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In-House Assays

EuroGentest Workshop on Genetic Testing and the In Vitro Diagnostic Directive

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Medical Devices in the EU

Devices covered are defined by its **scope**

Three main areas of involvement:

- Access to a common internal market
- Trade facilitation and regulatory convergence
- Competitiveness of industry



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in house concept - Article 1 (5)

This Directive shall not apply to devices manufactured and used only within the same health institution and on the premises of their manufacture or used on the premises in the immediate vicinity without having been transferred to another legal entity. This does not affect the right of Member State to subject such activities to appropriate protection requirements.



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in house concept – Motivation - Recital 10

- (10) Whereas, having regard to the principle of subsidiarity, reagents which are produced within health-institution laboratories for use in that environment and are not subject to commercial transactions are not covered by this Directive;



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***in house* concept and Article 9 (13) ?**

13. The provisions of this Article shall apply accordingly to any natural or legal person who manufacturers devices covered by this Directive and, without placing them on the market, puts them into service and uses them in the context of his professional activity.



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in house concept – Article 9 (13) motivation - Recital 11

- (11) Whereas, however, devices that are manufactured and intended to be used in a professional and commercial context for purposes of medical analysis without being marketed are subject to this Directive;



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in house concept

Raises more questions e.g:

- Harmonized interpretation in all Member States?
- Context of “Professional and Commercial”?
- What is a health institution?
- Are Laboratories health institutions?



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Annex II changes



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Annex II changes - Article 14

Article 14

Amendments to Annex II, and derogation clause

1. Where a Member State considers that:
 - (a) the list of devices in Annex II should be amended or extended, or
 - (b) the conformity of a device or category of devices should be established, by way of derogation from the provisions of Article 9, by applying one or more given procedures taken from amongst those referred to in Article 9,

it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. The measures shall be adopted in accordance with the procedure laid down in Article 7(2).



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Annex II changes - Article 14

2. When a measure is to be taken in accordance with paragraph 1, due consideration shall be given to:
 - (a) any relevant information available from the vigilance procedures and from external quality assessment schemes as referred to in Article 11;
 - (b) the following criteria:
 - (i) whether total reliance has to be placed on the result obtained with a given device, this result having a direct impact on subsequent medical action, and
 - (ii) whether action taken on the basis of an incorrect result obtained using a given device could prove to be hazardous to the patient, to a third party or to the public, in particular as a consequence of false positive or false negative results, and
 - (iii) whether the involvement of a notified body would be conducive to establishing the conformity of the device.



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Revision of Medical Device Directives

Implications for IVD Directive



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Revision of Medical Device Directives - Implications for IVD Directive

In theory, very little – Exclusion of ivds from the Biocides Directive

However:

- MDD and AIMD alignment highlights non-alignment with IVDD
- Revision of New Approach



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The End

Thank You

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