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Subject:	Proposal for a Regulation of the European Parliament and of the Council on **medical devices**, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

In document ST 11662/16 INIT on page 185, Article 81a(5) should read:

"5. Expert laboratories may be appointed by the Commission, following consultation with the MDCG, on the basis of their expertise in

- physico-chemical characterisation, or
- microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical biological/toxicological testing

of specific devices, categories or groups of devices.

The Commission shall only appoint expert laboratories for which a Member State or the Joint Research Centre have submitted an application for designation.".

On page 186, Article 81a(6)(b) should read:

"(b) to contribute to the development and maintenance of appropriate guidance and common specifications for

- clinical investigations,
- clinical evaluation and PMCF,
- performance studies,
- performance evaluation and post-market performance follow-up ('PMPF'),
- physico-chemical characterisation, and
- microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing

for specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices;".

On page 187, Article 81a(7) should read:

"7. The Commission shall facilitate the access of Member States and notified bodies and manufacturers to advice provided by expert panels and expert laboratories concerning, among others, the criteria for an appropriate data set for assessment of the conformity of a device, in particular with regard to the clinical data required for the clinical evaluation, with regard to physico-chemical characterisation and with regard to microbiological, biocompatibility, mechanical, electrical, electronic and non-clinical toxicological testing.".