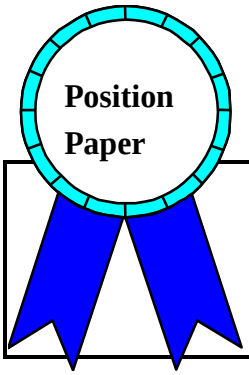

Languages and the IVD Directive

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European
Diagnostic
Manufacturers
Association

Place Saint Lambert 14
1200 Woluwé Saint Lambert
Brussels, Belgium
+32 2 772 2225 tel
+32 2 772 2329 fax
edma@edma-ivd.eu
www.edma-ivd.eu

1. THE POSITION OF THE IN VITRO DIAGNOSTIC INDUSTRY

EDMA has a view on languages in relation to the information provided with IVD Products for sale in the European Economic Area (EEA) that is as follows:

- There is no evidence that the language(s) used at present to label IVD products and to give information in the instructions for use of IVD products causes a problem for professional users of these products, or that it is a threat to the health of patients, or has any other negative influence. A change in current practice, for example the mandatory use of local languages in product labelling, will increase the cost of healthcare, without any corresponding benefit to patients. Therefore, until there is evidence of some benefit to patients or users that will outweigh any costs of a change, industry sees no value in such a change and is therefore opposed to it.

- For obvious reasons, all products that are designed for non-professional uses (e.g. self testing/by lay user) should be labelled and include instructions for use in the official language(s) of the country of sale.

The text of the IVD Directive allows Member States to require information supplied with an IVD product to be in local languages when the product reaches the final user (Article 4.4).
They may ask for the local language or another accepted EU Community language, taking into account the principle of proportionality and the final destination of the product (i.e. professional use or self testing)
Special provisions for self-testing products (Annex 1, B, Section 8, 1) state that the instructions for use and the label shall include a translation into the official language(s) of the Member State in which the diagnostic test reaches its final lay user.

2. HOW IS INFORMATION PRESENTED TO THE FINAL USER AT THE PRESENT TIME?

Many manufacturers produce one form of product for sale throughout the EEA and label in a number of major European languages (English, French, German and possibly Spanish and Italian). Instructions for use may be in a similar limited number of languages or there may be further languages included.

This does not mean that the final user will not have information in the local language. Further information is nearly always supplied in local languages by the local representative of the manufacturer or by the local distributor.
In addition, clinical laboratories may write laboratory-specific work protocols in local languages which include all or most elements of the instructions for use supplied by the manufacturer or distributor in another form (and eventually in another language). Such current practices at the laboratory level are the responsibility of the professional users and form part of the practice of clinical laboratory medicine. **It should be noted that professional users in Europe are used to English, because much of the professional or technical literature is in this language.**

Thus, in practice, the manufacturer, the local distributor and the professional in charge of the laboratory together ensure an adequate and effective transfer of information to the final user (who is usually a trained laboratory technician).

- A special case is the use of complex instruments (analysers) used in diagnostic systems. Usually such analysers require special training and follow up that is also provided by manufacturers and local distributors. It is in the interest of the manufacturer to make sure that the equipment is used correctly, because the sales of tests that are performed with the help of such analysers depend on their correct performance.

- In addition to the necessary instructions for use, manufacturers also provide extensive training of users and product literature as part of the information process.

3. WHAT ARGUMENTS DOES EDMA HAVE TO LIMIT THE REQUIREMENT FOR LABELLING IN LOCAL LANGUAGE(S) ?

There is a strong general tendency for the Member States of Europe to protect and support their national cultures. This includes strong protection of national languages. The efforts of certain MEPs to introduce into the Directive text the mandatory use of local languages on IVD products was regarded by EDMA as a manifestation of cultural nationalism expressed at the European level. In EDMA's view the use of local (Member State) language(s) can only be an individual Member State decision, in case of justified need.

Industry supports the IVD Directive as presented in the Common Position and will argue the language question at the Member State level. Here, industry must have the support of the professional users, whose opinion will carry more weight with the competent national authorities.

4. What will probably happen when the IVD Directive is transposed?

In the IVD Directive, it is up the competent authority of each Member State to decide about language(s). There would be several possibilities for Member States.

a) **Enforce national language(s).** This is a situation industry wishes to avoid.

b) **Not make any language requirements**.

c) **Require national language(s) for certain products that are considered particular in some way**

d) **Require national language(s) in principle, but upon request of manufacturer give exceptions for certain products** : sophisticated and complex high-technology products used by a relatively limited number of specialised laboratories; small volumes of reagents supplied in small vials (as the primary container) and in small boxes (as the secondary container), so that the lack of space on the labels makes physically impossible for manufacturers to give text in multiple languages.

The five major countries' languages are mostly covered by manufacturers and in these countries the competent national authorities would have the power to enforce national language if and when required. Among the smaller countries the aim should be to avoid such broad enforcement of local language(s).

A quite likely scenario would be the possibility (d). In practice this would mean that companies wishing to market products in smaller countries would have to ask for exemption from local language requirements if they are not prepared to

label them in local language(s). If this exemption is not granted the company might choose not to sell in the local country market. Presumably clinical laboratories will not be allowed to import products that do not fulfil local language requirements. This would not necessarily be beneficial for the patient health care.

5. WHAT COULD BE THE EFFECT OF MANDATORY LOCAL LANGUAGES ON IVD PRODUCTS FOR PROFESSIONAL USE?

- For "small" products:
  Smaller type face onto a label, decreased legibility

→ negative impact upon product safety

- For "high-technology" products manufactured in small batches:
  Dramatic increase of translation and labelling cost, product not available in certain (smaller) countries

→ danger to health

- For area-specific or language-group products:
  Loss of economies of scale

→ increase in cost.

- Trade barriers:
  Non uniformity of health care, no single market

→ parallel import problems.

- Central translation:
  Mistakes in translation, difficulties in translation control

→ danger to health

6. CONCLUSION

For products intended to be used by highly trained professional experts, EDMA opposes proposals that this information must be given in several additional languages (compared to current practice and legal requirements). This is not justified on the grounds of safety and would add significant costs - at time when governments, throughout Europe, are trying to contain increases in health-care expenditure

Labelling Working Party
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