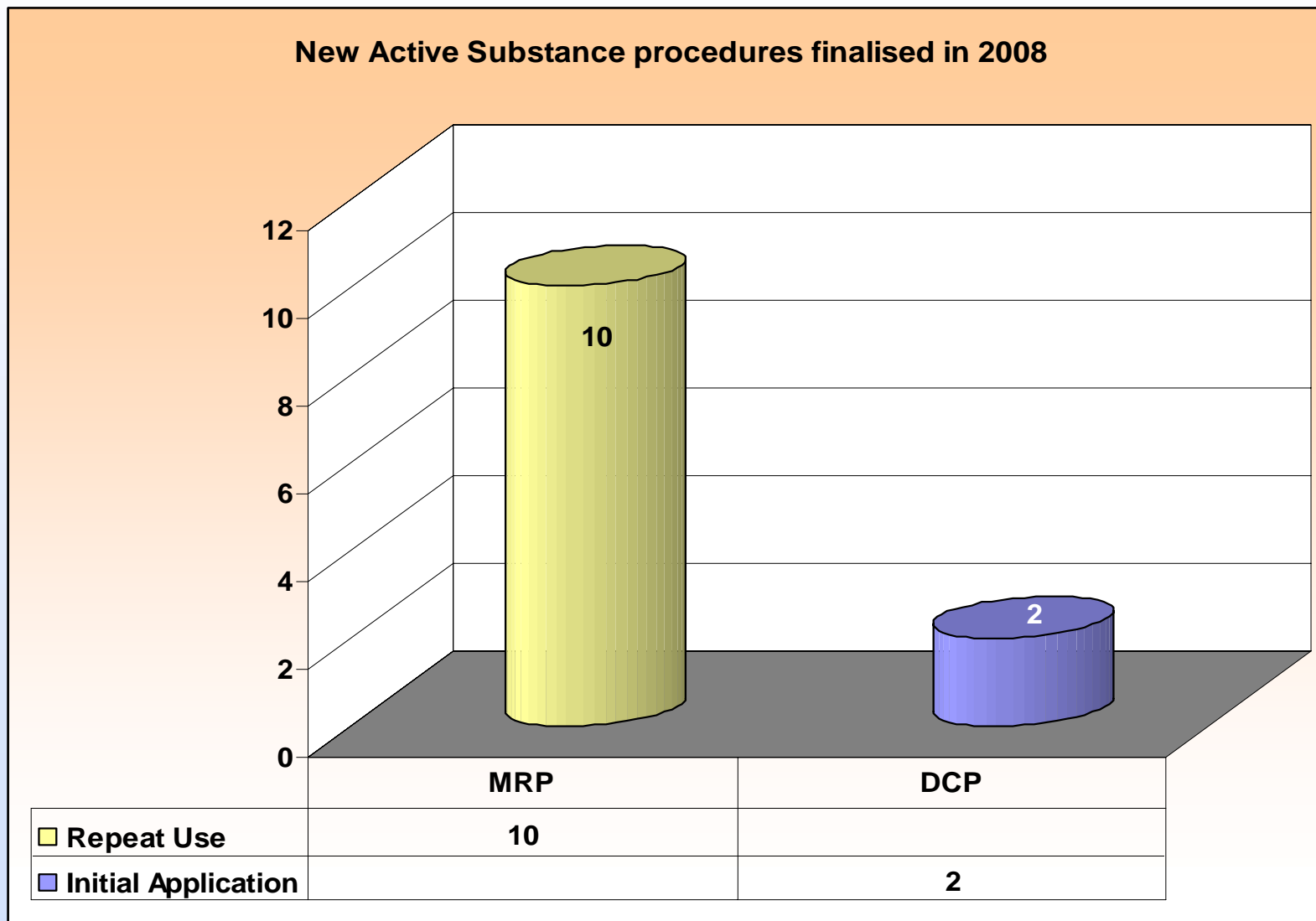
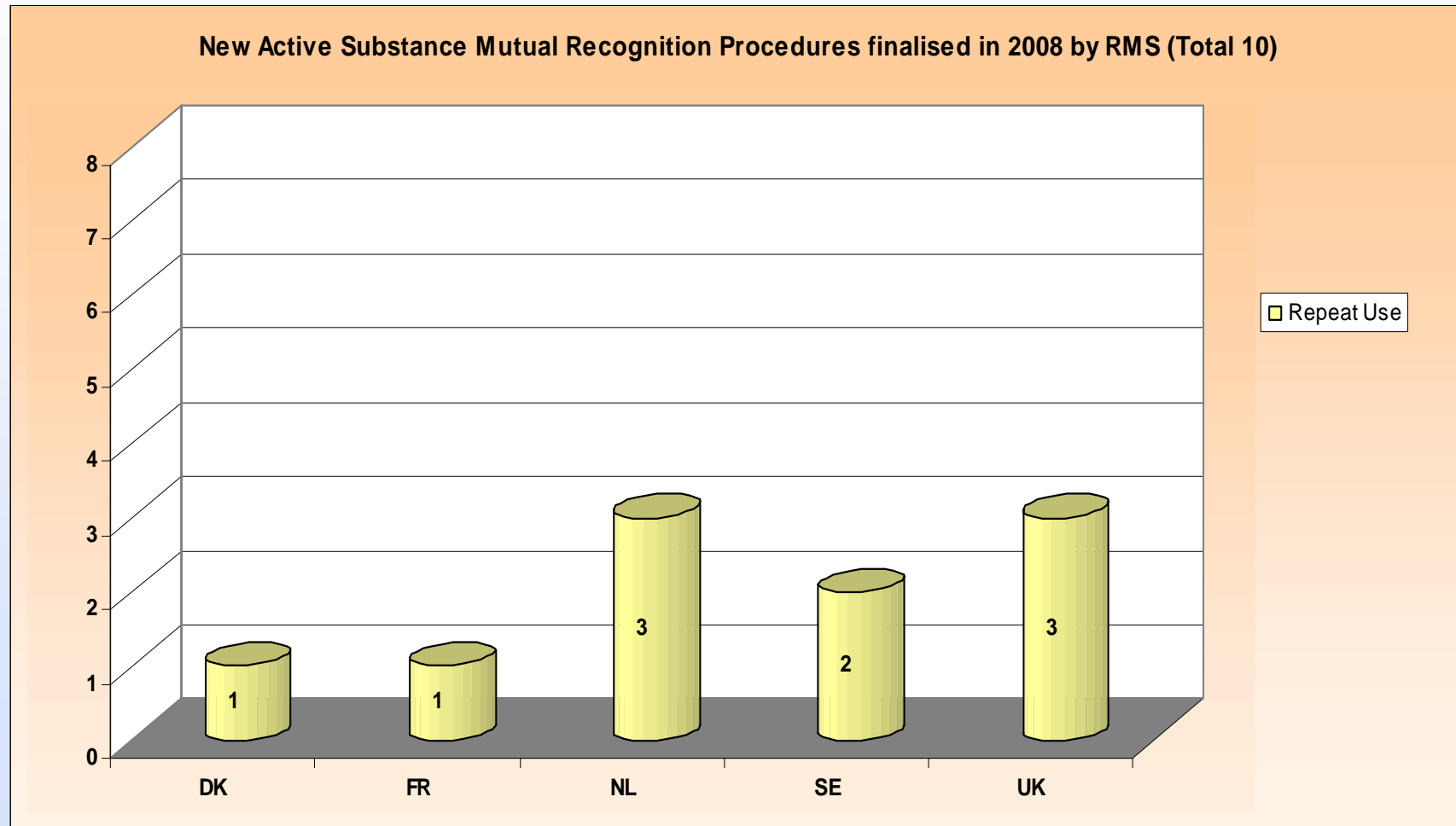


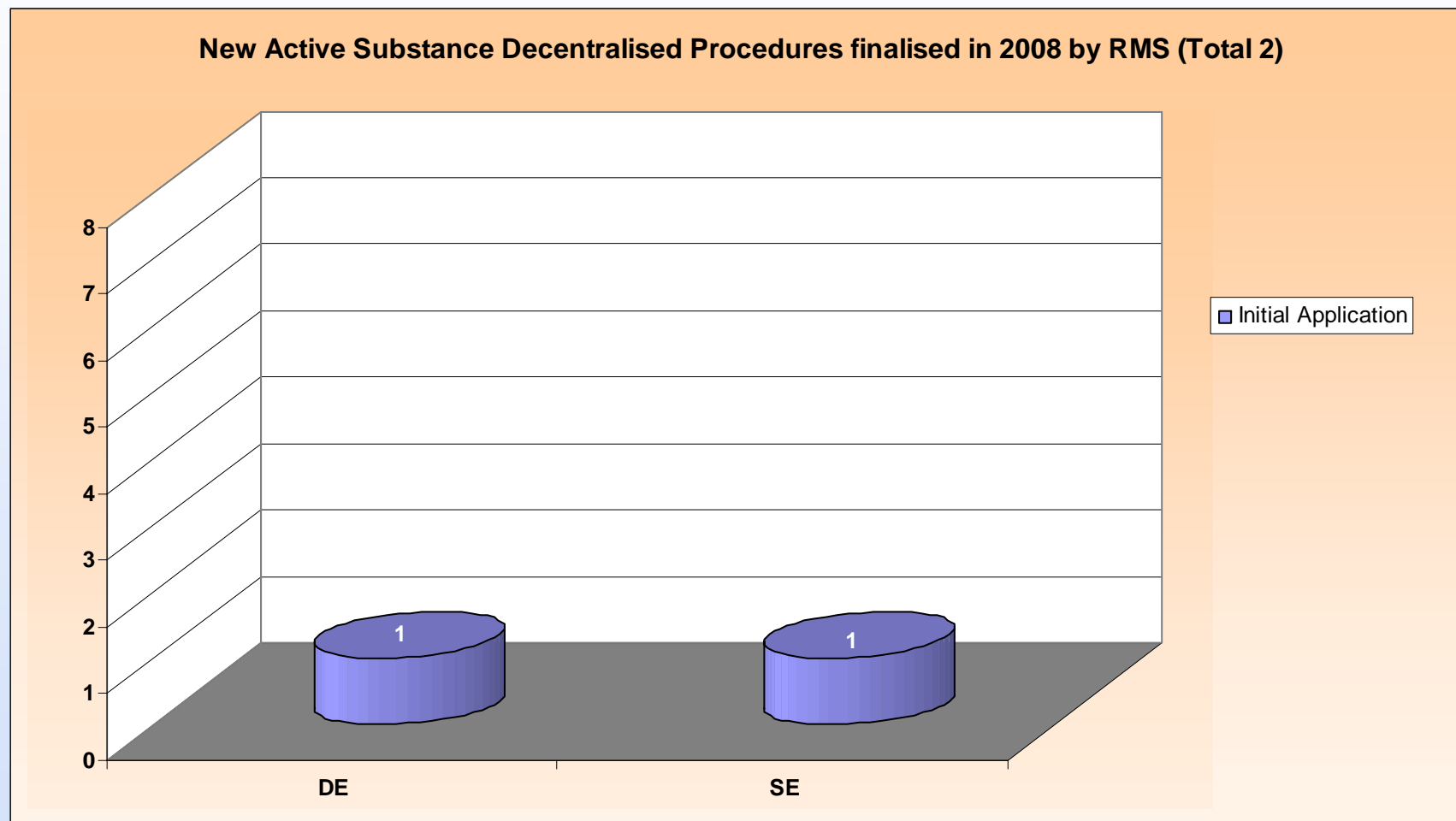
MRP and DCP new applications in 2008



MRP and DCP new applications in 2008



MRP and DCP new applications in 2008



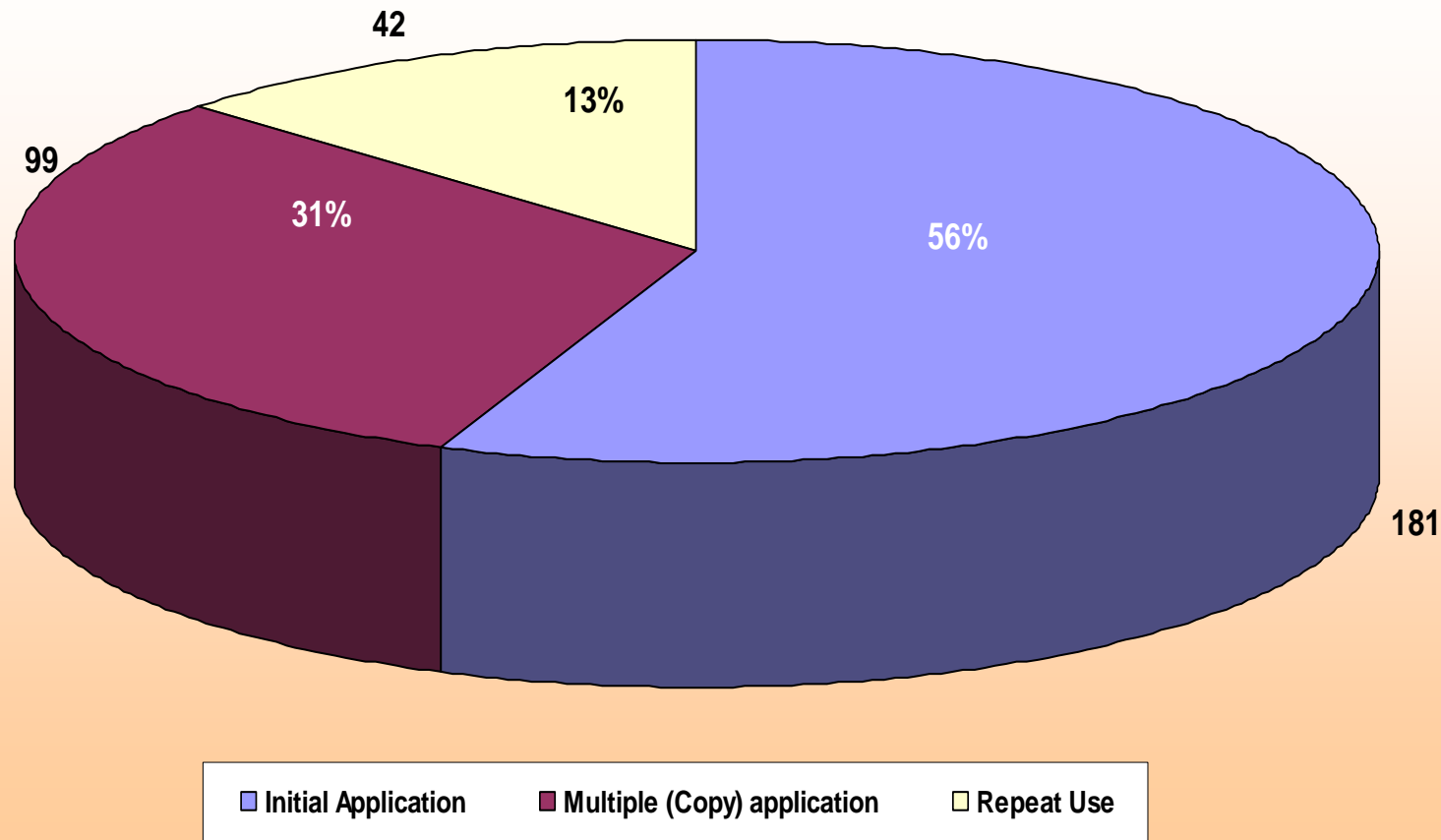
MRP and DCP new applications in 2008

DCP and MRP New Active Substances

	New Application	Repeat Use
MRP:		
		Elidel (pimecrolimus)
		Mifegyne (mifeprestone)
		Crestor 10 mg (rosuvastatin)
		Provisacor 10 mg (rosuvastatin)
		Rosuvastatin AZ 10 mg (rosuvastatin)
		Avodart (dutasteride)
		Fosrenol (lanthanum (III) carbonate)
		Alvesco 40 Inhaler (ciclesonide)
		Freathe 40 Inhaler (ciclesonide)
		Amavio 40 Inhaler (ciclesonide)
DCP:	Taflotan 15 Mikrogramm/ml Augentropfen (tafluprost) Priligy (dapoxetine)	

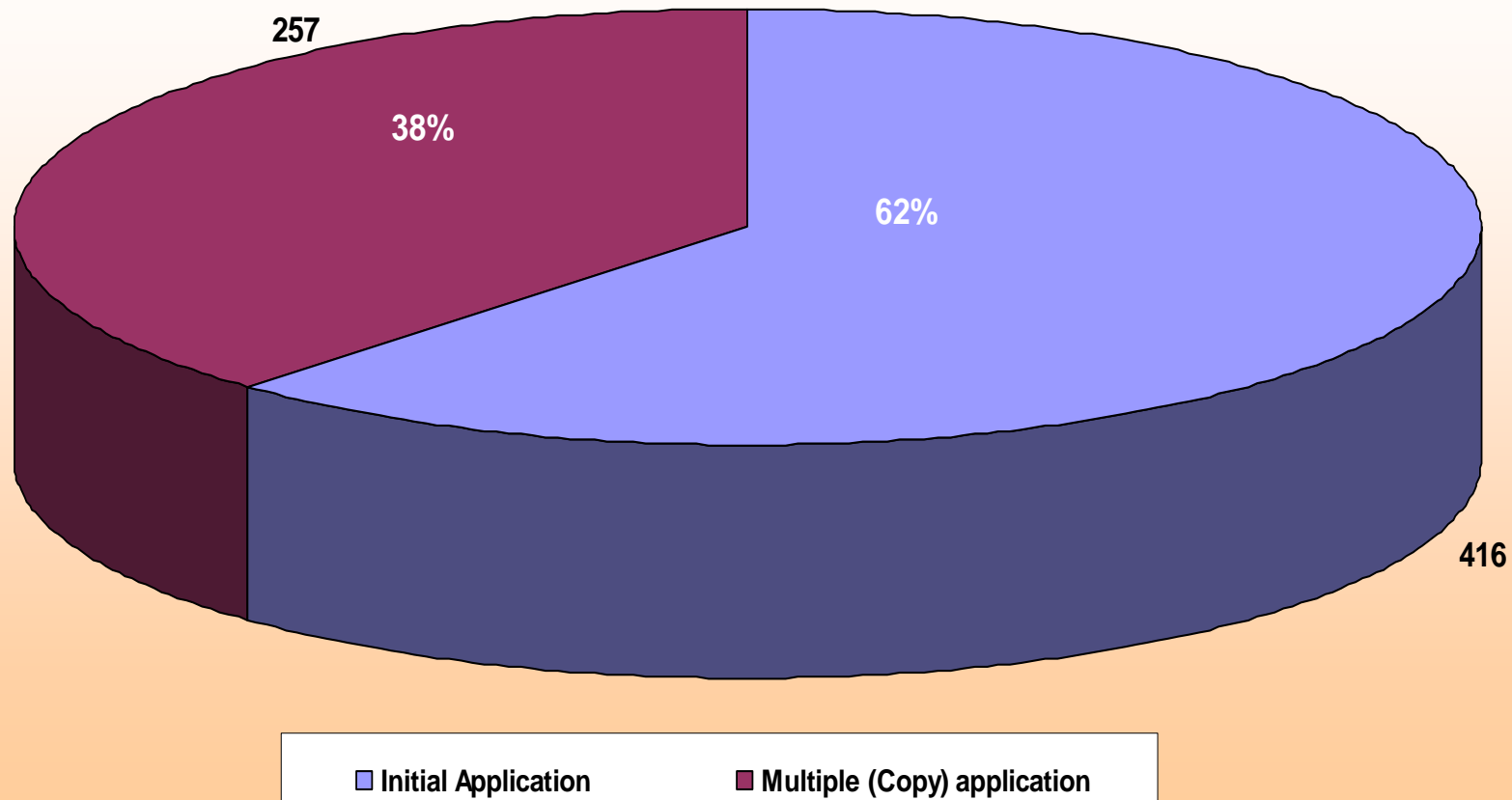
MRP and DCP new applications in 2008

Abridged Mutual Recognition Procedures finalised in 2008 (Total 322)



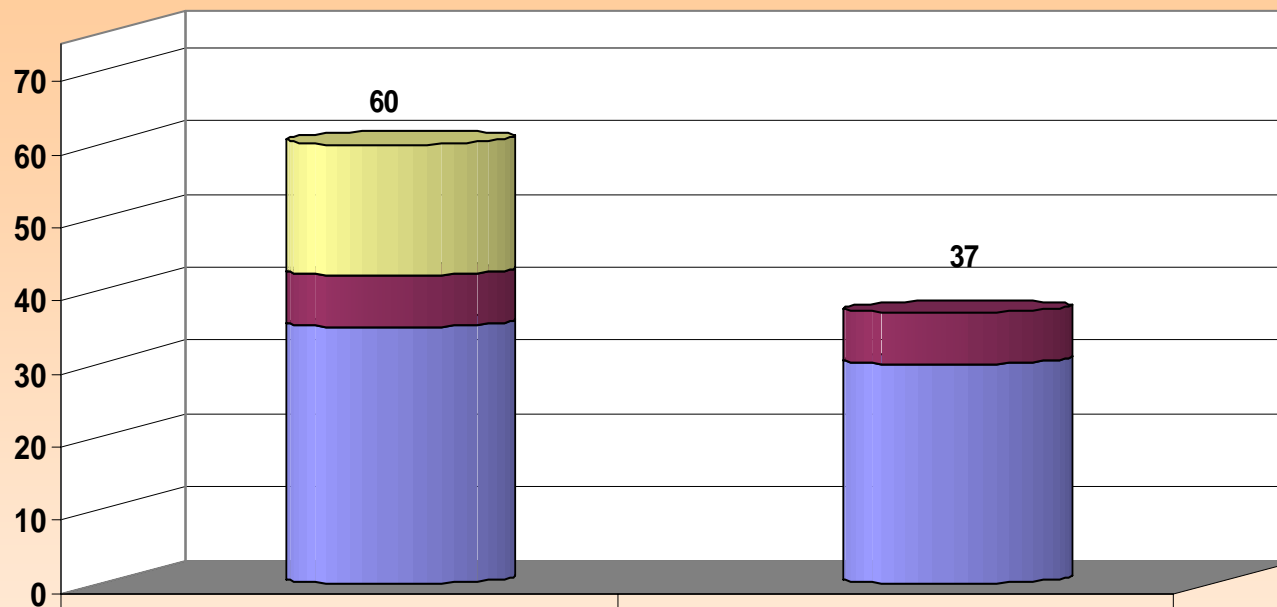
MRP and DCP new applications in 2008

Abridged DeCentralised Procedures finalised in 2008 (Total 673)



MRP and DCP new applications in 2008

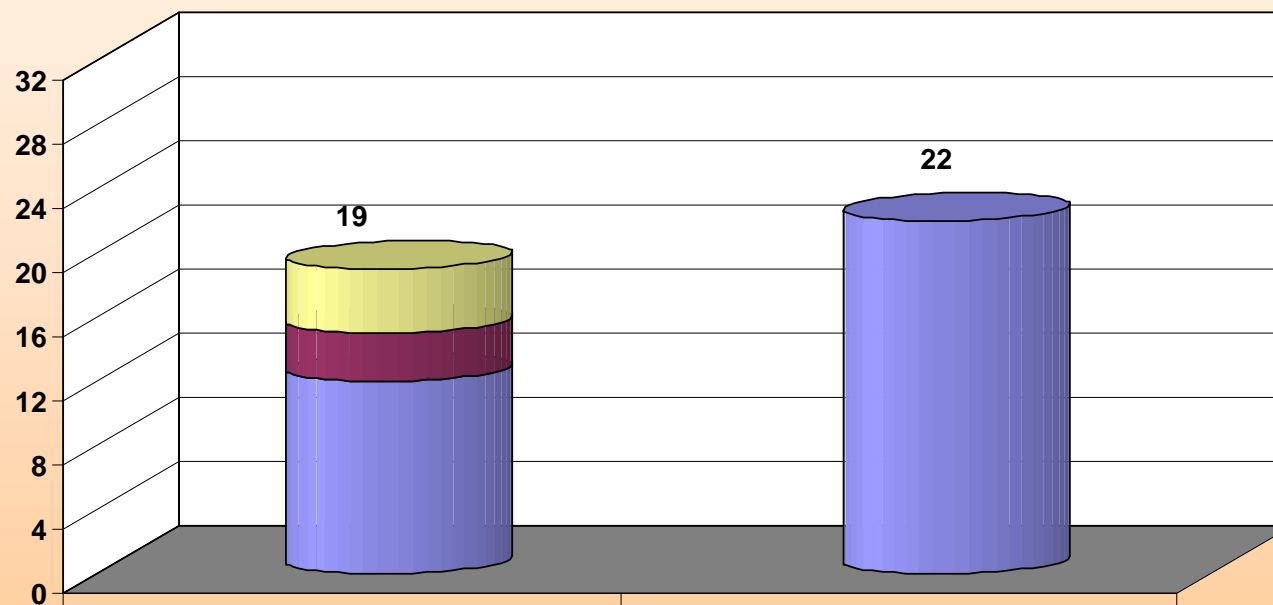
Known Active Substance procedures finalised in 2008



	MRP	DCP
Repeat Use	18	
Multiple (Copy) Application	7	7
Initial Application	35	30

MRP and DCP new applications in 2008

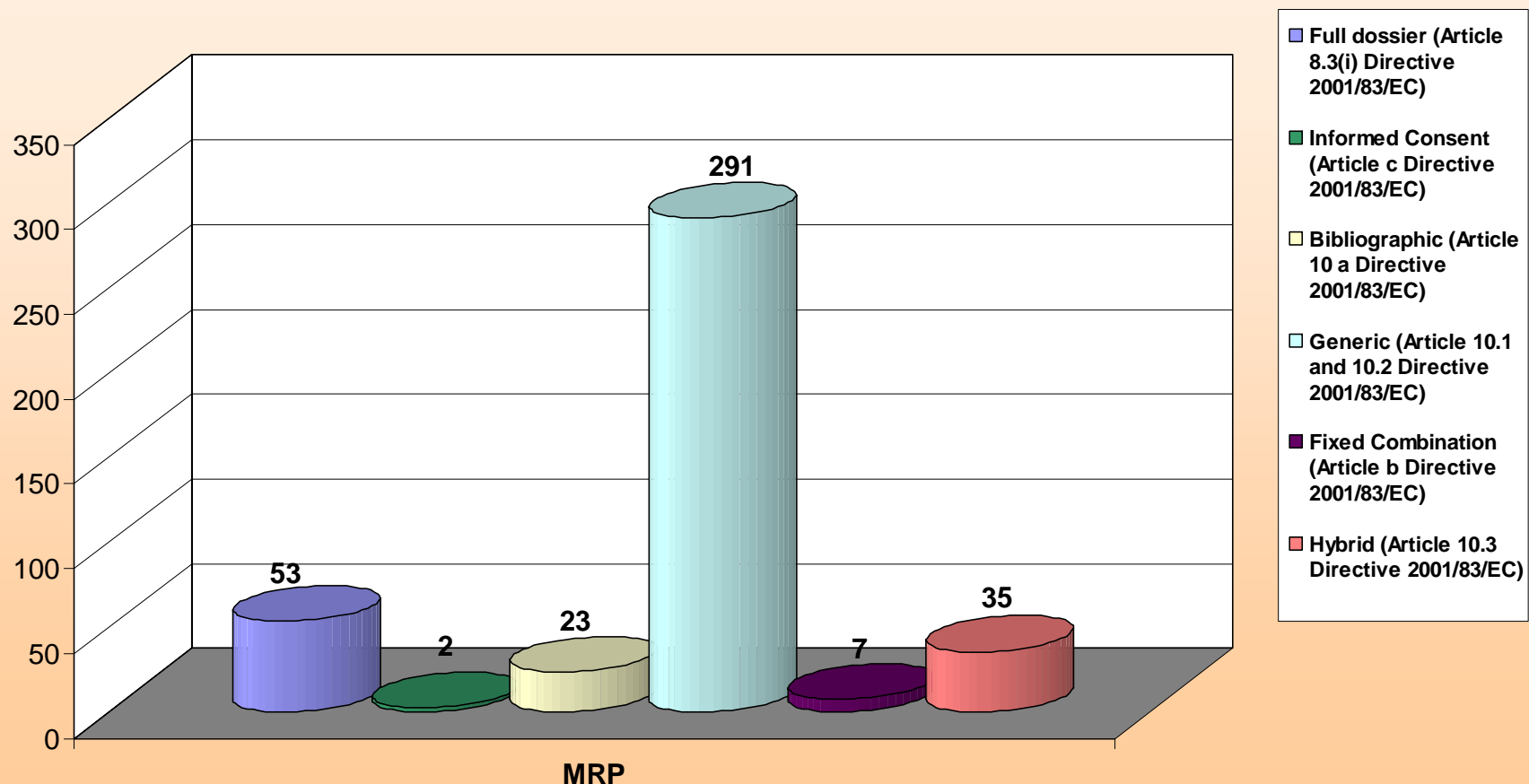
Line Extension procedures finalised in 2008



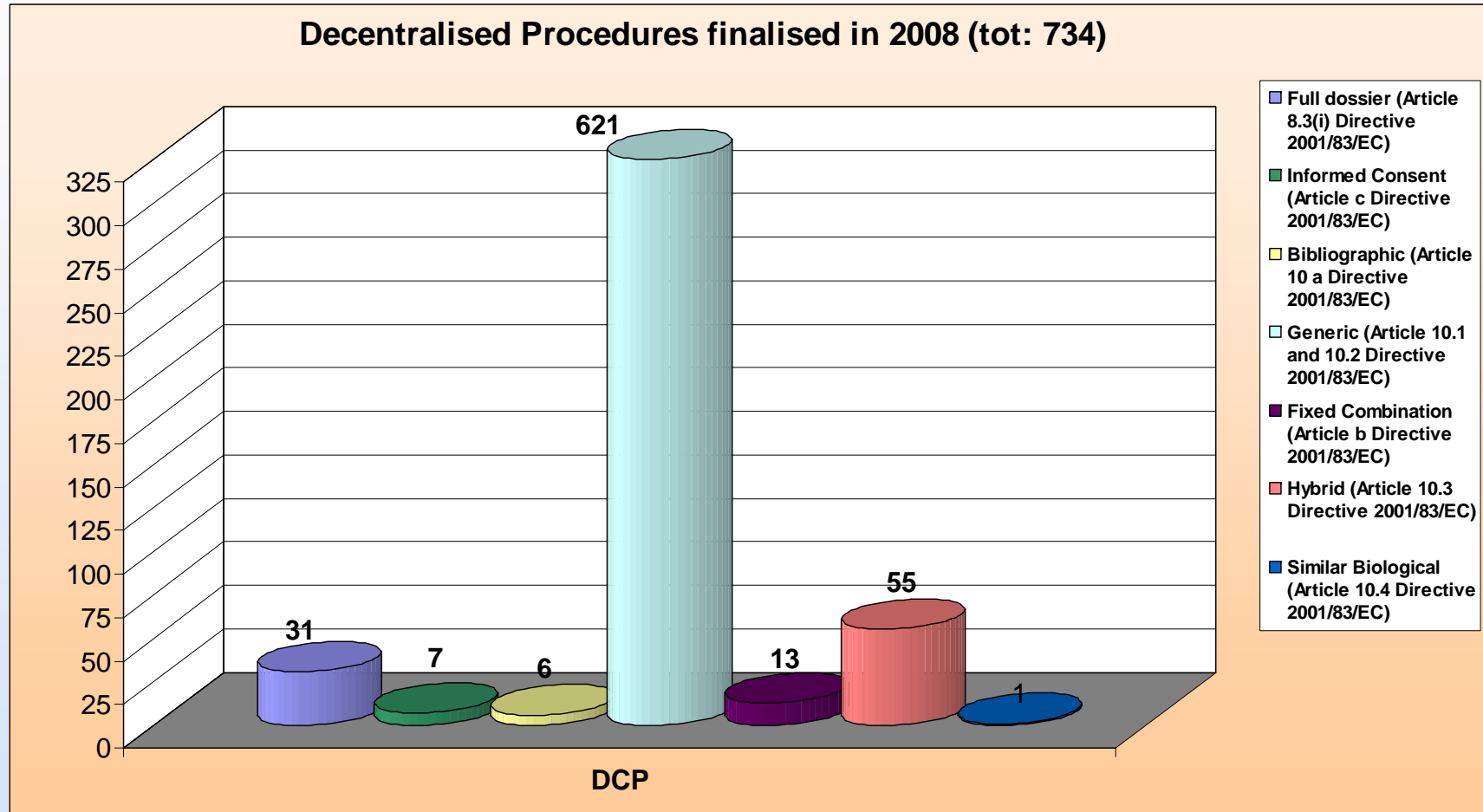
	MRP	DCP
Repeat Use	4	
Multiple (Copy) Application	3	
Initial Application	12	22

MRP and DCP new applications in 2008

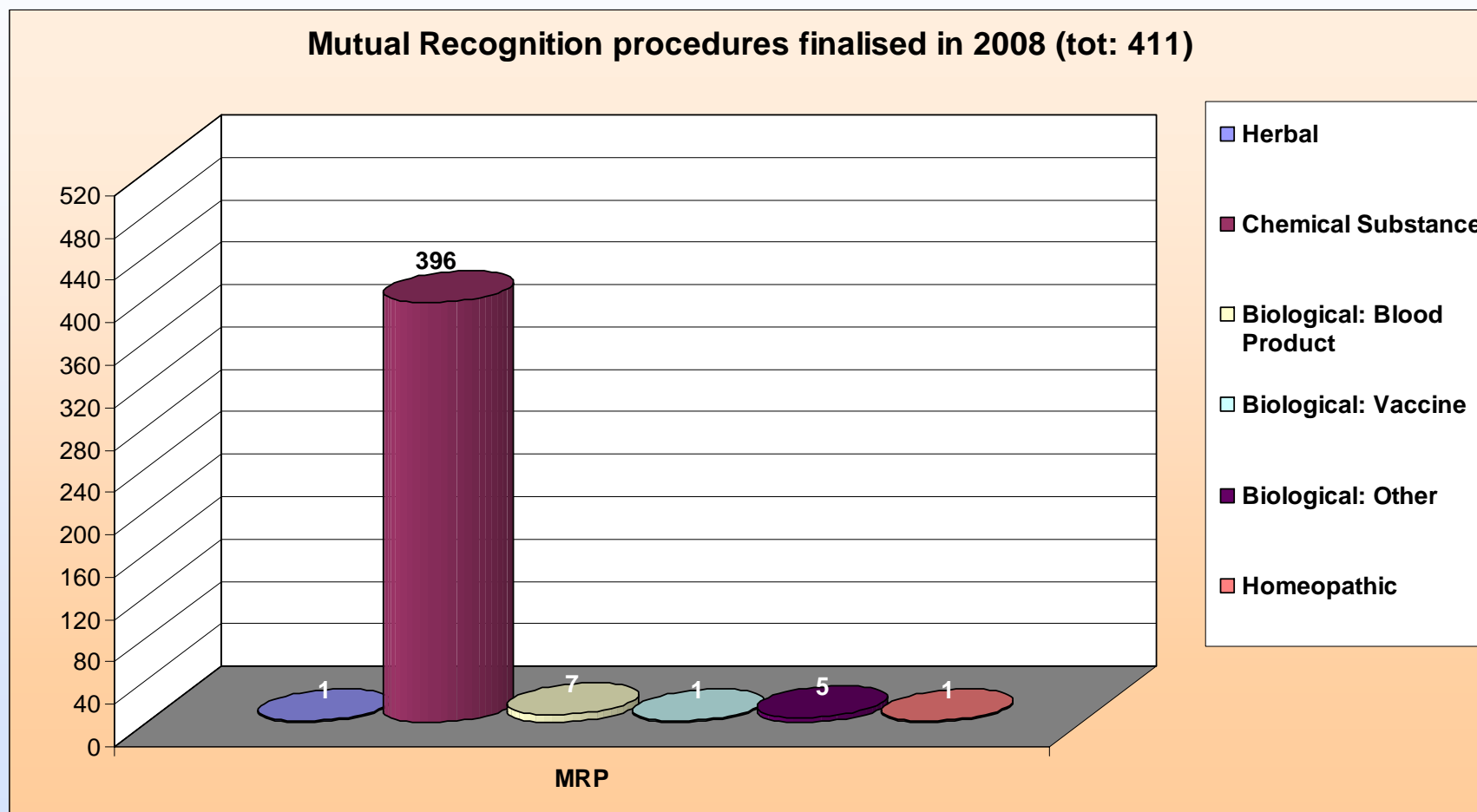
Mutual Recognition new application Procedures finalised in 2008 (tot: 411)



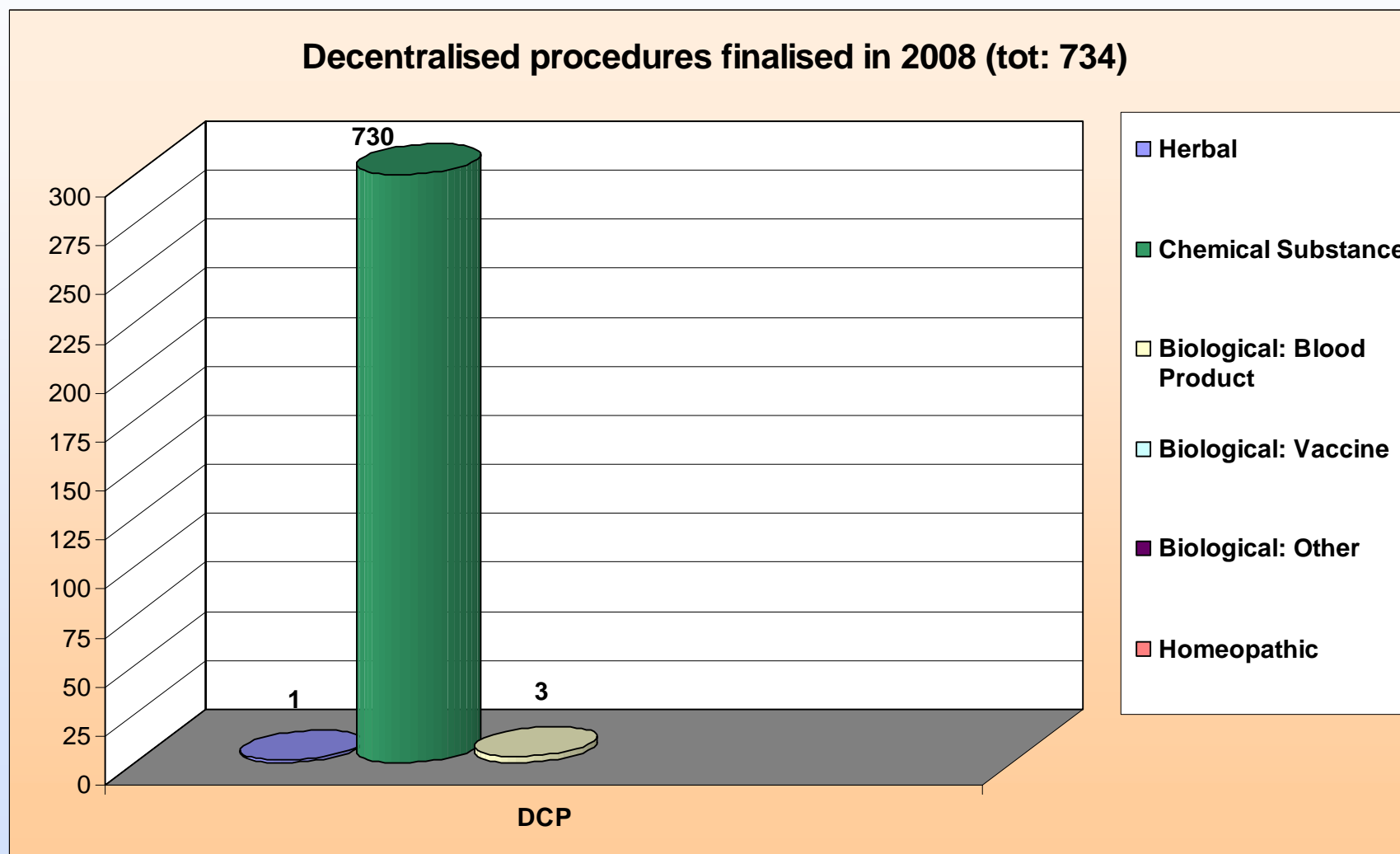
MRP and DCP new applications in 2008



MRP and DCP new applications in 2008

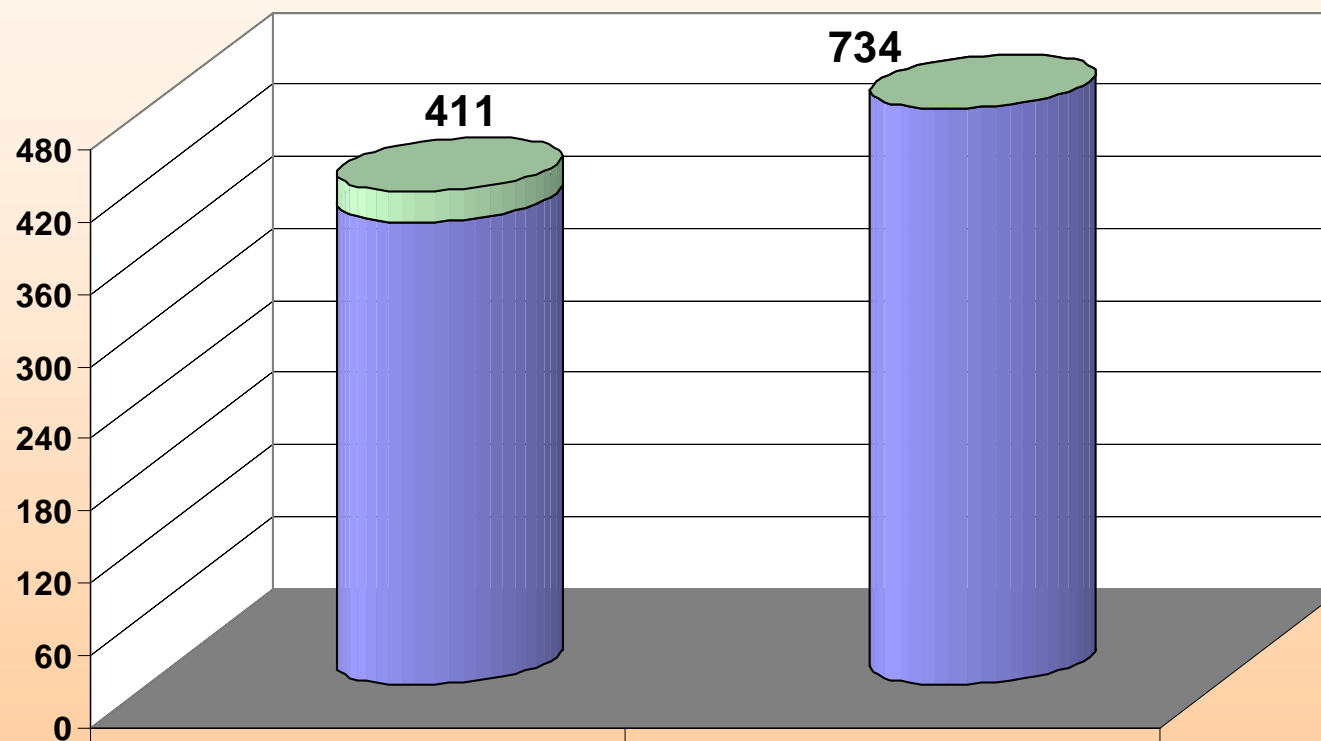


MRP and DCP new applications in 2008



MRP and DCP new applications in 2008

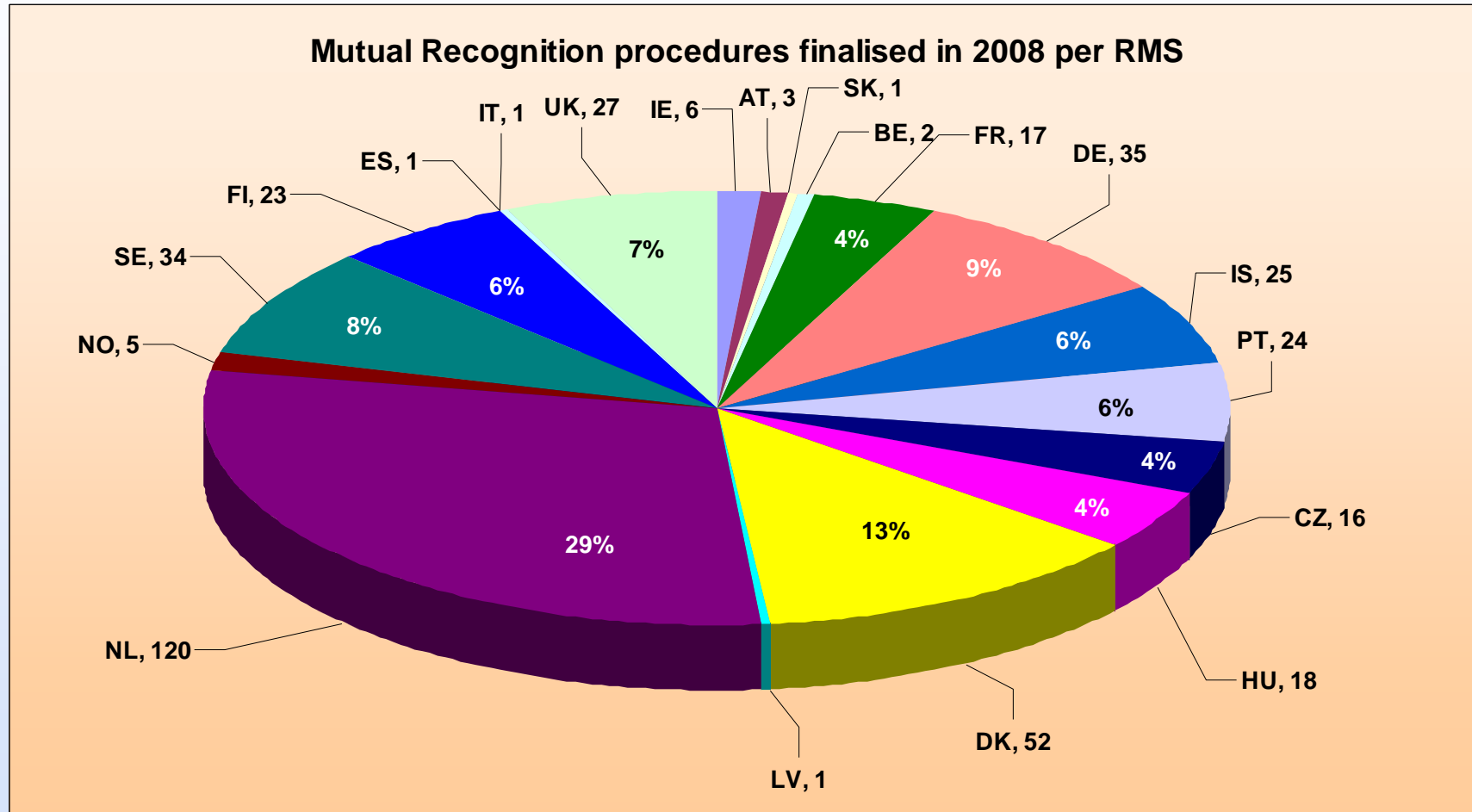
MRP and DCP procedures finalised in 2008



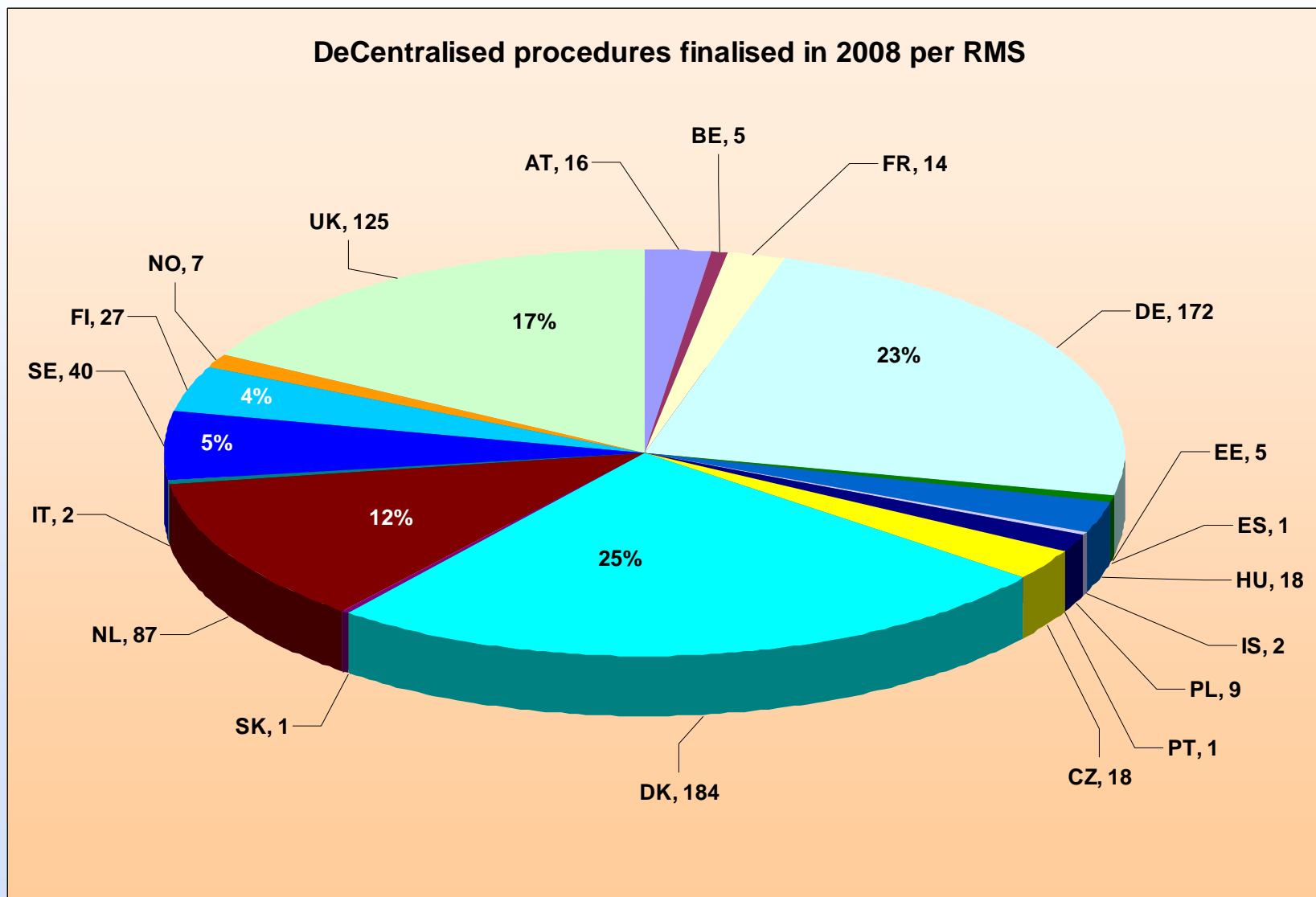
	MRP	DCP
Non Prescription*	25	18
Prescription only*	386	716

*As approved by the Reference Member State

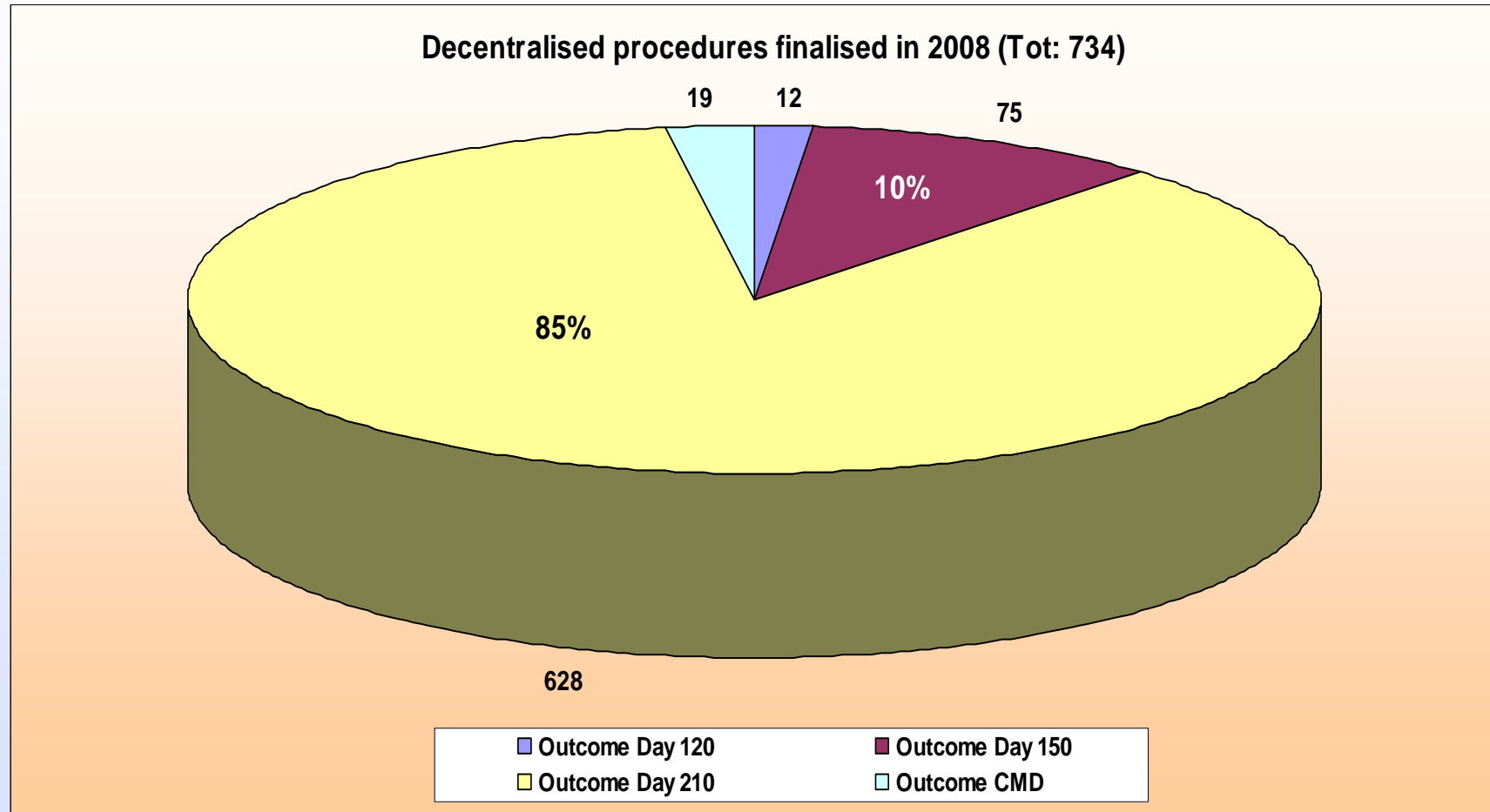
MRP and DCP new applications in 2008



MRP and DCP new applications in 2008



MRP and DCP new applications in 2008

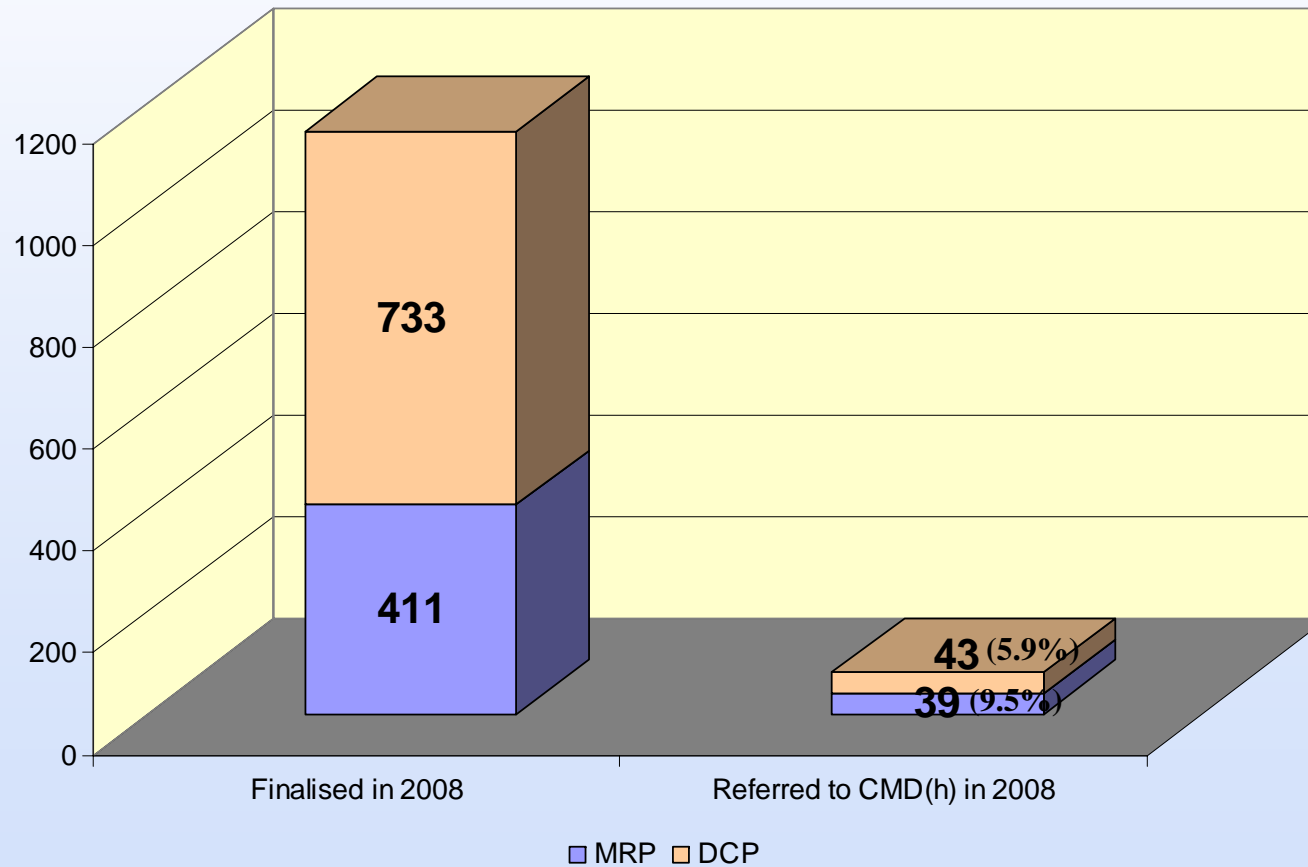


CMD(h) 60-day Referral Procedures 1st January to 31st December 2008

Per Type of Procedures (MRP/DCP)

Overview Finalised vs. Referred to CMD(h) in 2008*

* The numbers include 26 procedures (12 MRP, 14 DCP) referred to the CMD(h) on identical grounds



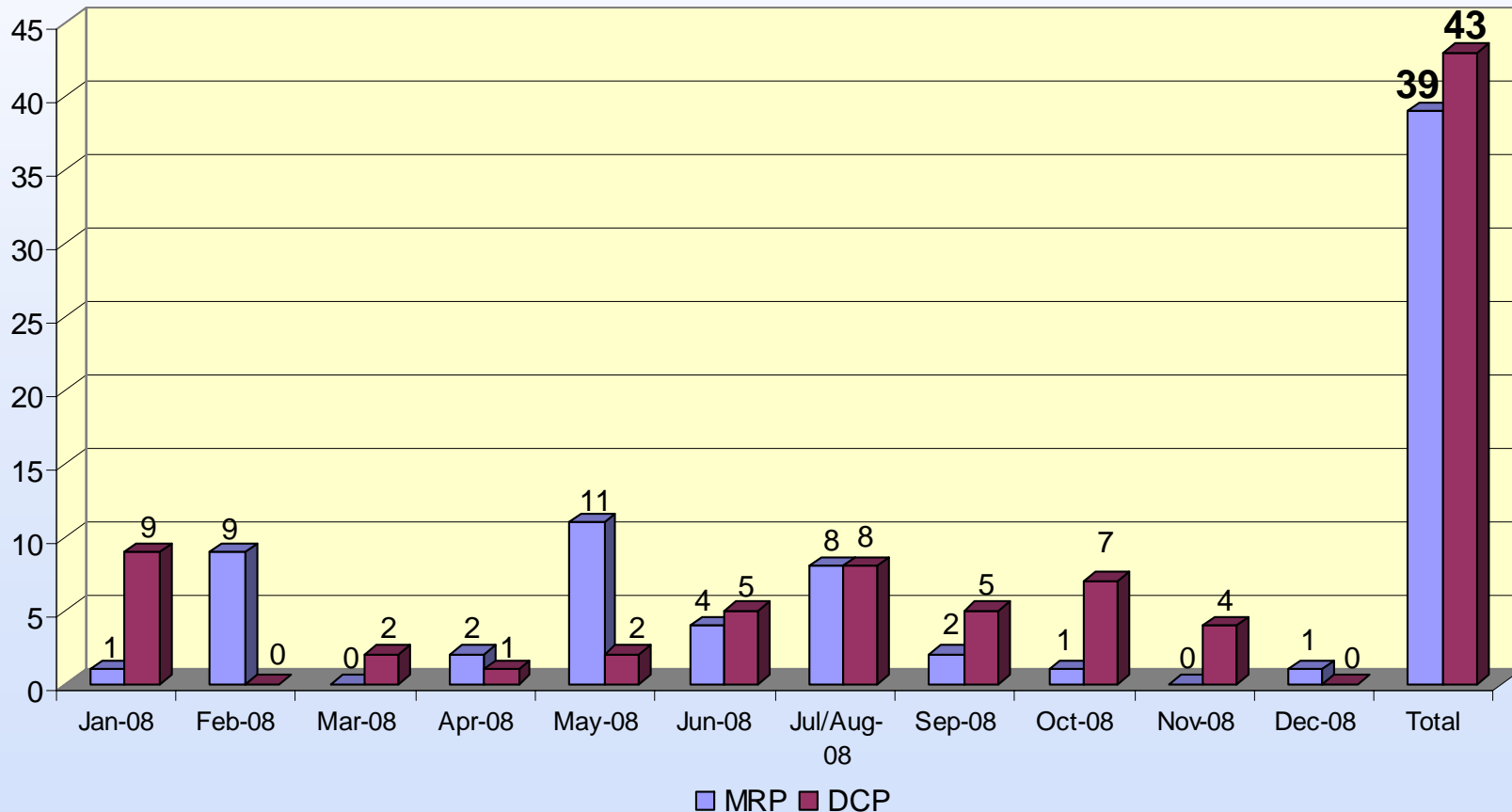
CMD(h) 60-day Referral Procedures

1st January to 31st December 2008

Per Type of Procedures (MRP/DCP)

Procedures referred to CMD(h) in 2008*

* The numbers include 26 procedures (12 MRP, 14 DCP) referred to the CMD(h) on identical grounds

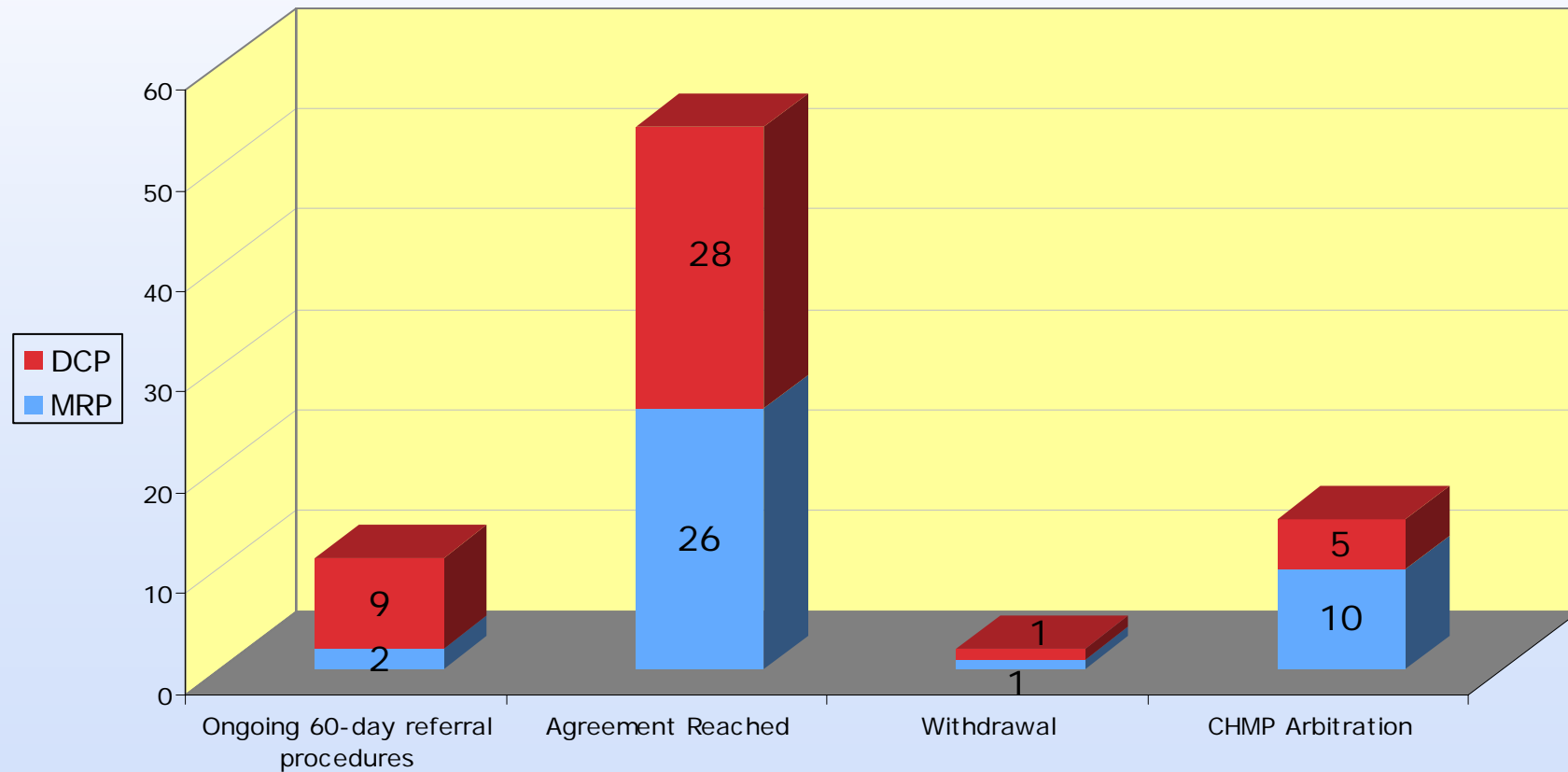


CMD(h) 60-day Referral Procedures 1st January to 31st December 2008

Per Type of Procedures (MRP/DCP)

Procedures referred to CMD(h) in 2008 – Status*

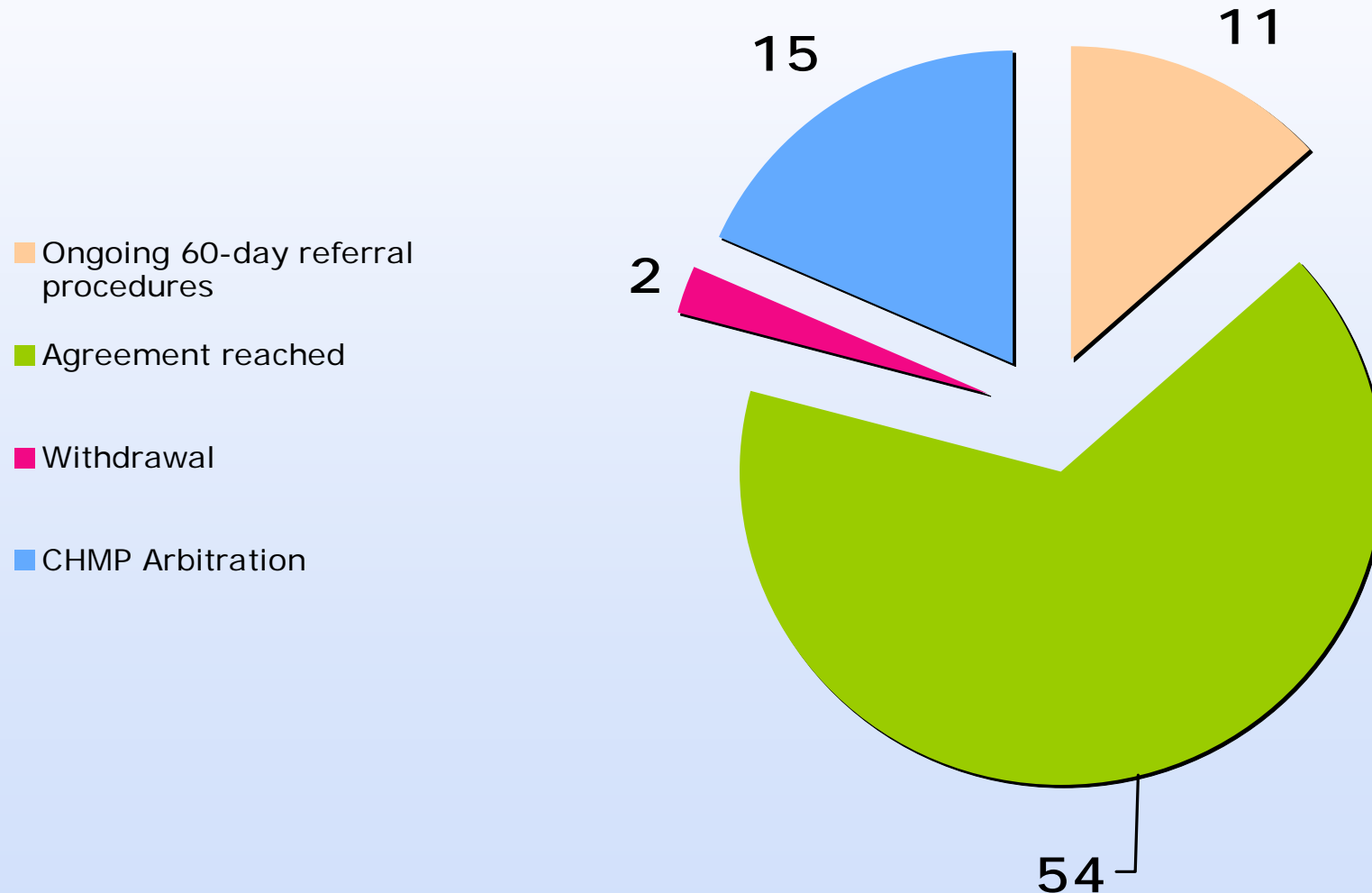
* The numbers include 26 procedures (12 MRP, 14 DCP) referred to the CMD(h) on identical grounds



CMD(h) 60-day Referral Procedures 1st January to 31st December 2008

Procedures referred to CMD(h) in 2008 – Status overview *

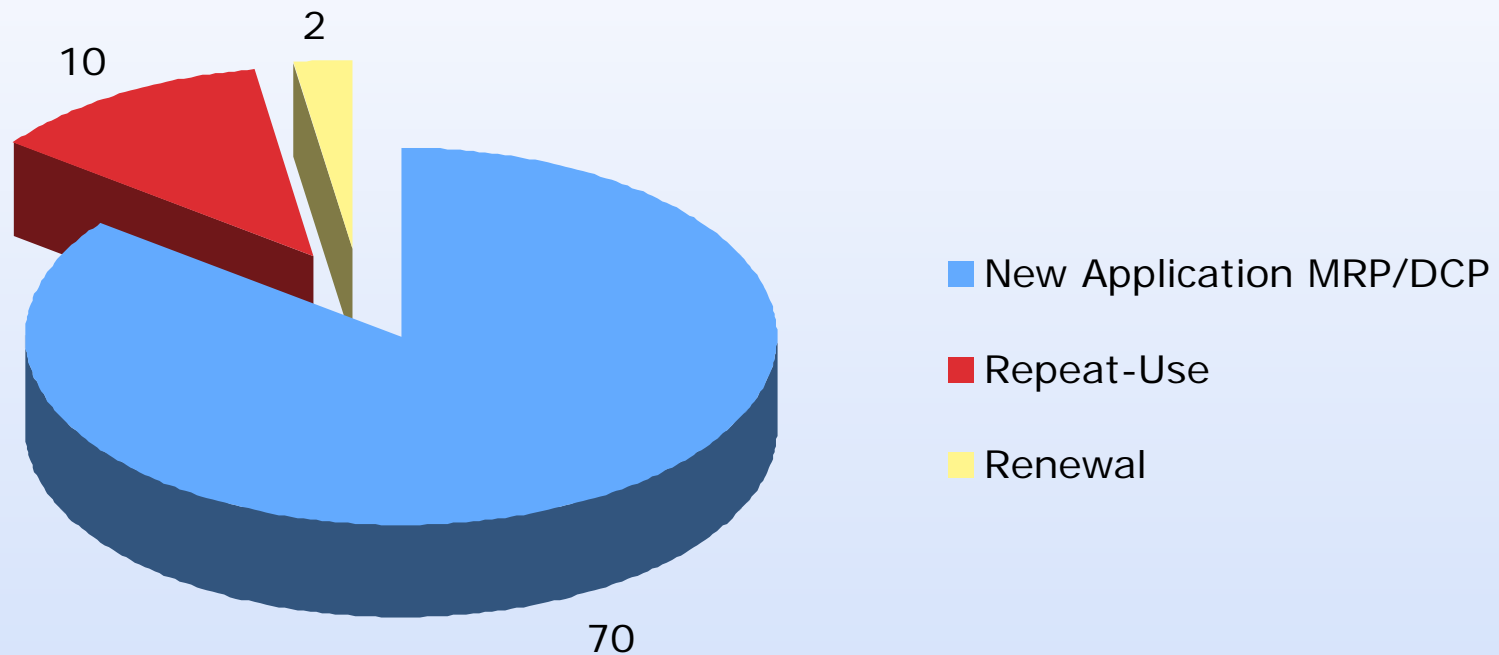
* The numbers include 26 procedures (12 MRP, 14 DCP) referred to the CMD(h) on identical grounds



CMD(h) 60-day Referral Procedures 1st January to 31st December 2008

Per Type of Procedures (MRP/DCP) Procedures referred to CMD(h) in 2008*

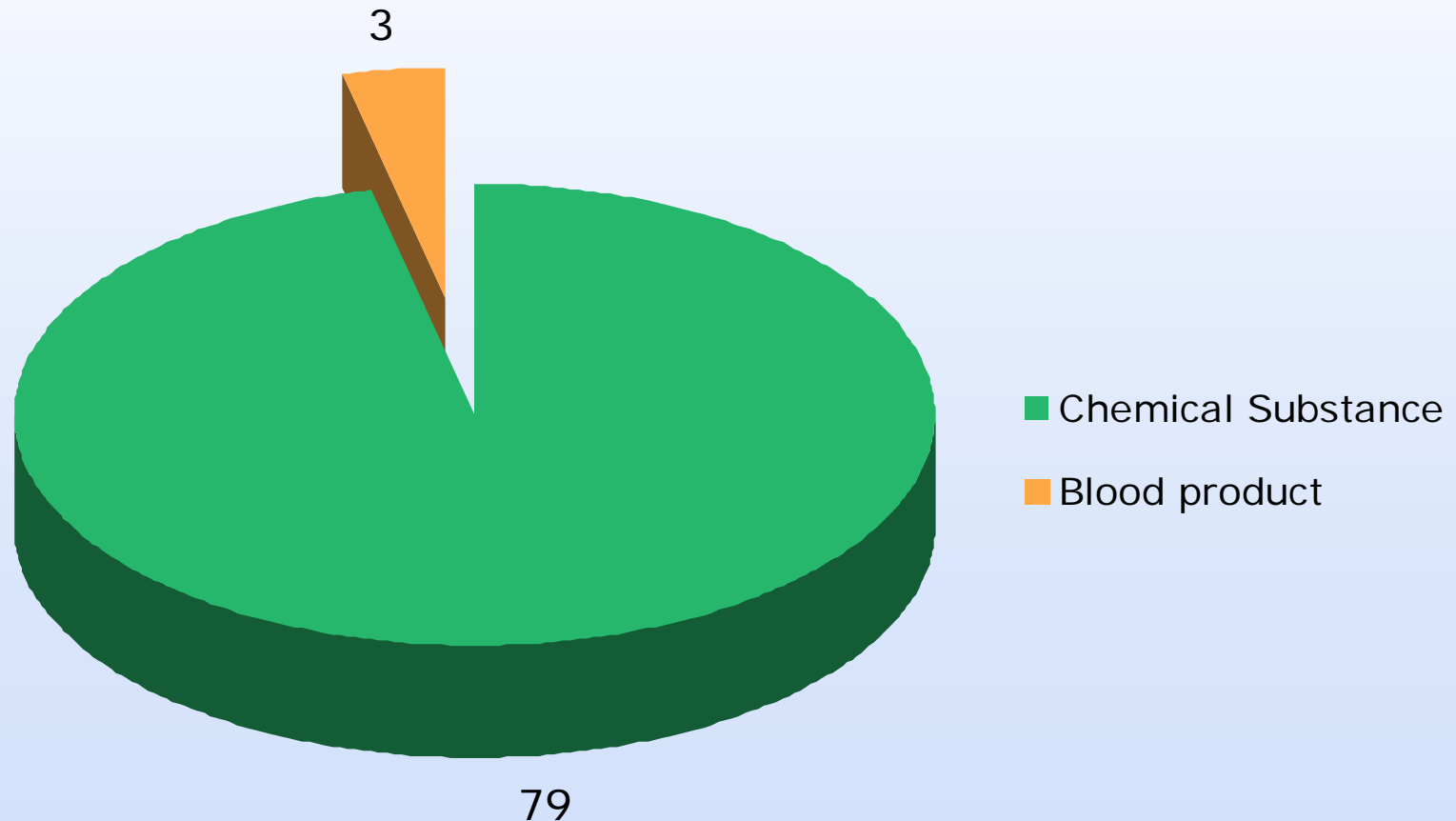
* The numbers include 26 procedures (12 MRP, 14 DCP) referred to the CMD(h) on identical grounds



CMD(h) 60-day Referral Procedures 1st January to 31st December 2008

Per Type of Product Procedures referred to CMD(h) in 2008*

* The numbers include 26 procedures (12 MRP, 14 DCP) referred to the CMD(h) on identical grounds

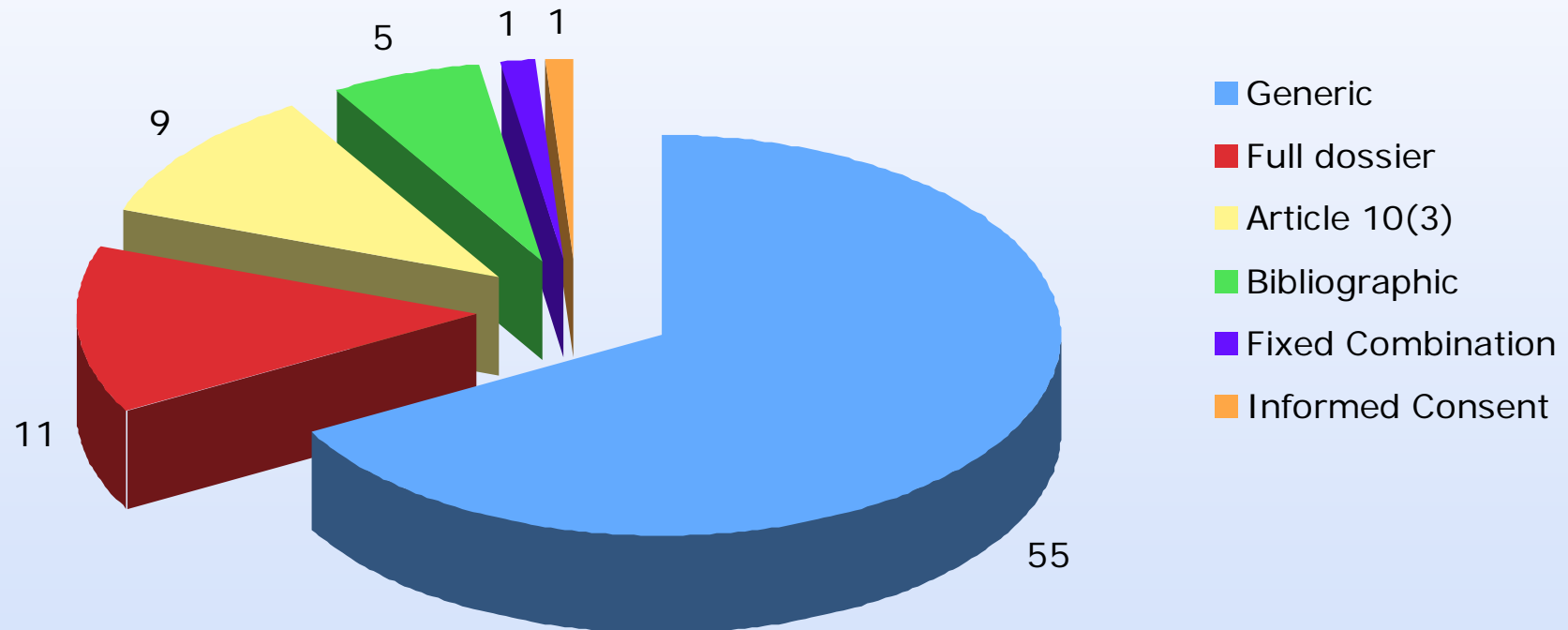


CMD(h) 60-day Referral Procedures 1st January to 31st December 2008

Per Legal Basis

Procedures referred to CMD(h) in 2008*

* The numbers include 26 procedures (12 MRP, 14 DCP) referred to the CMD(h) on identical grounds

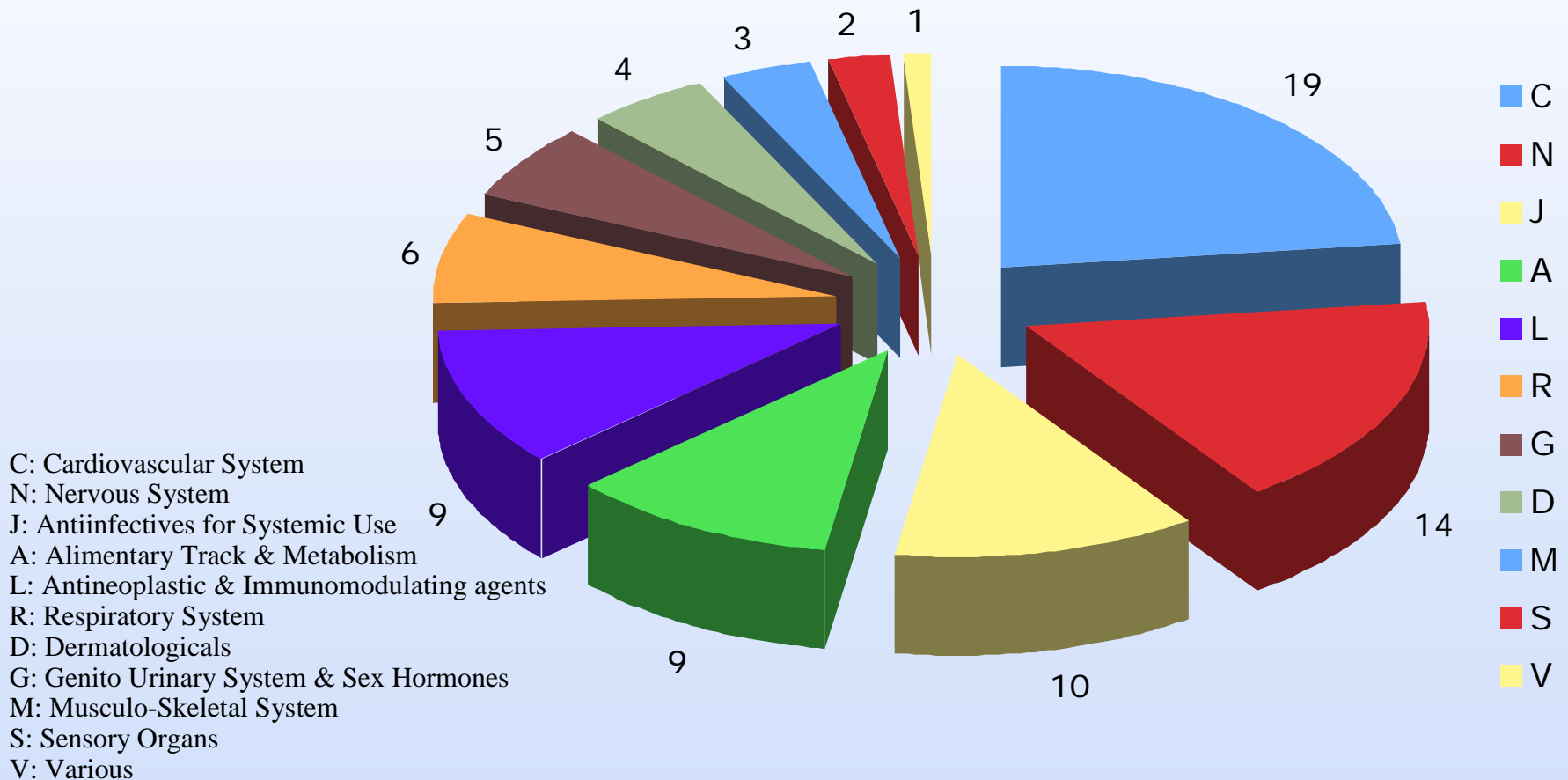


CMD(h) 60-day Referral Procedures 1st January to 31st December 2008

Per Therapeutic Area

Procedures referred to CMD(h) in 2008*

* The numbers include 26 procedures (12 MRP, 14 DCP) referred to the CMD(h) on identical grounds

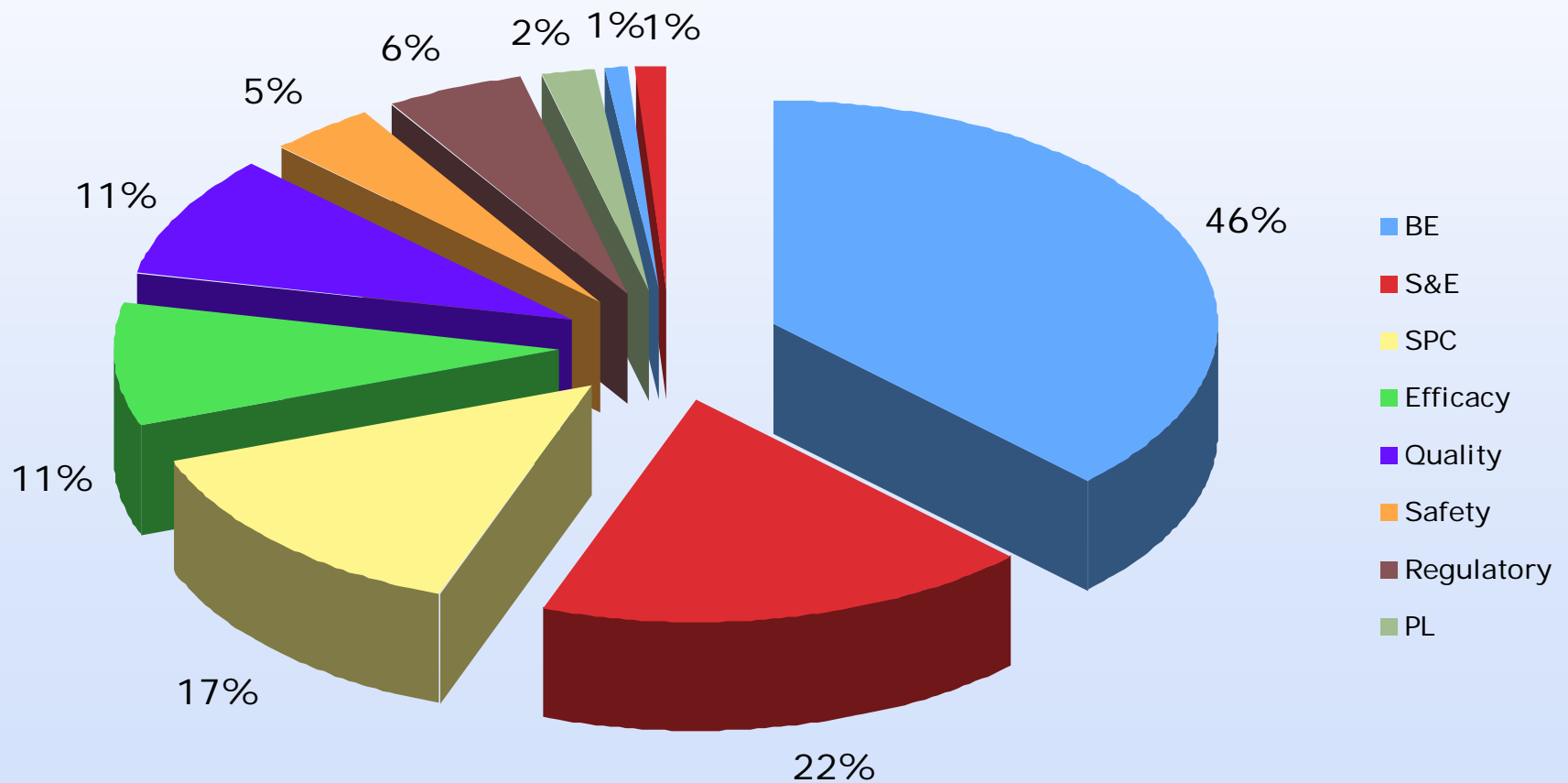


CMD(h) 60-day Referral Procedures 1st January to 31st December 2008

Per Grounds**

Procedures referred to CMD(h) in 2008*

* The numbers include 26 procedures (12 MRP, 14 DCP) referred to the CMD(h) on identical grounds



** one procedure may be referred on more than one ground

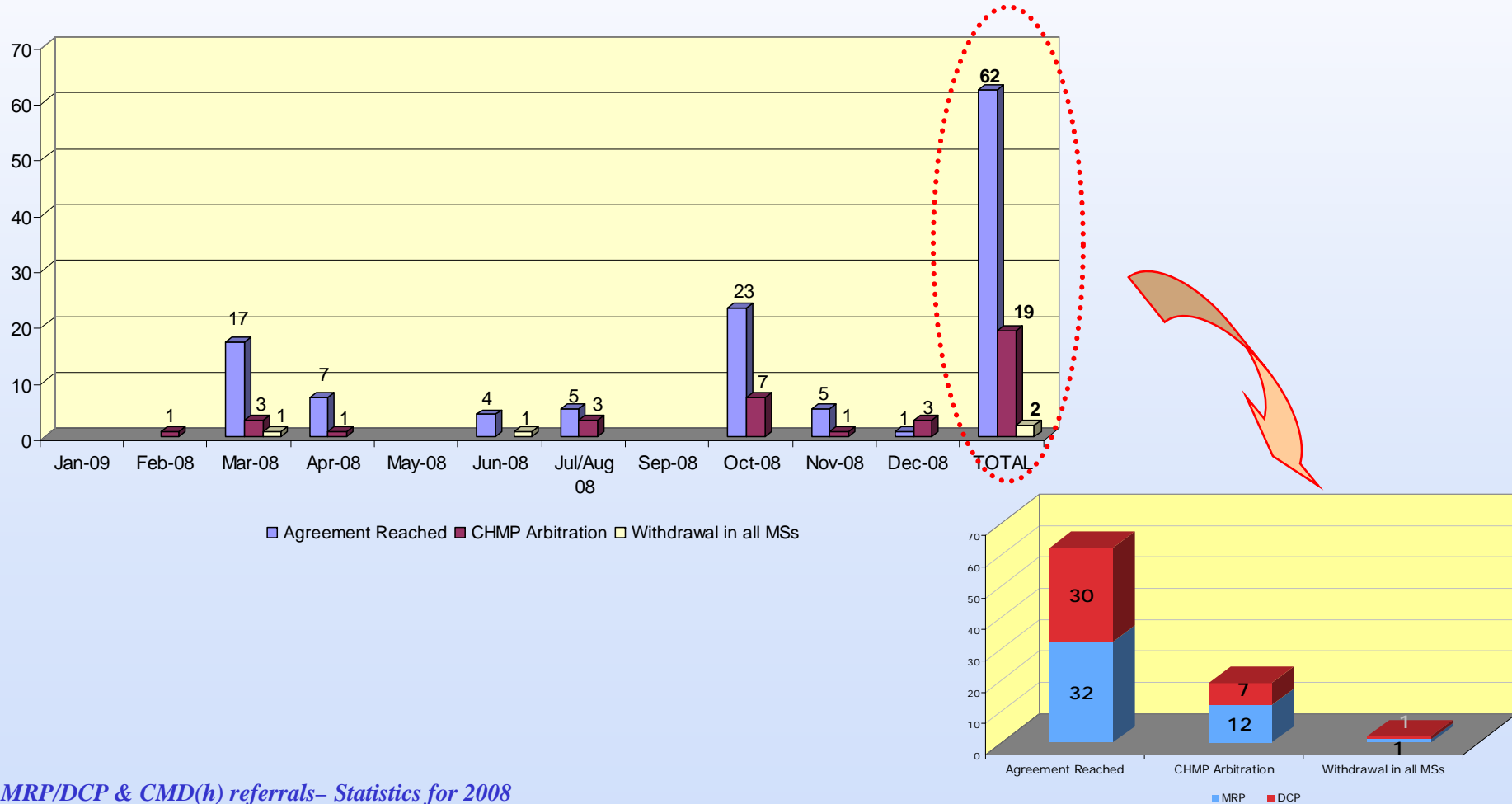
CMD(h) 60-day Referral Procedures 1st January to 31st December 2008

Per Outcome **at Day 60****

Procedures referred to CMD(h) in 2007 & 2008 - Overview*

* The numbers include 27 procedures (15 MRP, 12 DCP) referred to the CMD(h) on identical grounds

** Scientific discussions take place at every monthly CMD(h) meeting. However Day 60 may fall at the beginning of the following month.



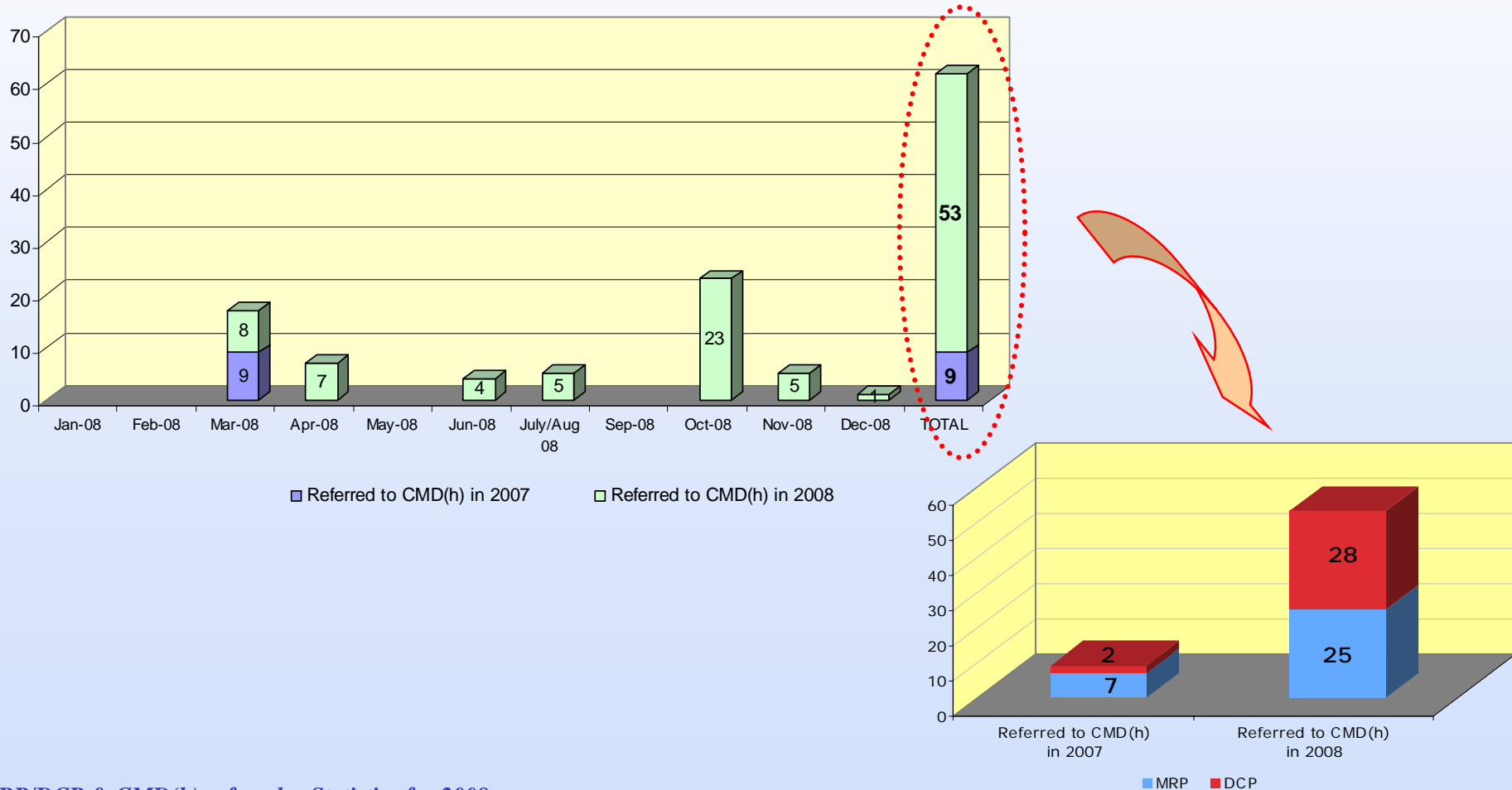
CMD(h) 60-day Referral Procedures 1st January to 31st December 2008

Per Outcome at Day 60**

(procedures referred to CMD(h) in 2007 & 2008) – Agreement Reached in 2008*

* The numbers include 27 procedures (15 MRP, 12 DCP) referred to the CMD(h) on identical grounds

** Scientific discussions take place at every monthly CMD(h) meeting. However Day 60 may fall at the beginning of the following month.



CMD(h) 60-day Referral Procedures 1st January to 31st December 2008

Per Outcome at Day 60**

(procedures referred to CMD(h) in 2007 & 2008) – CHMP Arbitration*

* The numbers include 27 procedures (15 MRP, 12 DCP) referred to the CMD(h) on identical grounds

** Scientific discussions take place at every monthly CMD(h) meeting. However Day 60 may fall at the beginning of the following month.

