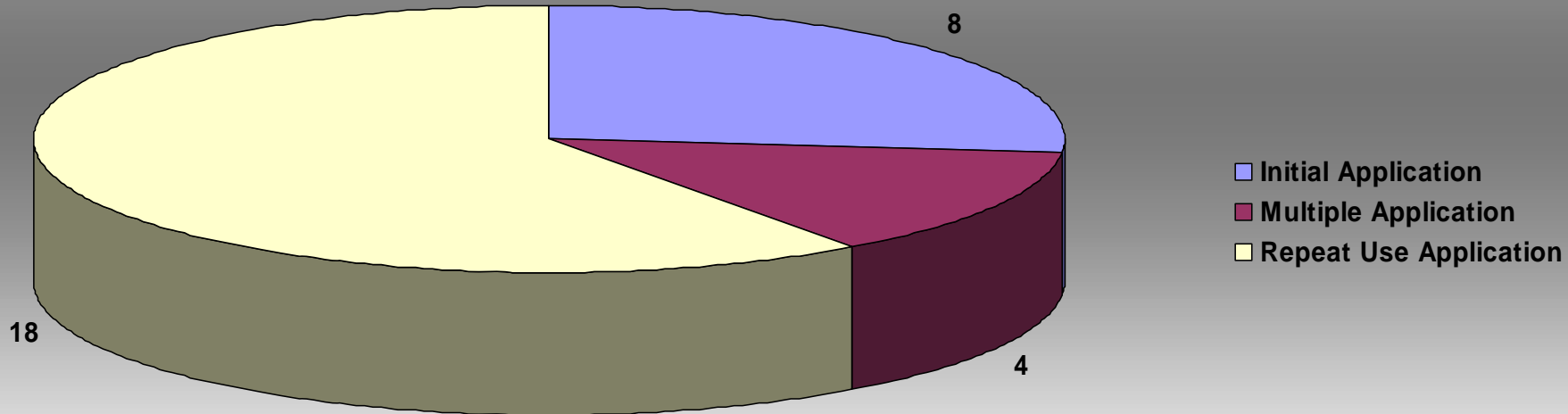
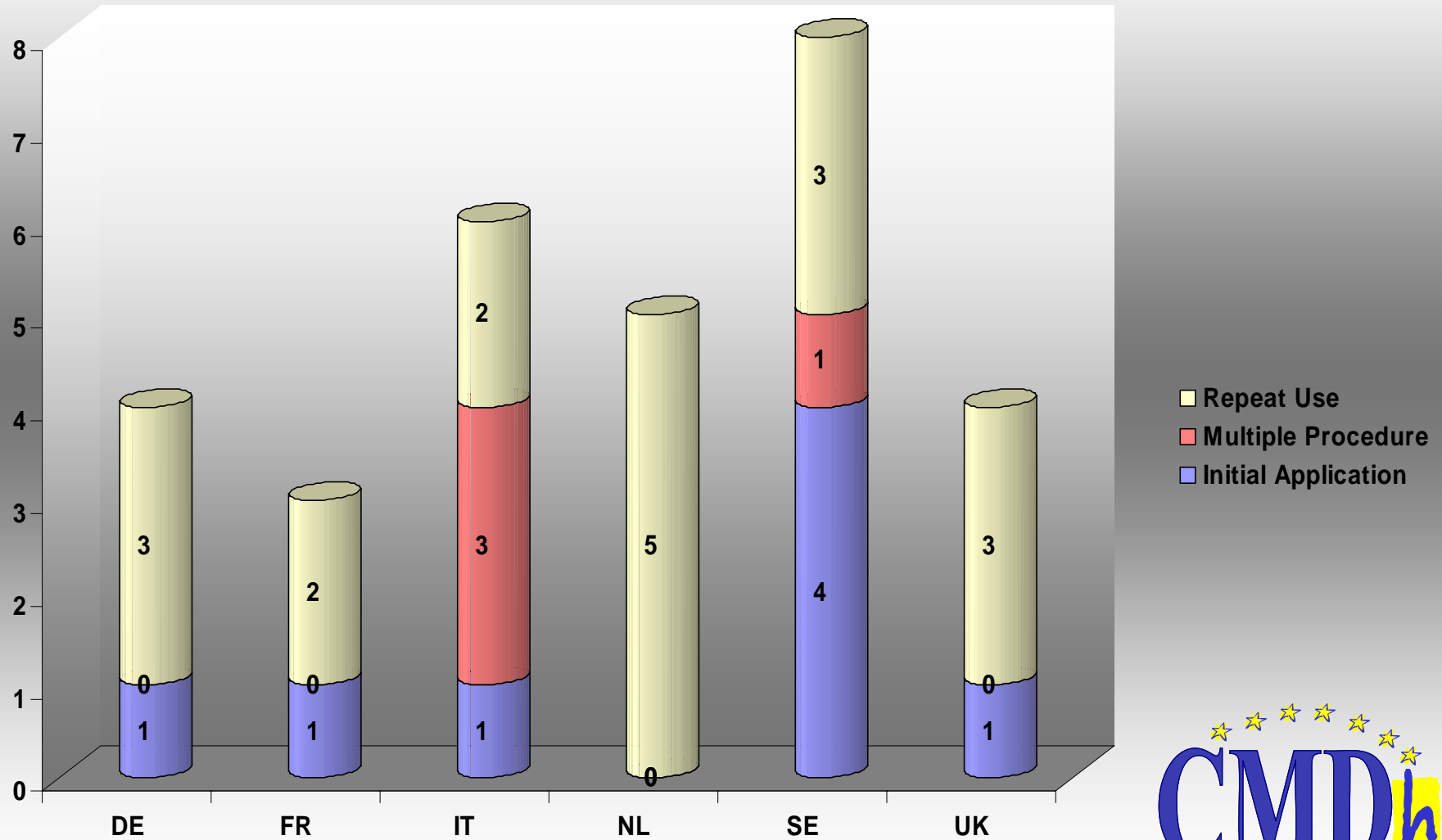


**New Active Substances
Mutual Recognition New Applications
finalised in 2005
(Tot: 30)**



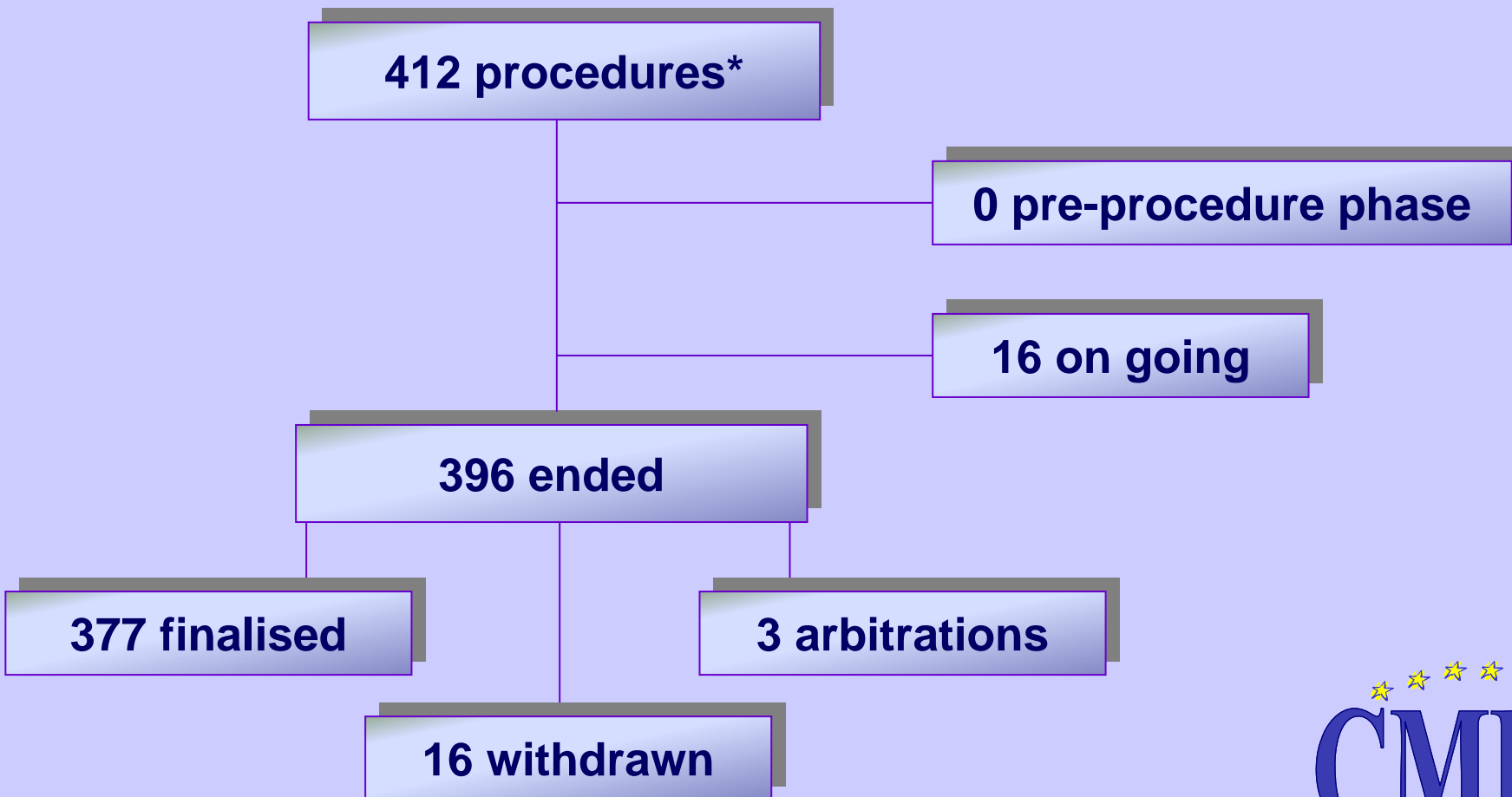
New Active Substances by RMS Mutual Recognition New Applications finalised in 2005



MUTUAL RECOGNITION

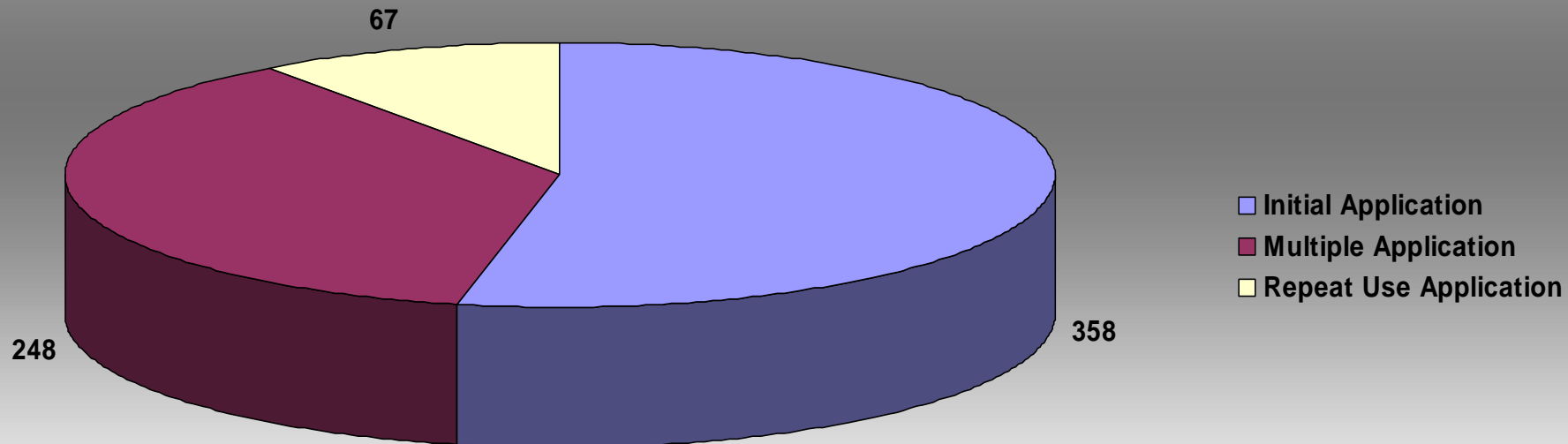
New active substances: STATUS OF THE PROCEDURES

(1995 to 2004)

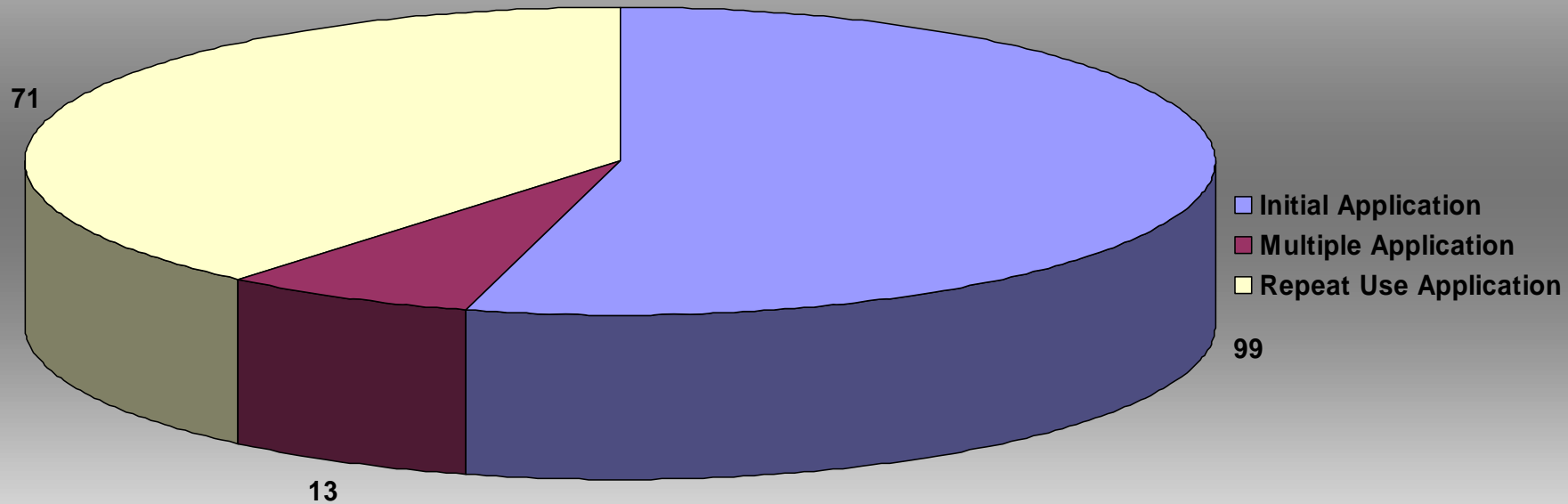


* The number includes multiple and repeat use procedures

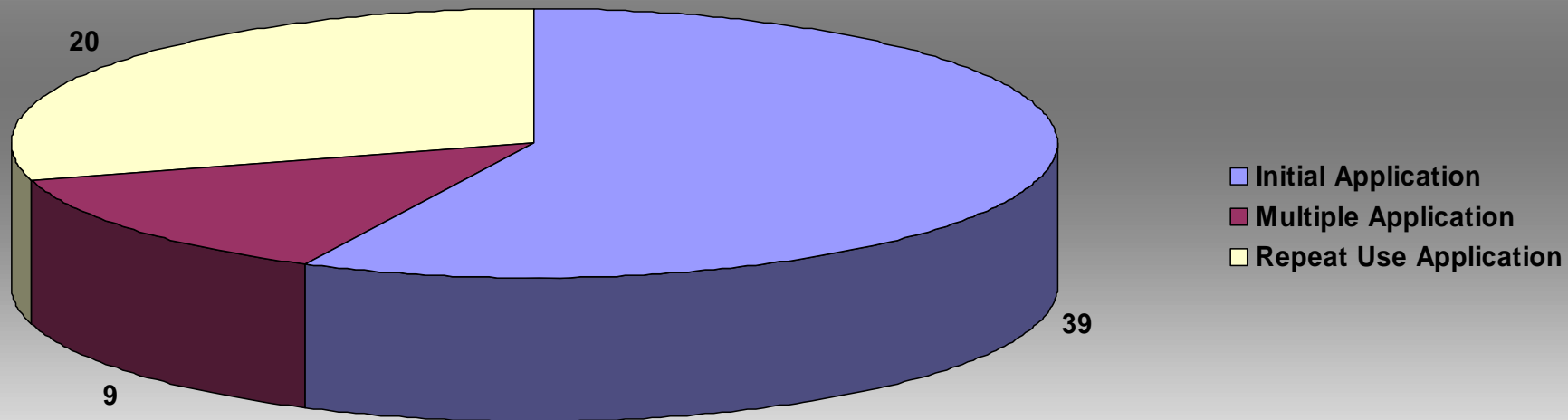
**Abridged
Mutual Recognition New Applications
finalised in 2005
(Tot: 673)**



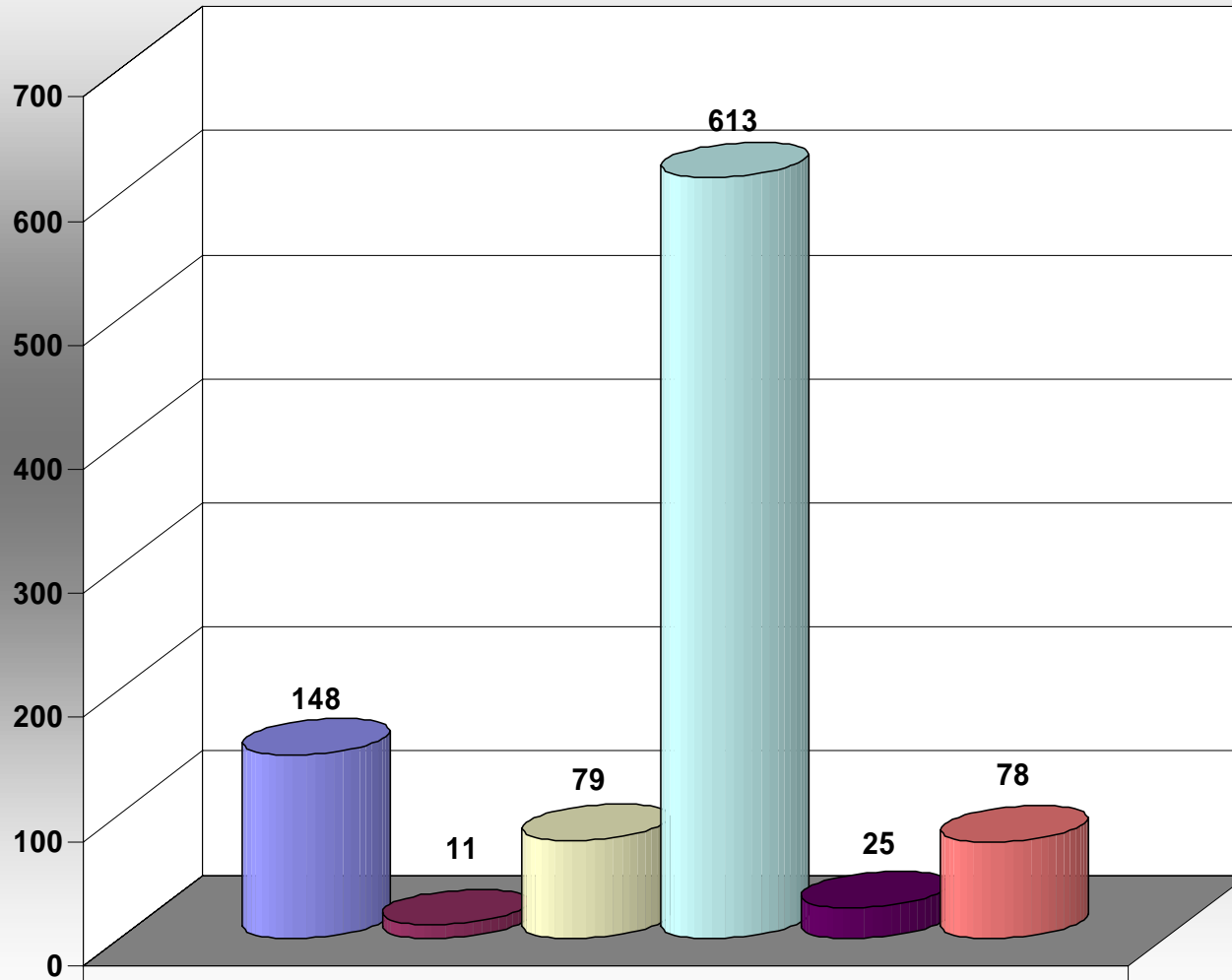
**Known Active Substances
Mutual Recognition New Applications
finalised in 2005
(Tot: 183)**



**Line Extensions
Mutual Recognition New Applications
finalised in 2005
(Tot: 68)**



Mutual Recognition New Applications finalised in 2005 (tot: 954)

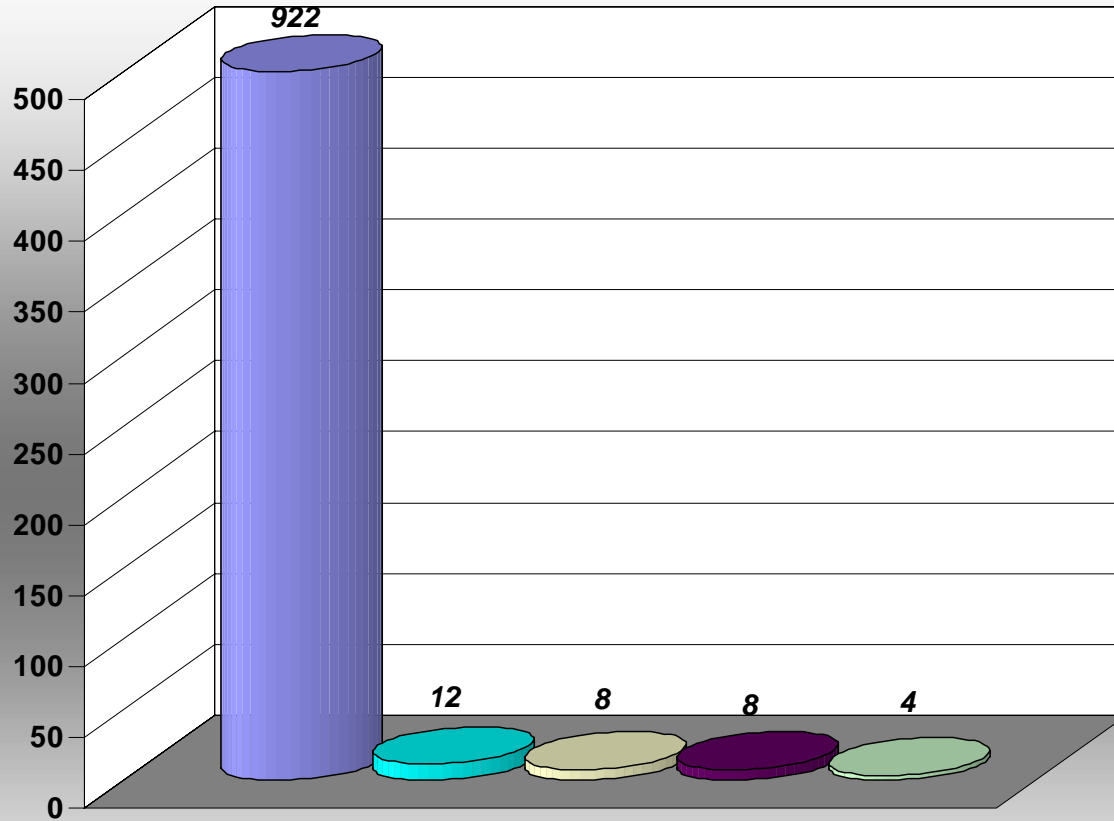


- Full dossier (Article 8.3 i Directive 2001/83/EC)
- Informed Consent Article 10.1.(a)i Directive 2001/83/EC
- Bibliographic (Article 10.1.(a)ii Directive 2001/83/EC)
- Generic (Article 10.1.(a)iii 1st paragraph, Directive 2001/83/EC)
- Fixed Combination Article 10.1.(b) Directive 2001/83/EC
- Different use, route or dose (Article 10.1.(a)iii last paragraph, Directive 2001/83/EC)



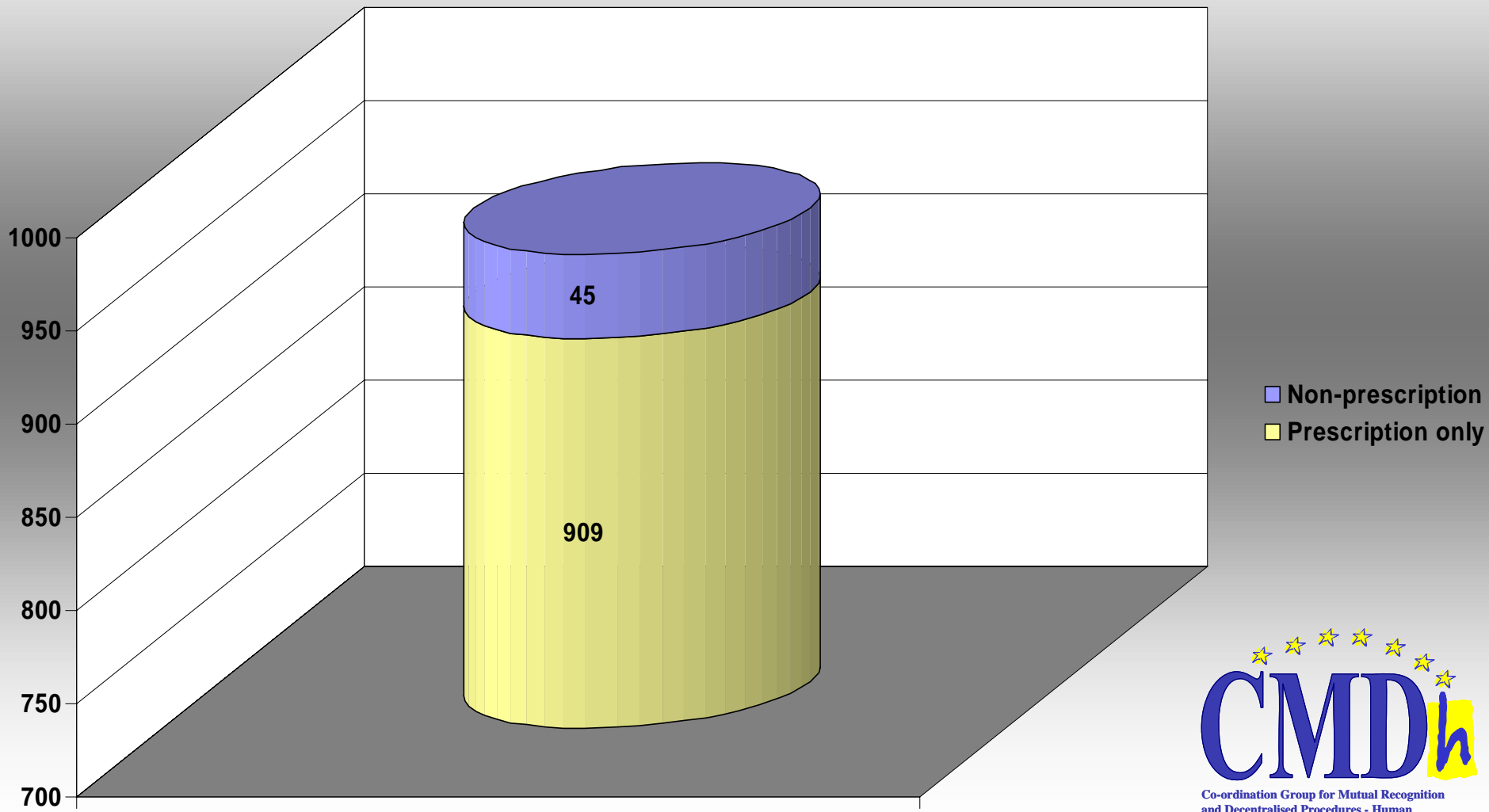
Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human

Mutual Recognition New Applications finalised in 2005



	<i>Number of finalised MR Procedures</i>
■ <i>Chemical Substance</i>	922
■ <i>Biological: Vaccine</i>	12
■ <i>Biological: other</i>	8
■ <i>Biological: Blood product</i>	8
■ <i>Herbal</i>	4

Mutual Recognition New Applications finalised in 2005



20/1/2006

EMA/CMDh/26235/2006

9

Mutual Recognition New Applications
finalised in 2005
by RMS

