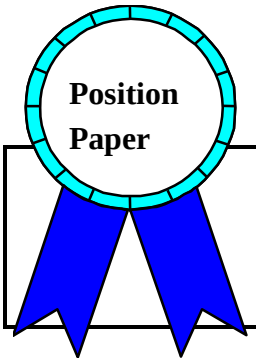

The IVD Directive and "borderline" products

November 2001

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INTRODUCTION

However good legislative definitions may be, their application to specific products is often difficult and unclear and there are always "borderline" products. The IVD Directive will be no exception.

In the case of the Medical Devices Directive (MD Directive) there are, for example, "borderline" issues between that Directive and the directives relating to medicinal products. However, those two sets of Directives are not mutually exclusive and Guidelines have been established to complement the legislative provisions regulating their concurrent application.

In the case of the IVD Directive and the MD Directive, issues will arise as to whether a product falls within one or other of them. This "medical device or IVD medical device?" issue is of particular significance because these two directives are mutually exclusive - that is to say that no particular product can fall within the scope of both Directives because Articles 1.5 (a) of the MD Directive specifically excludes its application to "in vitro diagnostic (medical) devices".

Moreover, in the case of the IVD Directive, issues will also arise as to whether a product that is intended to be used for or in connection with the analysis of human specimens is an "IVD medical device" or is not even a medical device at all. [This particular issue is dealt with in Question and Answer n° 44]

The purpose of this Guidance paper is to highlight some of the issues and arguments that members may find useful in considering the question of "borderline products".

IMPORTANCE OF THE DISTINCTION

The importance of knowing whether a product is a "medical device" or "an in vitro diagnostic medical device" lies in the fact that that fundamental decision determines which of the two mutually exclusive Directives is applicable and, while both Directives are expressly designed to ensure a high level of protection, it is important to understand that several important differences arise either from the specific texts of the two Directives or from their application.
For example:

- the essential requirements and conformity assessment procedures of the MD Directive were developed and adopted on the basis that that Directive would not apply to IVD medical devices and they are, therefore, different from those of the IVD Directive which were developed specifically taking into account the particular nature of IVD medical devices;

- the labelling provisions of the MD Directive were developed without any reference to the special nature and characteristics of the IVD medical devices and without regard to the specialised information needs of their professional and lay users. For example, understandably, the labelling provisions of the MD Directive do not require information to be given in the instructions for use about the specific analytical performance characteristics of the device whereas such information is of fundamental importance to the

professional users of IVD medical devices;

- unlike the IVD Directive, the MD Directive contains no provision for the development and adoption of common technical specifications and, therefore, devices falling within the scope of the MD Directive cannot be required to comply with any such quasi-mandatory specifications;

- harmonised standards developed, adopted and published in the Official Journal of the European Communities specifically for the purposes of the IVD Directive would not give rise to the legal presumption of conformity in respect of devices that fall within the scope of the MD Directive;

- notified bodies designated for the purpose of the MD Directive will not have (or are very unlikely to have) competence in the field of in vitro diagnostic medical devices and certainly any such competence that they may have will not have been assessed by the designating competent authority;

- unlike the IVD Directive, the MD Directive does not contain any requirements for mandatory batch verification by a notified body with regard to devices which would otherwise be covered by Annex II, List A of the IVD Directive.

These examples indicate the crucial nature of the decision that will sometimes have to be made as to whether a product is a medical device or an IVD medical device. They also demonstrate the need for authoritative Guidelines to be established to ensure as far as possible that, as regards any particular product and within the provisions of the two Directives, the most appropriate and consistent decision in the interests of public health is reached. Until such Guidelines have been developed, different and inconsistent decisions by manufacturers, by notified bodies and probably, by competent authorities are likely to be inevitable.
It is conceivable, for example, as explained below, that a device intended for the detection of HIV in a human specimen and which is required at some stage to come into contact with the patient (e.g. for the purpose of collecting the specimen) might be categorised as a medical device for that reason when, in reality, the primary intended purpose of that product is that of an IVD medical device and the interests of public health would seem to be better served by its being regulated by the IVD Directive.

THE "BORDERLINE" DEVICES INVOLVED

Broadly speaking, the basic distinction between the MD and IVD Directives is that the former applies to medical devices that are intended to be used by coming into contact in some direct or indirect way with the patient whereas the latter applies to medical devices that are intended to be used "in vitro" for the purpose of diagnostic examination and thereby of providing information from samples taken from the human body. For most devices this is a valid and workable distinction.

However, there are some devices where this distinction is blurred. For example, some devices which have always been regarded as IVD products need to be brought into contact with the patient, albeit momentarily, for the purpose of collecting the specimen that is to be analysed.. (Such a device might well be designed in this way if it were essential for fresh blood to be used in the test.) As is explained below, the position of such products may now have to be reconsidered.

This type of product can be illustrated, for example, by reference to cuvettes which contain some or all of the reagent material to be used and whose method of use involves their being placed on the patient briefly to collect a small, fresh specimen of

the patient's blood after a small prick has been made by a sterile lancet (a medical device). Laboratory analysis then follows. While some may argue that such a cuvette is a medical device because it comes into contact with the patient (as to which approach, see below) it is obvious that, in reality, the primary intended use of such a product is an IVD medical device and it ought to be regulated as such. One only has to think of such a test being intended for use in the detection of HIV to realise that public health interests would be best served and could only really be served by regarding it as an IVD medical device.

Other examples of such "borderline" products are:

- a breath test (e.g. for *Helicobacter pylori)* involving a reagent containing device with an integrated mouthpiece,
- a device involving the vacuum suction of mouth saliva into the integrated device handle which contains reagent material (e.g. for the detection of HIV),
- a device containing reagent material for blood glucose determination and which has its own in-built spring loaded finger prick lancet device,
- non invasive devices for the detection of blood glucose by energy emission (e.g. near infrared energy)

Developing technology will certainly produce more of these "borderline" products.

Discussion

Essentially, reagent devices of the type mentioned above fulfil all aspects of the definition of an "in vitro diagnostic medical device" for the purposes of the IVD Directive. Moreover, they are and have always been regarded by users as "IVDs" and, in so far as Member States have in the past had their own national regulatory systems for IVD products, this type of product has invariably been regarded as being within their scope.

However, there have been suggestions that, under the medical devices directives, such devices should be regarded as medical devices and not as IVD medical devices because, so it is said, either:

(1) since their intended method of use involves their coming into contact with the patient at some stage, then they cannot be said to be intended "to be used *in vitro* for the examination of specimens", or

(2) they are "....directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive 93/42/EEC....."

As to point (1), one of the determining points for a product to be an IVD medical device is that it should be ".... Intended by the manufacturer to be used *in vitro* for the examination of specimens ...". The devices under consideration are clearly intended for such use and, indeed, that is their principal intended purpose. The brief coming of the reagent material container or the reagent strip into contact with the patient in order to collect the specimen is only secondary to that purpose. That secondary purpose does not have and should not be given such significance as to take the product outside the scope of IVD Directive and put it within the scope of the MD Directive. To do so would mean in effect that a product which is generally accepted as being an "in vitro diagnostic medical device" would become subject to the provisions of a Directive which, ironically, is the very Directive that, in Article 1.5(a), specifically excludes its application to in vitro diagnostic medical devices.

In this same context, it has been suggested that these diagnostic reagent devices that come into contact with the patient, albeit

momentarily, should be covered by the MD Directive because Annex I of that Directive specifically addresses the question of the risk to the patient of infection and microbial contamination (Annex I, Section 8.1).

However, in exactly the same way, the IVD Directive itself addresses the same issues of risk "to the users and other persons" (Annex I, Part B, Section 2.1) and, in the context of these devices, "other persons" would obviously include patients. Any risk to which those patients may be exposed would be identified and assessed in the course of the required risk analysis and would have to be properly resolved in accordance with the requirements of the Directive. The very same state of the art solutions to protect those patients from any identified risks would have to be adopted as would have been appropriate had the device been considered as a medical device.

Historically such IVD medical devices that momentarily come into contact with the patient in the course of the specimen collection have been in widespread use for many years and have been licensed as IVD products. No patient harm, infection or contamination appears to have been reported.

As to point (2), the quotation cited is taken from the second paragraph of Article 1.2(c) of the IVD Directive which sets out the definition of "accessory" and it is important to note that this definition expressly only applies to an article which is not an in vitro diagnostic medical device. That being so, if the article in question is, in fact, an IVD medical device, then the question whether it is an accessory is wholly irrelevant and Article 1.2(c), including the second paragraph, should really have no application. That second paragraph is relevant only where the question is as to whether the article in question is or is not an "accessory" to an IVD medical device. This question does not arise in connection with the "borderline" devices that are subject matter of this Guidance paper because so it may be argued, they are in vitro diagnostic medical devices in their own right. It cannot have been the intention of the European legislator to take such IVD devices out of the scope of the IVD Directive and into the scope of a Directive that expressly does not apply to IVD devices by the side-wind effect of a short sentence in the second paragraph of the definition of "accessory".

EDMA'S VIEW

It is clear that the wording of some parts of both the MD Directive and the IVD Directive make it difficult to decide as regards some products which of the two Directives applies. At the same time, it is in the interest of all parties involved, i.e. manufacturers, notified bodies and competent authorities, patients and users, that different and inconsistent decisions are avoided. It may be that, eventually, amendments to one or both of the Directives in question will prove to be necessary if these difficulties are to be fully resolved, but that would take time to be achieved. In the meantime, the only way to avoid or to minimise the risk of inconsistent decisions is for the Commission together with the Member States to develop appropriate authoritative Guidelines. While it may not resolve all problems, it would be of considerable help if it were to be authoritatively stated in an authoritative Guideline that in determining which of the two Directives applies to a particular device, the principal intended purpose of the product should be taken into account. That criterion appears in Article 1.6 of the MD Directive in relation to issues arising between that Directive and the Personal Protective Equipment Directive and it would be of considerable help if it applied in connection with issues between the MD and the IVD Directives. Incorporated into a Commission MEDDEV guidance document together with well-chosen agreed examples, such a statement would save all interested parties a great deal of time and confusion.

It is to be noted that, while the Commission is legally bound by Article 11.4 of the MDD to submit a report in the next few months to the Council about the operation of certain

provisions of that Directive, the Commission and the Member States have agreed that, at the same time, a review should also be conducted into the operation of various other aspects of the medical devices directives and one of these other aspects is the borderline between the various "new approach" directives. One such borderline that is to be considered is the one between the MD Directive and the IVD Directive and, in this context, EDMA will continue to press for appropriate Guidelines to be developed as quickly as possible.

EDMA EdiCo
November 2001