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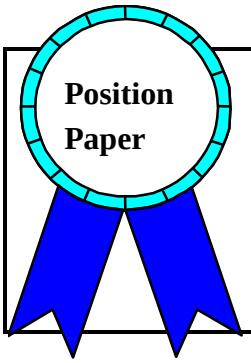

Supply of Instructions for Use by other means

(for IVD reagents for professional users)

October 2000

INTRODUCTION

Many years of experience in the area of laboratory medicine have shown that in vitro diagnostic medical devices (IVD) are safe and reliable in the hands of trained professional users. The appropriate information provided by the manufacturer to the customer as Instructions for Use (IFU) of the device not only ensures the safe and proper use of the device but also establishes a proper scientific and technical relationship between the two parties involved. Nowadays, IFU are provided mostly in English, but also in a few other major European languages. The advent of the IVD Directive 98/79/EC not only means more control on design and manufacturing of IVD but also more strictly regulates the supply of information from the manufacturer to the customer.

However, now that (draft) transpositions are available in most Member States, it appears that the IFU will need to be supplied in the future in more national languages than today. Although the requirement for providing labeling in national languages is not contested in any way, continuing to supply IFU in the traditional way (i.e. including in the packaging of one or more devices) will increase logistical complexity and cost.

The IVD Directive states under article 4.4:

> *"Member States may require the information to be supplied pursuant to Annex I, part B, section 8 to be in their official languages when a device reaches the final user.*
>
> *Provided that safe and correct use of the device is ensured, Member States may authorise the information referred to in the first subparagraph to be in one*
>
> *or more other official Community language(s).*
> *In the application of this provision, Member States shall take into account the principle of proportionality and, in particular:*
> *a) Whether the information can be supplied by harmonised symbols or recognised codes or other measures;*
> *b) The type of user anticipated for the device."*

For devices for self-testing, the necessity to provide IFU together with the device in the required national language(s) is clearly recognized by all parties taking into account the type of user, i.e. lay persons.

Applying the same requirement to IVD for professional use regarding the means of supplying IFU does not seem to take full account of the type of user anticipated.

The following aspects clearly differentiate professional users from lay persons:

- The competence and skill sets of clinical laboratories and their staff (ensured at national level by regulations governing the practice of medicine),
- Training of users,
- The frequency of use of the device and
- The widespread access, knowledge and use of modern communication technology in the medical laboratories.

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Moreover, because of their interests to incorporate IFU in their quality systems to facilitate accreditation and to reduce the amount of laboratory waste, professional users have requested to be supplied with IFU by other means.

The goal of the following proposal, which enables other means of supplying IFU for IVD for professional use only, is to find the right balance between ensuring the safe and proper use of the device, the needs of the targeted customer (professional user) and the waste reduction and preservation of the environment. At the same time, it meets the interests of all parties involved.

PROPOSAL

Industry feels that besides the traditional "*IFU in the kit*"-concept, other means of supplying IFU should be carefully considered such as:

- IFU in printed form, provided separately from the device, but available to the customer at the time of use (e.g. by mail, through local sales organization)
- IFU provided by other means (e.g. by fax, by CD-ROM, ...)
- IFU made available electronically (e.g. through Internet, ...)

In order to ensure a proper and safe use of the device by the professional user, manufacturers shall supply together with the device in the national language(s) the following information:

- a reference to the relevant version of the IFU,
- indication of the various options to obtain the relevant version of the IFU to meet the customer need,
- warnings and precautions, where appropriate,
- any specific batch related information not provided in the IFU, where appropriate,

and in case of revision to the IFU:

- Clear indication of the revision placed on the outer label or provided within the device packaging.

It is the manufacturer's responsibility to carefully consider the feasibility of these options especially in the light of professional users' needs. The manufacturer will make certain that the user has the technical means to receive IFU by the chosen option. In any way, the chosen options of supply of IFU must ensure security (e.g. data protection against fraud in case of Internet), and safe use.

BENEFITS

The benefits of this proposal can be summarised as follows:

- Focusing on essential information and elimination of redundant information :
  - By supplying IFU only in the required language(s)
  - By supplying IFU only when needed.
- Protection of environment through reduction of paper and packaging waste.
- Avoidance of logistical complexity and its associated costs.

Additionally, in case the IFU is made available through electronic means (e.g. Internet):

- The proposal enables professional users to incorporate the IFU into their Quality System, thus facilitating laboratory accreditation, while minimising the risk of retyping errors.
- The proposal provides access to the IFU in all required languages for all parties involved (Professional users, Notified Bodies, Competent Authorities), wherever and whenever needed.

CONCLUSION

Based on the above, one can conclude that it is in the interest of all parties involved to enable the supply of IFU by means other than the traditional '*IFU in the kit*' concept. Moreover it opens the way for future adoption of new state of the art communication technologies.

The proposal ensures that the user will always have available to him the relevant IFU at the time of use of the device.

Of course, the alternative options provided should ensure security and should warrant a safe and proper use of the device, providing a level of safety at least equivalent to or better than the current practice.

A consensus with the Competent Authorities in the different countries is needed to allow the manufacturers to put in place the structures necessary to supply IFU by other means. Industry should be happy to get any comments back from the Competent Authorities and the European Commission.

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