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GUIDELINES ON MEDICAL DEVICES

IVD GUIDANCES: Supply of Instructions For Use (IFU) and other information for *In-vitro* Diagnostic (IVD) Medical Devices

A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

Note

This guideline is part of a set relating to the application of EC Directive 98/79/EC on *in vitro* Diagnostic Medical Devices (IVD Directive). It is not legally binding but has been jointly drafted by various interested parties including Competent Authorities, the European Commission services and industry. As such it can be taken as reflecting positions taken by those stakeholders in the medical device sector and it is anticipated that they will be followed within the Member States and help ensure uniform application of relevant provisions of the Directive.

1.0 Introduction

Annex I, section 8.1 of the IVD Directive 98/79/EC requires manufacturers, to supply the information necessary for the safe and proper use of the device but does not provide a lot of details on how this should be done (Annex I, section 8.1 also indicates that in duly justified and exceptional cases no such instructions for use are needed for a device if it can be properly and safely used without them).

Currently most instructions for use (IFU) are provided in paper format. However, these documents can be very lengthy due to the need to include multiple printed versions in all the required languages. Also, the cost of using paper can be high to both manufacturers and the environment. Given that most IVDs are used by healthcare professionals in a clinical environment, with relatively common access to computers and internet facilities, the possibility of issuing the IFU for professional users in a format other than paper for example, by CD-Rom or DVD or through different means of supply, for example, an Internet website, has been raised.

2.0 Scope

This guideline has been developed to advise manufacturers on how to provide IFUs and other information for the safe and effective use of IVDs while taking into account any limitations or safeguards to be employed appropriate for the user population and the media or means of supply chosen. It should be read in association with the labelling requirements of Annex I, section 8 of the IVD Directive 98/79/EC and with the language requirements of the transpositions of article 4(4) of the IVD Directive 98/79/EC by the Member States.

3.0 Definitions

- **Instructions For Use (IFU)**
Information provided by the manufacturer to inform the device user of the product's proper use and of any precautions to be taken as outlined in Annex I of the IVD Directive 98/79/EC.
- **Different media:** other than paper form, e.g. CD-Rom, DVD, etc.
- **Different means of supply:** provision of IFU by sales force, fax, internet, etc, rather than by inclusion of paper IFU with the device itself.
- **Layperson**
An individual who does not have formal training in a specific field or discipline (Source ISO 15197 and GHTF SG1 N043). (Training received by a diabetic patient for the safe use of, for example, a glucose meter would not constitute "formal training" in the context of this definition.
- **Professional Use**
Use by personnel who have received specialised education and training with regard to procedures utilising *in-vitro* diagnostic medical devices (Source EN 375).
- **Point of Care Testing**
Testing that is performed near or at the site of a patient with the result leading to a possible change in the care of a patient. (Source ISO 22870)
- **Self-Testing**
Use in the home or similar environments by a layperson who will relate the results of the test to him or herself (Source EN 376).

4.0 Provision of the IFU for an IVD

The IVD Directive 98/79/EC clearly states that each IVD must be accompanied by the information needed to use it safely and properly taking into account the training and the knowledge of the potential user. The format in which the IFU shall be supplied is not specified in the IVD Directive. However, the stakeholder consensus is that the appropriate media and means of supply is dependant on the category of users.

IVDs can be split into two major categories with respect to their user population i.e.:

- IVD for self testing
- IVD for professional use

4.1 IVDs for Self-Testing

The IVD Directive defines such devices as those intended by the manufacturer for use by laypersons in a home environment. Such a user need have no formal education and / or training in using IVD tests. Self-test IVDs may be single use devices e.g. pregnancy tests or may be used regularly by a layperson to monitor and control a particular disease e.g. glucometers for diabetes. Typically, the result is used directly by the user who is the patient.

IFUs for IVDs to be used principally by laypersons shall always be provided in a paper format with the device. This is because the user needs ready access to the IFU but cannot be assumed to have access to the necessary information technology systems to access an electronic format or to obtain the IFU by other means.

4.2 IVDs for Professional Use

In general, these IVDs are used in a healthcare institution e.g. medical laboratory, by professionals who have a formal education and expertise in performing IVD tests and using IVD instrumentation. These IVD tests are typically carried out repetitively and in a routine setting as part of a healthcare service to the patient. Test results are interpreted by a healthcare professional as part of the clinical management of a patient.

The IFU for IVDs intended for professional use can be provided in either paper or non paper form or be supplied by different means such as:

- providing a free of charge **telephone** number that can be contacted to have the IFU faxed, mailed or e-mailed
- making the IFU available at a fax call in number: **fax polling**
- making it available through a designated **internet** website
- or distribution through local **sales organisation**

Where the manufacturer elects to supply the IFU in a format other than paper, he shall provide a 'free of charge' contact number that can be used in order to have the IFU faxed, mailed or e-mailed to the user.

Exception

IFUs for IVDs that are specifically intended by the manufacturer for use at point of care shall be provided with each device in paper format. This is because there may not be ready access to information technology systems at the point of use of the IVD.

5.0 Instructions for Use for Reagents, Reagent Kits, and Specimen Receptacles for Professional Use

This section outlines the conditions for the provision of the IFU in a format other than paper and the minimum information that shall accompany an IVD if a manufacturer chooses to provide the IFU by other means of supply. In all cases the manufacturer shall comply with the labelling requirements outlined in Annex I, section 8 of IVD Directive 98/79/EC and with the language requirements of the transpositions of article 4(4) of the IVD Directive 98/79/EC by the Member States.

Note: Under article 10.2 of the IVD Directive, the manufacturer may be requested by the Competent Authority to provide information on the labelling and the IFU. The information provided at that moment should be equal to what is provided to the user irrespective of the media or means of supply.

5.1 Conditions for the Provision of an IFU by other Media or Different Means of Supply

1. The device must only be used as outlined in section 4.2
2. The manufacturer must ensure the proper design and function of the IFU for all media and means of supply and document the verification and validation of same as part of the quality system. This should be reviewed by a Notified Body, if applicable, as part of the conformity assessment process.
3. The manufacturer, informed by the views of healthcare professionals, must have carefully considered as part of his risk management, the risks associated with the provision of the IFU by other media and means of supply especially in light of the product usage and the professional users' need. This should be reviewed by a Notified Body, if applicable, as part of the conformity assessment process.
4. The user should be informed via the catalogue and / or the device labeling and / or any other appropriate communication that the IFU for the device will be supplied by other means to ensure that the user will have the IFU at the moment of use including any necessary equipment to read the IFU.
5. Where IFUs are posted on an internet website, manufacturer must comply with the additional requirements as defined in section 5.3 below.
6. The manufacturer must have a system in place to provide in a timely manner a paper version of the IFU on request by the user at no additional cost.
7. The manufacturer must comply with the information requirements as defined in section 5.2 below when the IFU is provided by different means of supply.
8. For revisions to the IFU there shall be a clear indication on the device label to indicate to the user that the IFU has been changed by reference to the latest revision.
9. If a revision to the IFU is necessary due to a field safety corrective action the manufacturer must ensure that each user of the device, that is already placed on the market, is informed about the change and provided with either the information on how to obtain the latest version of the IFU by other means or be provided with the IFU as a paper copy or other appropriate media.

5.2 Information to be Supplied with IVD when the IFU is Supplied by Different Means of Supply

The following information shall be supplied with each device when the IFU is provided by other means:

- The name and address of the manufacturer or authorized representative
- The various options to obtain, free of charge, the applicable version of the IFU, except when provided with the initial delivery of the instrument in a controlled way.
- A unique reference (and any other information needed by the user) to identify the right version of the IFU. This reference should allow the user to retrieve the applicable IFU using any of the options provided.
- When the IVD is considered dangerous for the user (e.g. chemical, radioactive and/or biological risk), the outer container should include the appropriate hazard symbol(s) and the corresponding risk and safety phrase numbers. But in case of specific biological risk, e.g. where an IVD reagent includes substances of human or animal origin, or when no symbol is available, a warning should be given in the additional information supplied with each device concerning their potentially infectious nature taking into account the risk posed by the nature or amount of the substances.
- Where appropriate, any batch specific related information not provided in the IFU obtained by other means (e.g. the value of a certain parameter to be used on an instrument or any specific settings to be used on a particular type of instrument etc).
- In case of revision to the IFU a clear indication on the device to alert the user that IFU has changed. This also applies in situations where the IFU is changed as a result of a safety field corrective action.

This information can appear on the device label if space permits or can be provided on a separate sheet included with the device.

The following is an example of how this information may be presented with an IVD when the IFU is provided by other means of supply:

PRODUCT NAME	CATALOG NUMBER
Manufacturer/Authorised Representative Name	
Valid edition of the instructions for use: 2003-10	
If you do not have this edition, you can obtain it free of charge:	
1. from Internet under www.edma-ivd.be/IFU	
2. by calling up free of charge the following phone number: +32 2 ...	
<u>SAFETY WARNING</u>	
The calibrators have been prepared exclusively from the blood of donors tested individually and shown by official approved methods to be free from HbsAg and antibodies to HIV 1, HIV 2 and HCV. As the risk of infection cannot be ruled out with certainty, however, the product must be handled just as carefully as patient specimens.	

Note 1: This is only an example and is not binding for format or content.

5.3 Internet Website – Additional Requirements for Provision of IFU

In addition to the conditions outlined in section 5.1, the manufacturer shall also meet the following requirements for the supply of the IFU by Internet website:

- Provide clear instruction to the user to readily locate the IFU on a dedicated area of the Internet website.
- Adhere to appropriate data security requirements in terms of:
 - Physical security (availability of hardware and software and intrusion protection)
 - Server certification (to ensure the user logs on to the appropriate server).
- File format - IFU should be available in a generic read-only file format, such as PDF (portable document format). In any case, the manufacturer must ensure that documents displayed and printed via this route are identical in content to those included in the IVD kit when made available in paper format.
- Access to the reader of the provided file format is necessary (for example by providing a link for download).

6.0 Instructions for Use for instruments / Software for Professional Use

Instructions for use for instruments (sometimes also called user's guides) shall be provided in a paper copy or on different media with the initial delivery of an instrument but shall not be provided by different means of supply at the initial delivery of the instrument.

For changes as part of / an upgrade and / or field corrective action, the manufacturer shall

1. include any changed page of the IFU provided in a paper copy with clear instructions on how to include them into the initially provided IFU and which old pages to be removed or
2. include a full new paper copy or
3. include a new copy of the IFU on a CD-Rom (or other suitable format other than paper) with clear instructions to destroy the previous version of the CD-Rom.



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