   - The Request is not 'duly substantiated', as required under Article 13(1)(b) MDD.

   - Neither the Request or the draft Directive refer to the information available in France and the UK on joints failure which, in Eucomed's assessment, does not indicate that there have been safety alerts related to the design of relevant joint replacements.
   - The assumption that many joints fail because of faulty design is not made out. In fact, Eucomed reads available evidence as pointing to the

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[5] Recital (5).

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conclusion that other considerations are more important - the experience of health care professionals involved, operative techniques, the conditions of the patient, etc. These factors would not be addressed by a case-by-case examination of joints (which would happen were they to be reclassified under class III) and therefore, in Eucomed's assessment, the objectives of the draft Directive and the Request would not be achieved.

- In addition to these technical arguments, Eucomed has made a number of policy arguments (such as inhibitions on innovation, increased costs for no respective safety benefits, inability of Notified Bodies to deliver individual assessment on this scale etc.) which are not discussed in this memorandum.

9. We understand that Eucomed is in the process of compiling a technical paper which will set out in greater detail the technical arguments summarised above.

QUESTIONS POSED BY EUCOMED

10. Eucomed's concern is to explore specific legal questions on reclassification under Article 13(1)(b) of the MDD:

(a) Can the Commission act upon the Member States' Request, given that it is not accompanied by any technical data or other evidence; is the Request 'duly substantiated' and therefore admissible?

(b) In light of the above, is there a general legal obligation to consult competent scientific committee(s) on the substantive issues raised by the Request/the draft Directive? If so, how does this obligation arise and how does the precautionary principle impact upon this question?

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11. In addressing these questions we have reviewed, amongst other things, the cases referred to us in your e-mail of July 25.

(a) Can the Commission act upon the Member States' Request, given that it is not accompanied by any technical data or other evidence; is the Request 'duly substantiated' and therefore admissible?

12. There is no express requirement in Article 13(1)(b) of the MDD for a Request to be accompanied by any *particular* set of documents or scientific materials. This does not, however, imply that a Request can be submitted with no supporting materials.

13. The Commission may accept a Member States' Request (and therefore proceed to the CMD with a draft Directive) only where the request is 'duly substantiated'. This phrase is not defined in the MDD. Neither the core provisions or its recitals give any further clarification of what this term means. The recitals do indicate, more generally, that 'Class III is set aside for the most critical devices'. This indicates that that a *prima facie* case needs to be made out by some supporting material, above and beyond a mere 'assertion' that there is a public health risk.

14. The MDD is silent as to the standard of proof or evidential burden which a notifying Member State needs to achieve in order to duly substantiate a Request. It is clear, however, that a 'duly substantiated' request must be received *before* the Commission can table necessary measures in response to the CMD.

15. Article 10 of the MDD includes a detailed procedure for recording and evaluating centrally, amongst other thing, 'any malfunction or deterioration in the characteristics and/or performance of a device... which might lead to or

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might have led to the death of a patient or user or to a serious deterioration in his state of health....'. None of this information has been presented along with the Request. This is clearly very relevant.

16. We have looked to other pieces of Community legislation and to relevant case law for guidance on what the term 'duly substantiated request' means in other contexts, but have not identified any indication, favourable or otherwise, on this issue.

17. The key question is what the threshold is for a request to be 'duly substantiated'. The natural meaning is that it compels the Commission, as the Guardian of the Treaty, to actually check that requests are substantiated. This may be described as a quasi-administrative task. It does not mean that the Commission must check that the evidence is in fact conclusive, but rather that there is enough evidence upon which the CMD *could* conceivably form an opinion as to whether a reclassification is justified. It is clear that the question of whether the issue in fact merits a reclassification is solely within the responsibility of the CMD, rather then the Commission, as it is the CMD which votes on measures proposed by the Commission under the procedure set out in Article 7(2) of the MDD.

18. The Commission is required to positively verify that there is sufficient scientific data in support of the Request *before* proposing a draft measure to the CMD. Unless this is the case, it may not lawfully propose a draft Directive. Furthermore, any Directive adopted in these circumstances would be unlawful.

(b) In light of the above, is there a general legal obligation to consult competent scientific committee(s) on the substantive issues raised by the Request/the draft

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Directive? If so, how does this obligation arise and how does the precautionary principle impact upon this question?

19. It follows from the answer to question (a), above, that the draft Directive may not lawfully be presented to the CMD. The legislative process should stop now therefore and the Commission declare the UK/France Request inadmissible on the basis that it is not 'duly substantiated'. However, we understand that the draft Directive will be placed before the CMD imminently. In these circumstances, Eucomed must consider the grounds on which a CMD decision could otherwise be taken. It must be borne in mind in this regard that even a 'duly substantiated' Request may not be *sufficient* in its substance to warrant a reclassification. This is because - again - even a 'duly substantiated' request does not address the *merits* of whether a reclassification should take place but only whether there is enough evidence to require the Commission to draft measures in response for the CMD.

Consultation

20. There is no express obligation in the MDD for the Commission or the CMD to consult any scientific body. However, our review of the relevant case law[6] indicates that there is clearly a requirement - in the circumstances of this case - for scientific input to be sought by the Commission. (There is no, more general, duty to consult *per se*.)

21. Indeed, in *Angelopharm GmbH v Freie und Hansestadt Hamburg*[7] the Court of Justice noted, in a different context, that:

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6 See paras. 24-27 below.

7 Case C-212/91, 25 January, 1994.

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> '...the Commission is not in a position to carry out [scientific and technical] assessments of this kind...
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> The [relevant Standing Committee, made up of Member State representatives]...is similarly not in a position to make such an assessment...[it] must, in the nature of things and quite apart from any provisions laid down to that effect, be assisted by experts on scientific and technical issues delegated by the Member States...
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> The [Scientific Committee]...has the task of assisting the Community authorities on scientific and technical issues in order to enable them to determine from a fully informed position....
>
> ...the Commission accepted that consultation [of the Scientific Committee]...made it possible to ensure that the measures had a scientific basis, that they took account of the most recent scientific and technical research and that only prohibitions necessary on grounds of public health were imposed.'[Emphasis added.][8]

22. The obvious scientific committee that should be consulted on reclassifications is of course the Scientific Committee on Medicinal Products and Medical Devices ('SCMPMD'). The recitals to the Decision establishing the SCMPMD[9] provide, amongst other things, that: 'the Commission must be able to obtain sound and timely scientific advice'. 'The Commission may also decide to consult them on other question of particular relevance to consumer health...'.[10] The Commission has not yet asked for an opinion on this issue. Eucomed may consider asking

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8 Paras. 32-34 and 36

9 Established by Commission Decision 97/579/EC of 23 July 1997; Official Journal L 237 of 28.08.97, setting up Scientific Committees in the field of consumer health and food safety.

10 Article 2(1).

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Member States to request that the Commission seeks independent advice from the SCMPMD.

23. Note also that the SCMPMD may also, of its own initiative, '...draw the Commission's attention to any specific or emerging problem falling within their remit relating to consumer health...'[11]. Having reviewed the summary reports of the SCMPMD meetings, we see that (on at least one occasion) the issue of reclassification has been raised by a member (Prof. Goëau-Brissonniere). The response from the Commission representative was that 'the question of reclassification of medical devices is a matter for the relevant Committee [i.e. the CMD] as laid down in the Medical Devices Directive'.[12] There may however, be a difference in approach taken by the Commission, chairing the SCMPMD, and its members, and which could be 'leveraged' by Eucomed. A recent summary report indicates that members have 'requested that...[the SCMPMD] be consulted on all scientific subjects on medical devices'.[13] This apparent difference of view between the Commission and members should be noted. At the very least, if the SCMPMD commenced work on this issue this would, logically, warrant the CMD postponing a vote until a scientific opinion was issued.

Precautionary Principle

24. As regards the 'precautionary principle' it is conceivable that this might be used by the Commission and Member States to justify the draft Directive. (We note

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11 Article 2(4).

12 Summary report of the 16th meeting held on 26 February 2001, adopted on 28 may 2001.

13 Summary Report of the 21st meeting held on 26 September 2002, adopted on 12 February 2003.

that it does not currently form part of the express rational.) Even if the precautionary principle is not invoked by them, the ability of the Community legislature to take measures such as those contained in the draft Directive - in circumstances in which there is scientific uncertainty - could involve the application of the precautionary principle. Whether the tests met for its application are satisfied remains a key issue for Eucomed.

25. The precautionary principle is mentioned in the EC Treaty only in connection with environmental policy but has been recently acknowledged by the Court of First Instance in *Artegodan v Commission* as being broader in scope:

> 'It is intended to be applied in order to ensure a high level of protection of health, consumer safety and the environment in all the Community's spheres of activity. In particular, Article 3(p) EC includes 'a contribution to the attainment of a high level of health protection' among the policies and activities of the Community. Similarly, Article 153 EC refers to a high level of consumer protection and Article 174(2) EC assigns a high level of protection to Community policy on the environment. Moreover, the requirements relating to that high level of protection of the environment and human health are expressly integrated into the definition and implementation of all Community policies and activities under Article 6 EC and Article 152(1) EC respectively.
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> It follows that the precautionary principle can be defined as a general principle of Community law requiring the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment...Since the Community institutions are responsible, in all their spheres of activity, for the protection of public health, safety and the environment, the precautionary principle can be regarded as an autonomous principle...

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> It is settled case-law that, in the field of public health, the precautionary principle implies that where there is uncertainty as to the existence or extent of risks to human health, the institutions may take precautionary measures without having to wait until the reality and seriousness of those risks become fully apparent (Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 99, and Case T-199/96 *Bergaderm and Goupil* v *Commission* [1998] ECR II-2805, paragraph 66).[14]' [Emphasis added.]

26. The case law indicates that before the Community can act there must be substantiated a specific, identified risk - although there may be scientific uncertainty surrounding that risk. (As we have already noted, above, the Commission is - in this case - under a duty to consult to get this information substantiating a specific, identified risk.) In *Alpharma Inc. v Council*[15] the CFI summarised the position as follows:

> '...as the Court of Justice and the Court of First Instance have held, where there is scientific uncertainty as to the existence or extent of risks to human health, the Community institutions may, by reason of the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks become fully apparent (the *BSE* judgment, cited at paragraph 135 above, paragraph 99, the *NFU* judgment, cited at paragraph 135 above, paragraph 63, and the judgment at first instance in *Bergaderm and Goupil* v *Commission*, cited at paragraph 136 above, paragraph 66)...
>
> Thus, in a situation in which the precautionary principle is applied, which by definition coincides with a situation in which there is scientific uncertainty, a risk assessment cannot be required to provide the Community institutions with

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