Question for written answer E-004765/2013
to the Commission
Rule 117
Anna Rosbach (ECR)

Subject: Medical devices and translation

EU legislation on medical devices has so far been marked by great differences between how Member States have implemented that legislation and between the requirements which exist in individual Member States.

One of the ways in which these requirements differ is in relation to translation. Some countries believe it to be acceptable for instructions to be written in English alone, while others require that these be translated into the native language(s). The same principle applies for the labels that either go outside or inside the packaging of medical devices or on the device itself.

In light of the above, could the Commission answer the following:

1. What language requirements are applicable to instructions for medical devices for patients in each Member State?

2. What language requirements are applicable to instructions for medical devices for healthcare practitioners in each Member State?

3. What language requirements are applicable to the labelling of medical devices in each Member State? Also, are there differences between the requirements for labelling which appears inside the packaging and that which appears outside? If so, what are they?