EuroGentest

Regulation of in-vitro Diagnostic Devices

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Background

Diagnostic tests, known as *in vitro* diagnostic devices or IVDs

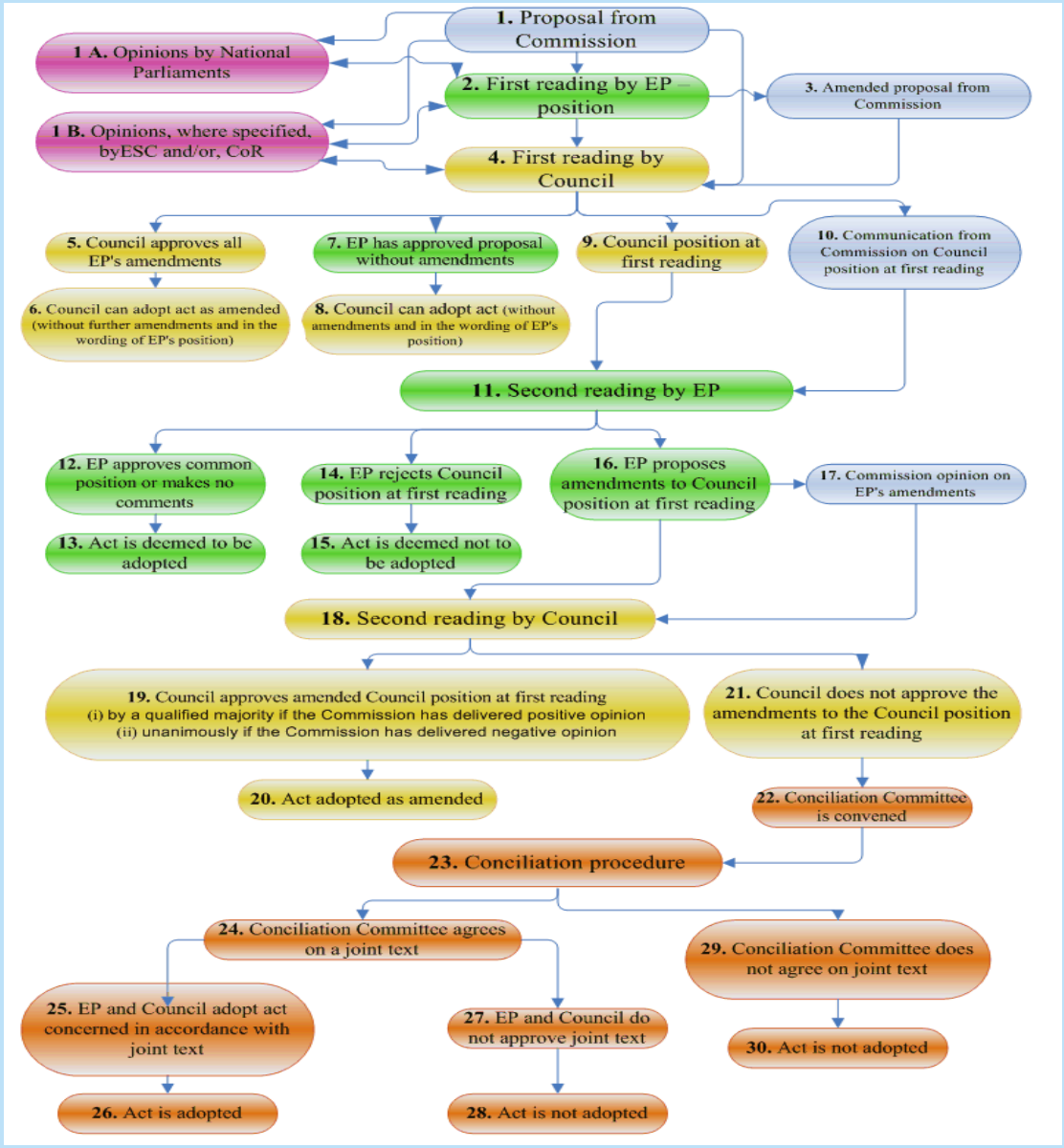
Regulated at European level under the IVD Directive (1998) ➔ National laws

IVD Directive is being replaced by an EU Regulation – direct EU law

New Regulation

- Complete re-write of the legislation
  - Medical devices and IVDs
- Public Consultations 2008, 2010
- Proposal issued September 2012
- Many improvements on current IVD Directive

The co-decision process...according to the EU



The co-decision process...in simple terms

1. Commission publishes proposal ✓

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2. Proposal is considered by European Parliament & working party of Member States – amendments proposed to text

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3. Aim to come to an agreed position on the text

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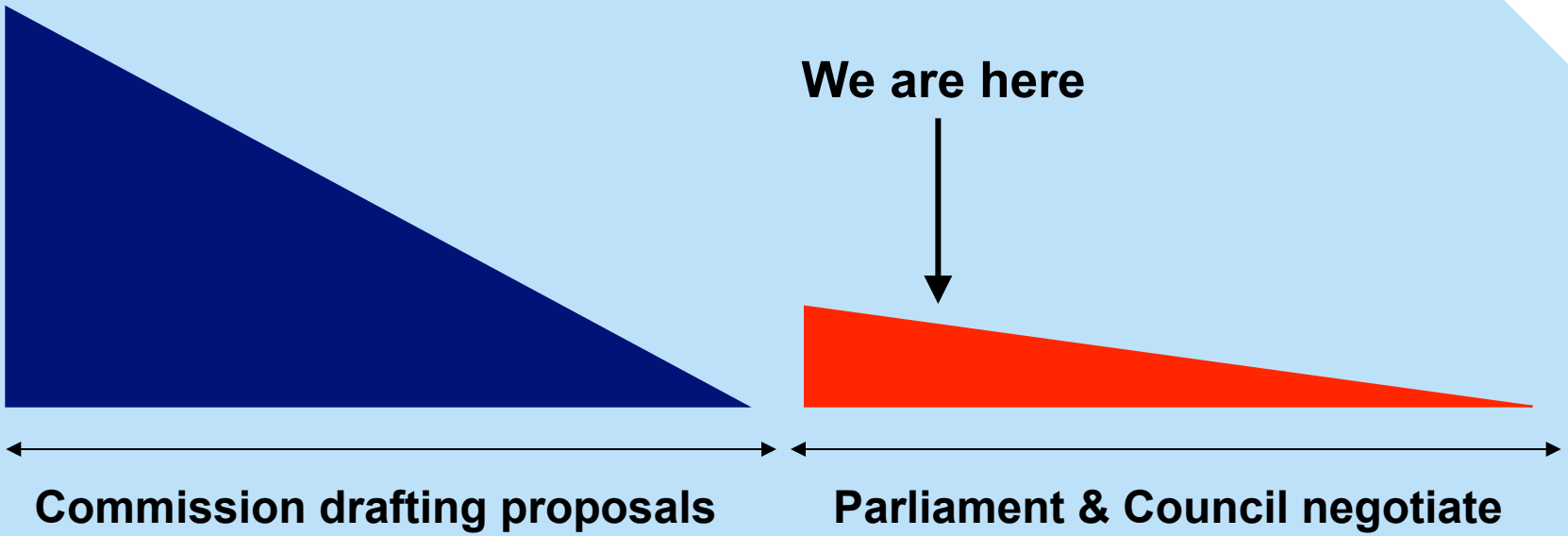
4. Disagreements negotiated through a 'conciliation committee'

Scope to influence legislation



- Door shut to changing Commission's text
- Focus switched to Member States & MEPs – political process

Mutual interests

- EuroGentest promotes harmonization and quality in genetic testing in Europe

- The medical device regulations seek to ensure the safety, quality and performance of IVD medical devices (including genetic tests)

ENVI Committee

- EP committee on Environment, Public Health and Food Safety
- Peter Liese, Rapporteur on IVD Regulation
- Workshop February 2013
  - Major focus on genetic testing
- Draft report April 2013
  - Proposed new article on clinical genetics

Genetics Article

- Seeks to regulate the practice of Clinical Genetics via the new IVD Regulation:

"1. A device may only be used for the purpose of a genetic test if that test is conducted by persons admitted to the medical profession under the applicable national legislation"

"3. Before using a device for the purpose of a genetic test the person referred to in paragraph 1 shall provide the test subject concerned with appropriate information on the nature, the significance and the implications of the genetic test"

Genetics Article

"No prenatal genetic examination designed to detect the genetic predisposition of an embryo or a foetus to a disease may be conducted if, on the basis of current medical knowledge and technology, it is generally accepted that the disease in question will not manifest itself before the individual concerned reaches the age of 18"

"A device may only be used for the determination of gender in connection with prenatal diagnosis, if the determination fulfils a medical purpose and if there is a risk of serious gender specific hereditary diseases"

ESHG Position Statement

Issued 8 May, 2013

"ESHG views this proposal as unworkable in the daily practice of genetic medicine"

"The inclusion of the proposed new article as written would place a severe burden on genetics services which operate with limited resources, inevitably meaning that fewer, not more, patients would benefit from genetic testing"

National Societies

- Contact MEPs in your country
  - Especially those involved in ENVI committee
- Contact your national medical devices/IVD regulatory body
- Contact your Health Ministry

- Endorse the ESHG position

www.europarl.europa.eu/committees/en/envi/home.html

EuroGentest Team

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Thanks to:

- Alda Sousa, MEP