Question for written answer E-007052/2013
to the Commission
Rule 117
Anna Rosbach (ECR)

Subject: Different wording in different language versions of a directive

It is important that the meaning of EU legislation should always be clear, regardless of which of the official languages it is translated into. However, mistakes can and do happen. One such case seems to be the Medical Devices Directive 93/42/EEC. In Annex 1 to this directive, Essential Requirements, Section 13, Information supplied by the manufacturer, subsection 13.6, it says:

> 'Where appropriate, the instructions for use must contain the following particulars:
> (q) date of issue or the latest revision of the instructions for use'.

However, in other language versions (such as Spanish, Italian and Dutch) there is no 'or'; instead, it is stated that the instructions for use must contain:

> 'the date of publication of the latest version of the instructions for use' (in Spanish: 'fecha de publicación de la última revisión de las instrucciones de utilización').

In connection with this, can the Commission please answer the following:

1. Is it really sufficient to include only the date of issue in the instructions for use of a medical device, rather than the 'latest revision of the instructions for use'?

2. What does the Commission intend to do about this discrepancy in meaning between the language versions?

3. Does the Commission know if this difference in wording has led to the Member States implementing the directive in different ways?

4. If citizens, organisations or companies discover such a discrepancy among translations, is there an easy way for them to report it? And can it then be ensured that a correction is made – or at least a memo published explaining the differences and stating which is the valid interpretation of the text?