ANNEX A

LEGAL OPINION

OWN BRAND LABELLING OF MEDICAL DEVICES

1. This memorandum analyses the law on two related issues:

   (a) Who is a manufacturer under the MDD?

   (b) What are the labelling requirements in relation to identification of the legal manufacturer of a given product?

   It is easy to confuse the second question with the first.

Legal definition who is the "manufacturer" of a product

2. The obligations under the MDD, to ensure that a device which is placed on the market only if it conforms to the essential requirements and bears CE marking, apply to a "manufacturer". The term "manufacturer" has a specific legal meaning and is defined as:-

> *"The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.*
>
> *The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This sub-paragraph does not apply to the person who, while not a manufacturer within the meaning of the first sub-paragraph, assembles or adapts devices already on the market to their intended purpose for an individual patient". (Emphasis added.).*[1]

3. The above legal definition is in accordance with the general approach to this issue in all New Approach Directives, set out in guidance on the concept of a manufacturer in the Commission's Guide to the Implementation of Community Harmonisation directives based on the new approach and the global approach, 1994:

> *"The manufacturer is responsible for; designing and manufacturing the product in accordance with the essential requirements laid down by the directive and following the procedures for certification of conformity of the product with the requirements of the directive in question (declaration of conformity, application for type examination, affixing of the CE marking, preparation of file, forwarding of file to the competent authorities etc).*

[1] MDD. Article 1.2(f)

The manufacturer may subcontract some of these operations, including the design - if he physically manufactures the product - or the manufacture - if he designs it - provided he retains overall control and responsibility.

In principle, the manufacturer may employ ready-made parts or components in the product, without affecting his status as manufacturer.

Any maker of a new finished product from existing finished products is regarded as the manufacturer of the new product.

Anyone who changes the intended use of a product is regarded as the manufacturer of that product and, as such, remains subject to the requirements which the directive in question places on manufacturers and assumes responsibility accordingly.

Anyone who imports a used product from a third country with a view to bringing it into line with the essential requirements of the directive in question must comply with the requirements imposed on manufacturers by that directive and assumes responsibility accordingly." (Emphasised added.)

Labelling requirements

4. Having identified the "manufacturer" of a product, one then has to ask what labelling requirements that person has to observe in order to identify himself on his product. This is a separate issue.

5. It is a requirement for the name or trade name and address of the "manufacturer" to be included on the label and any instructions for use[2].

6. Where a device is imported into the Community, the label (or the outer packaging or instructions) must contain, in addition, (a) in the case of Class I device or custom-made device, the name and address of the person established within the Community responsible for marketing, or (b) the name and address of the authorised representative or importer, in either case established within the Community[3].

Legal analysis

7. Two quite separate questions need to be considered when considering a given situation or given labelling:-

   (a) Who is the "manufacturer" of this product?, and

   (b) Given the identity of the "manufacturer" of this product, has he fulfilled the MDD's requirements on manufacturers? In particular has he completed a declaration of conformity and has his name and address appeared on the labelling?

[2] MDD. Annex I, para. 13.3(a) and 13.6(a)
[3] *Ibid.*

The tests for a "manufacturer"

8. The focus of the definition of "manufacturer" is on the person who takes regulatory responsibility for a device before it is placed on the market under his own name. In effect, the "manufacturer" is the person who takes regulatory responsibility for placing the product on the market, before it is placed on the market. Those regulatory responsibilities, which are subject to enforcement by regulatory and criminal sanctions under national legislation, are personal to the "manufacturer" and may not be avoided. A "manufacturer", by placing a product on the market under his own name, takes the commercial benefit but also the regulatory risk.

9. It is clear from the legislation that the functions of design, manufacture, labelling, promotion, lodging an application with a Notified Body, undertaking assessment of conformity, physical application of CE marking and post-marketing obligations such as vigilance, may all be undertaken by a person(s) other than the "manufacturer". The "manufacturer" may delegate all the above functions normally associated with manufacture and placing a product on the market to sub-contractors, component manufacturers or own branders. Thus, delegation of the labelling function means that the legal "manufacturer" does not need to be the person who physically places his own name on the product: the labelling can be printed/affixed by someone else under the "manufacturer's" responsibility.

10. The Annexes in the MDD suggest that the only function which the "manufacturer" must perform himself, and which cannot be delegated, is that of making and holding a Declaration of Conformity for the product[4]. It is generally agreed that the other regulatory functions, such as applying to a notified body, or carrying out a conformity assessment procedure, can be carried out on the "manufacturer's" behalf by a sub-contractor.

11. The definition of "manufacturer" in the Directive does not state a single explicit test for determining who the “manufacturer” of a given product is. Two basic tests are in fact stated[5]: one based on *responsibility* (person who has responsibility for the product) and the other on *name used* (placed on the market under his own name). In many situations the answer will be obvious and both the responsibility test and the name test will give the same result. In some more complex situations, however, the responsibility test and the name test conflict and lead to different results. It is, therefore, important to decide how correctly to interpret the definition of "manufacturer" in the MDD: in practice, this means deciding whether the responsibility test or the name test is paramount.

12. Whether a person has regulatory responsibility for a product is ultimately a matter for considering the evidence. Clearly, the question of what name has been used on the product is highly important evidence. However, there is no reason under the MDD or national laws on evidence why the evidence

[4] See e.g. MDD, Annex II, para. 2.

[5] A number of other factors might in theory be relevant, including:

(a) Who has taken responsibility for the product *before* it is placed on the market?

(b) Who has *caused* the product to be placed on the market?

(c) Who has *physically* placed the product on the market?

(d) Who has *placed his name* on the product (or caused this be done)?

should or must be restricted to looking solely at the product and its labelling. Other evidence may well be relevant to decide whether a person has taken regulatory responsibility for a product.

13. Such further evidence is likely to include (i) verification of who holds the Declaration of Conformity, (ii) whose notified body is involved, (iii) what is recorded in any documents relating to the relationship between two or more entities which are both involved in the production and marketing of a product. The most important and conclusive of such documentation will be any written contract between the entities. This evidence should reveal, in most cases without any difficulty, whether the relationship between, for example, two entities involved is that of

(a) Sub-contractor and principal (e.g. OEM [6]and OBL[7]), with principal taking responsibility as "manufacturer", or

(b) "Manufacturer" and distributor.

14. The conclusion must be that the responsibility test is paramount. There are several reasons for reaching this conclusion.

15. First, the natural construction of the words in the definition of "manufacturer" clearly indicates that the responsibility test has primary importance. It is stated prominently and before the name test. The definition of manufacturer in the Commission's Guidance on New Approach Directives adopts the responsibility test and omits the name test[8]. If it had been intended to state a test based on name alone, or to make the name test paramount, the MDD would have used different wording.

16. Second, the name test cannot give a satisfactory result *in all cases.* If the name test were the only and sufficient test, the words "person with responsibility for...before it is placed on the market" would have no meaning. That could not be correct. The name(s) on the product will be important evidence of who has taken responsibility for the product before it is placed on the market, but not necessarily the sole or sufficient evidence. A competent authority might argue that it would rather not have to investigate any evidence other than the name(s) which appear on the labelling because it is inconvenient to do so. However, the answer to that point of view is that the authority must follow whatever the law requires and mere inconvenience is no excuse.

17. Third, only the responsibility test gives a satisfactory solution to the situation where there is inadvertent mislabelling or counterfeiting. In reality, of course, a competent authority might initially only have available to it a label. The competent authority would have to start its investigation by approaching the person(s) whose name(s) are on the label. If only one name and address is on the label (e.g. A), it may often be the case that A is the manufacturer but it would not be a legally correct interpretation of the MDD that the name that appears is inevitably that of the "manufacturer". It might be that A has taken responsibility for the product. But it might also be that A has not. For example, A's name might have been stated in error (e.g. the name of the wrong subsidiary has inadvertently

[6] Original equipment manufacturer
[7] Own brand labeller

been stated) or fraudulently. In these situations, and almost certainly where the product is counterfeit, A may have had nothing to do with the product. Alternatively, he might have been involved with the product in some way but not intended to take responsibility as "manufacturer". In these situations, the name test breaks down. A would be the "manufacturer" if only the name test is applied, but in reality A could not rationally be the "manufacturer". However, the responsibility test gives a satisfactory answer: A has not taken responsibility for the product and is not the "manufacturer". The person who has taken responsibility for the product has, however, committed the offence of not stating his name and address on the labelling.

18. Fourth, it is interesting that the requirement in Article 1.2(f) relates to the *name* of the "manufacturer". In contrast, the labelling requirements in Annex I refer explicitly not just to the name but make clear that either the name or the trade name on the labelling. This is consistent. If labelling merely shows an abbreviated name or trade name (such as "NA"), one has to inquire precisely which company owns that designation (it might be Norbert Anselmann GmbH, or N.A. Laboratoires S.A. or Anselmann Inc.). All of these companies might operate from the same address in a particular country. This is another failure of the name test: it may well not identify the precise corporate entity which is the "manufacturer" in many instances, particularly relating to multi-nationals.

19. There is no prohibition under the MDD on the use of any other names or marks on the labelling of persons in addition to the name and address of the "manufacturer". Any number of other names could appear[9], as long as it is clear who is taking responsibility for the product and his own name (and address) appears on it identifying him as "manufacturer". It is obviously sensible for the labelling to make clear the capacity in which multiple names appear, so as to avoid creating the impression that one of them is taking responsibility for the product when he is not e.g.

"Manufacturer: X"
"Distributor: Y"

Own branding

20. Companies sometimes wish to arrange that company A will make a product but company B will market or distribute it. It might be that A also makes the same product which he sells himself separately as "manufacturer": that is irrelevant for these purposes. They have a choice of various regulatory solutions.

Situation I

21. They might decide that A will be "manufacturer". In this case, A's name and address must be stated on the label. The label might also state B's name or logo or address or branding, or it might also state

[8] Guide to the implementation of Community Harmonisation directives based on the new approach and the global approach. Commission of the European Communities. 1994. Sheet I/B, para. 3.
[9] There might be a problem under national trade description law if descriptions were misleading.

similar information for C, D, etc who might be local distributors or A's sub-contractors or parent company: all that is optional and has no regulatory significance. If more than one name appears, it should be made clear that A is the "manufacturer", for example by stating" manufacturer: A" and "Distributor: B" and so on.

Situation II

22. They might decide that B will be the "manufacturer". In this case, B's name and address must be stated on the label. They might decide that the label would include nothing more. But they could decide to state A's name if they wished, as long as the label makes clear which name and address is that of the "manufacturer", as discussed for Situation I.

23. In either Situation I or Situation II, the parties might wish to use trademarks, branding or colours associated with A or B or anyone else. If the name test were applied in the situation where the name or branding of the person was used who did not hold the Declaration of Compliance or notified body authorisation or otherwise intend to be "manufacturer" (in addition to a statement such as "Manufacturer: X"), it might lead to the conclusion that X was not the "manufacturer". This conclusion could only be reached on the basis that one name is more prominent or larger than the others which appear and that explicit wording identifying who is taking regulatory responsibility for the product is ignored. That result could not be correct as a matter of common sense or construction of the definition of "manufacturer". The words "placed on the market under his own name" do not support the interpretation as if they read "placed on the market so as to give the overall impression or expectation that the principal name appearing is the manufacturer". This situation is, therefore, another reason why the name test cannot be paramount or conclusive. There is no reason why a product should not be labelled "Manufacturer: B Made by A. Distributor: C" and include the trademarks and branding of one or more of these three, without disturbing the legal conclusion that B is the "manufacturer". The strict regulatory and labelling requirement is satisfied but so are the commercial interests of those involved. Maintenance of public safety and regulatory surveillance of the market is also satisfied.

24. Thus, if the name test were paramount, it would drive manufacturers towards the result either that only one name or brand could ever be used on a product, or that product labelling must be tailored to conform to a "most prominent name" test, which would have an uncertain outcome in any given case since it is a test of subjective impression. This approach would restrict industry's commercial freedom. It is an unnecessary approach since the responsibility test coupled with the labelling obligation explained above gives a perfectly satisfactory workable approach.

25. The relative sizes or colours of any names which might appear on labelling are irrelevant, as long as it is made clear by other means which is the name of the "manufacturer".

26. The underlying purpose of the legislation is simply to enable regulators and consumers to be able to contact the "manufacturer". This will be achievable as long as his name or trade name and address are

stated and, if more than one name appears, the "manufacturer" is identified as such. The fact that other names might also be stated should be of no regulatory significance but merely improves product safety by giving customers, healthcare professionals, notified bodies and competent authorities increased options for contacting persons who are involved in the chain of manufacture and distribution, who should be able to channel information back to the "manufacturer". The legislation does not include a "customer expectation" test as to who is "manufacturer".

"Manufacturers" outside the EU

27. The same considerations apply where companies outside the EU are involved. There is merely the extra labelling requirement noted that in addition to stating the name and address of the "manufacturer" (who may be located anywhere in the world), the label must state the name and address either of the "manufacturer's" authorised representative in the EU or of the importer into the EU. This is so that there is always some person within the EU who can be contacted in relation to safety information and who should be able to contact the manufacturer. The reference to an importer is to cover the situation where an EU based entity without the instructions of the foreign "manufacturer", imports a product which already bears CE marking, i.e. grey imports in which the authorised representative is not involved.

Wording difficulties

28. The short result is that the labelling obligation in Annex I of the MDD is simply being interpreted as requiring, where more than one name and address is used on the label, identification of which name and address is that of the "manufacturer". Where only one name and address appears, this is unnecessary.

29. There can be confusion in English with use of the words "manufactured by" or "manufacturer", since these might refer on a label to the person who physically made the product, who might be either a sub-contractor or the legal "manufacturer". Similarly, the words "made by" would not necessarily indicate whether the person was a physical or legal manufacturer. The term 'placed on the market by" has some advantages but is subject to the confusion that recital 14 of the MDD states that authorised representatives of non-EU "manufacturers" are stated to place products on the EU market. On balance, the best recommendable form is "Manufacturer: A" and not "manufactured by A" or "made by B for A". Development of a harmonised symbol for "manufacturer" would be a good idea and entirely consistent with the approach to safety and regulation set out above.

Advisability of contracts

30. Where two or more parties are involved with a product, it is advisable for them to set out their understanding of their respective roles in a written contract. The contract should identify such matters as:

    a. Who is to be "manufacturer";

b. Who is to hold the Declaration of Conformity;

c. Who is responsible for notified body application and approval, and on whose behalf;

d. Who (if any) is a sub-contractor or a distributor;

e. Who is to hold the technical file and have access to what documentation: there is no regulatory reason why the "manufacturer" must hold or have access to all or any of such documentation - it is merely a question of what the parties will agree given the strength of their commercial bargaining positions and the degree of confidentiality which each may wish to maintain in his documentation;

f. Access to information by notified bodies and competent authorities;

g. Indemnities or exclusions of liability;

h. Obligations to pass on information.

31. Whilst it is advisable for contracts to define responsibilities, contracts might not be correct or conclusive. For example, if A and B intended A to be "manufacturer" of the product and B mere distributor, a court might find either that:

(i) the totality of the evidence was that B was "manufacturer", in which case the contract would contain some clauses which were inoperable as between A and B, or

(ii) A was the "manufacturer" but had committed a labelling offence in failing to state his name on the product.

Conclusion

32. The test of who is the legal manufacturer of a product has to be decided on the responsibility test, not ultimately the name test.

33. Whoever is the "manufacturer" of a product, his name or trade name and address must be stated on the label.

34. It is irrelevant how many names, logos, colours etc appear on the label and what their relative size or prominence might be.

35. If the "manufacturer" is located in the EU, the label should state:

"Manufacturer": name/trade name and address"

36. If the "manufacturer" is located outside the EU, the label should state

"Manufacturer: name/trade name and address

Authorised representative (or importer): name and address"