

Stockholm 13 September, 2010

To the European Commission Health and Consumers Directorate-General

Revision of directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices – Public Consultation

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The Swedish Society of Medicine appreciates the opportunity for public consultation and would like to address the following issues.

**Question 1 through 6:** *Our opinion of a risk-based classification and conformity assessment.*

Yes, we regard a risk based classification of IVD medical devices an improvement compared to the current system. Regardless of which of the suggested models that is selected for pre-market control, it is essential that an efficient post-market surveillance is implemented.

**Question 8:** *If the exemption provided for by article 1(5) of Directive 98/79/EC should be clarified of limited, what is appropriate in order to clarify the scope of this exemption and ensure a high level of safety?*

We consider **item 4** most appropriate. *(To submit the health institutions and premises referred to in Article 1(5) of Directive 98/79/EC that manufacture “in house tests” to accreditation based on ISO 15189 or equivalent regulation at national level.)*

If the laboratories that manufacture and perform “in house tests” are compliant with ISO 15189, their tests are validated and documented. In addition it is essential that the quality and performance of “in house tests” are observed through post-market surveillance and demonstrated in inter laboratory comparisons.

Furthermore, we would like to point out that it is appropriate that results from external quality assessment are utilized by the manufacturers of *in vitro* diagnostic medical devices to monitor performance of their products, as a part of their post market surveillance procedure. If the schemes are performed with detailed and correct information about the devices and procedures used in the market, the results can be used to compare performances both with comparable products and with agreed standards.



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