Brief EU regulatory Update

Doris-Ann Williams

The political timetable

slide provided by the MHRA

January 2014
Greeks chair Member State meetings

Spring 2014
European Parliament campaigns

May 2014
European Parliament elections

July 2014
Italians chair Member State meetings

October 2014
New European Commissioners

January 2015
Latvians chair Member State meetings

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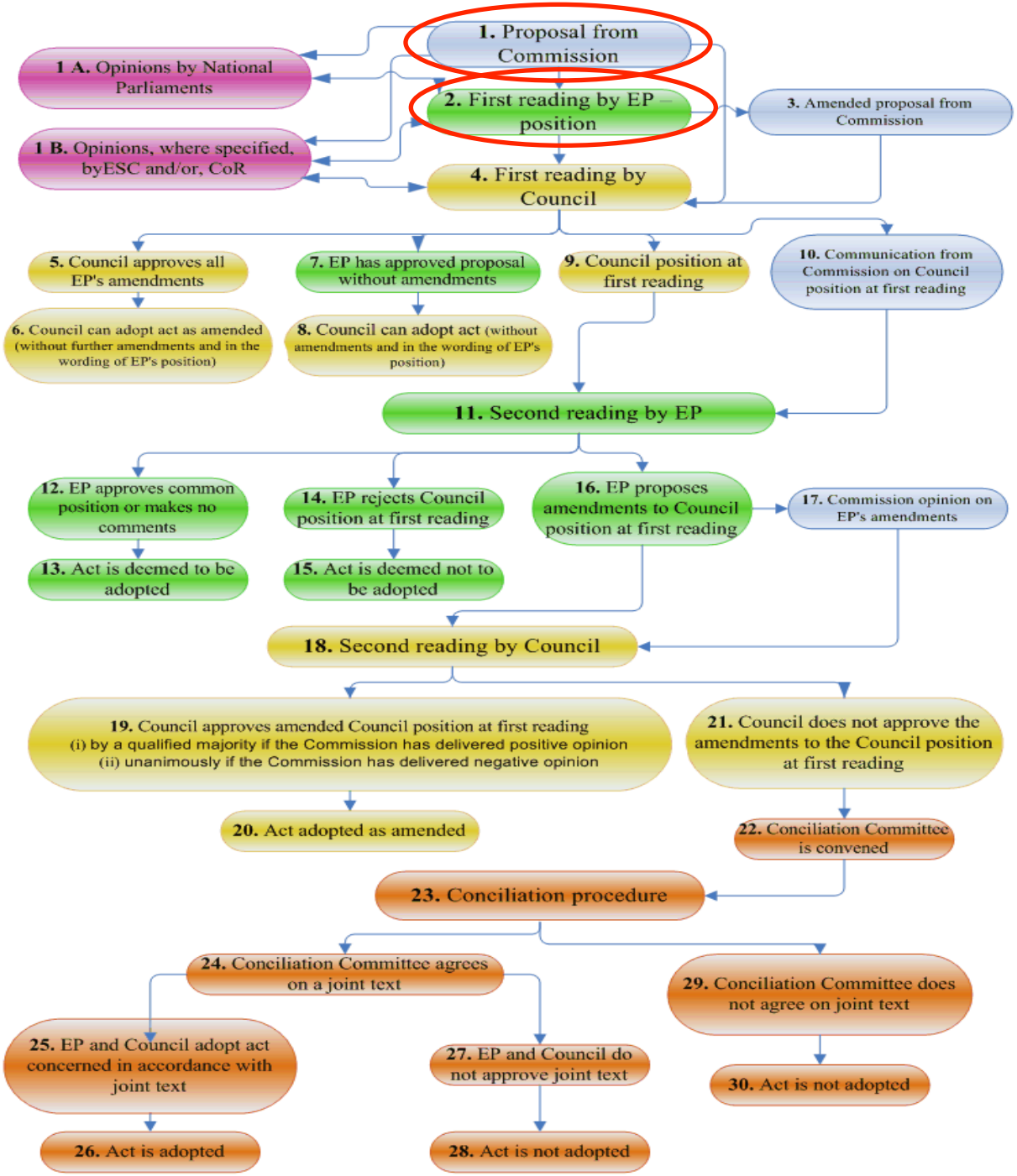
Progress!

Slide provided by the MHRA



Proposed Classification

In the new classification system, IVDs will be divided into four classes of risk:
A (lowest risk), B, C and D (highest risk)

The conformity assessment procedure for class A devices will be carried out, as a general rule, under the sole responsibility of the manufacturer

For devices of classes B, C and D an appropriate level of involvement of a Notified Body is compulsory proportionate to the risk class

Devices of class D will require explicit prior approval of the design and of the quality management system before they may be placed on the market
In the case of class B and C devices, a Notified Body is required to check the quality management system and additionally, for class C, the technical documentation of representative samples.

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Clinical evidence requirements

Covered in Annexes XII and XIII

Extended from analytical validity to

Scientific validity

ie association to a clinical condition or a physiological state

(from existing tests; literature; expert opinion; results of proof of concept studies; results from clinical performance studies)

Requirement for clinical evidence report

Analytical & scientific validity + performance studies

'Living' document expanded and amended with post marketing data

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