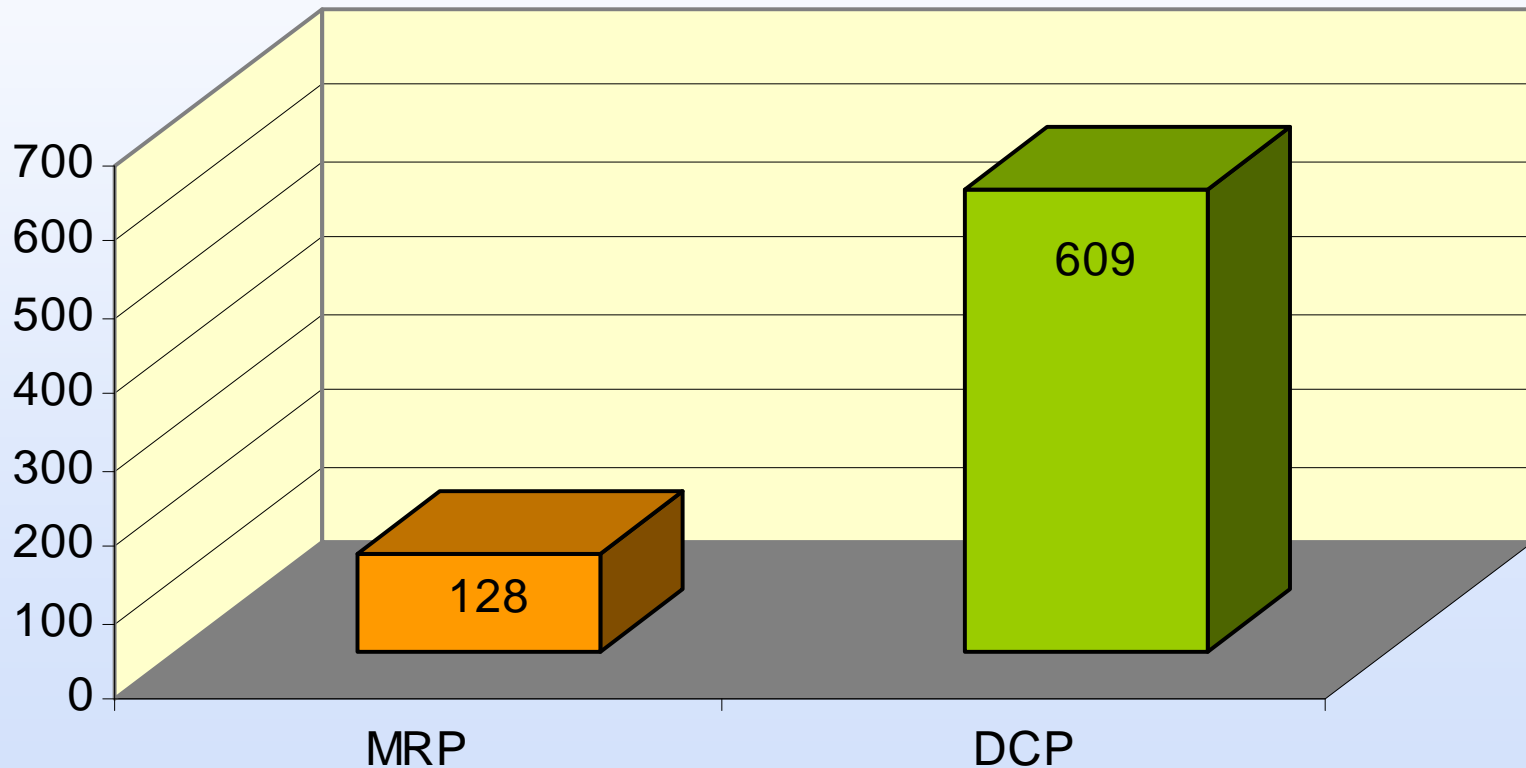


# MRP/DCP New applications 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## FINALISED Procedures\*

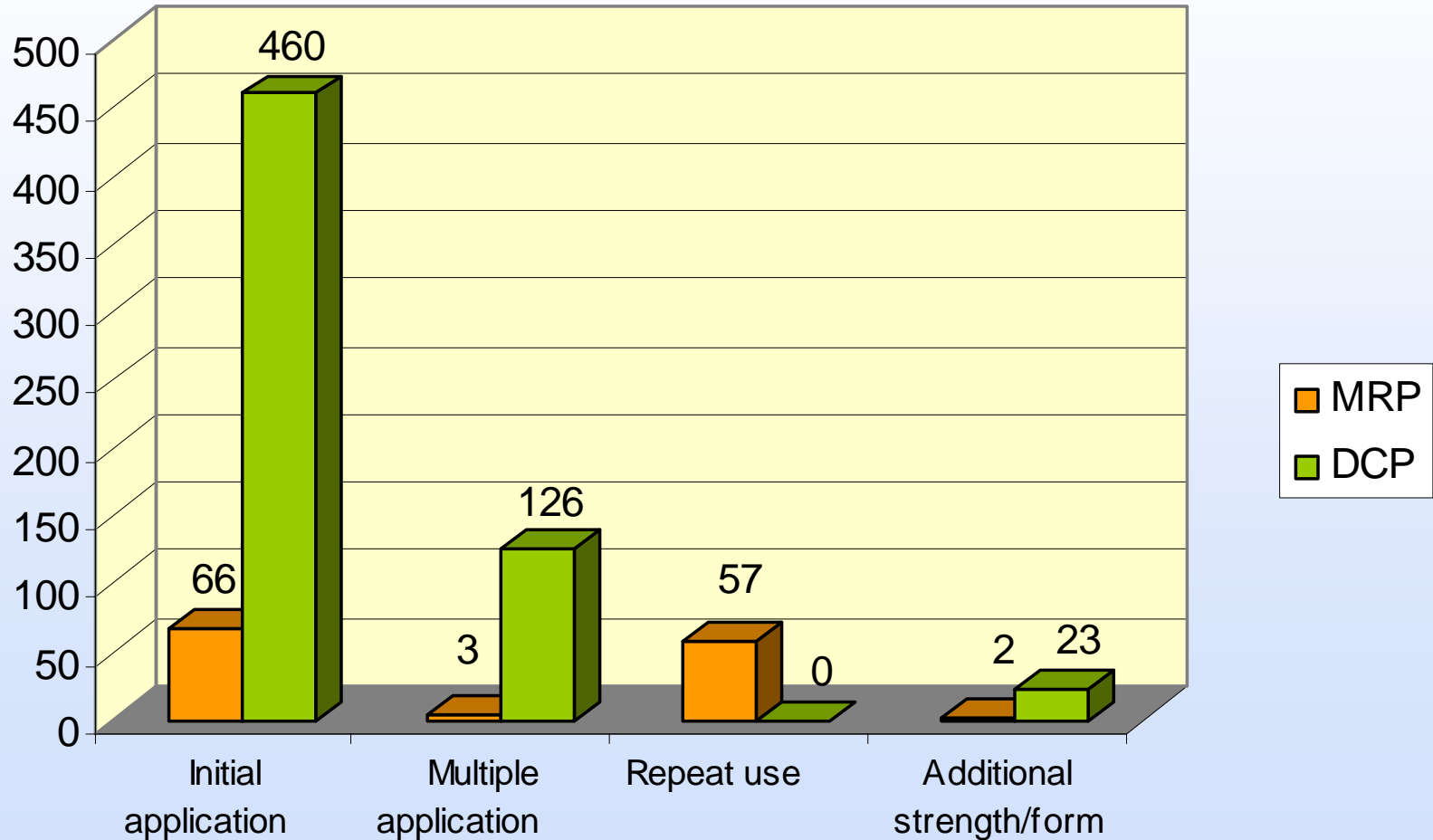
*Total: 128 MRP and 609 DCP (regarding 272 and 1254 products respectively)*



*\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised'*

# MRP/DCP New applications 1<sup>st</sup> January to 30<sup>th</sup> June 2011

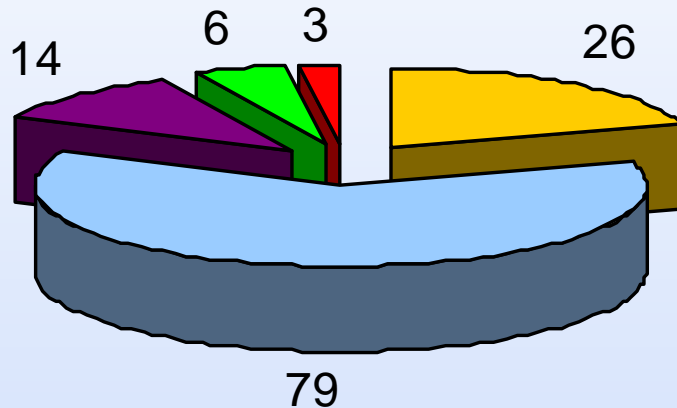
## FINALISED Procedures – MRP/DCP per type of procedure\*



\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised

### **FINALISED Procedures - MRP per legal basis\***

*Total: 128 MRP (regarding 272 products)*

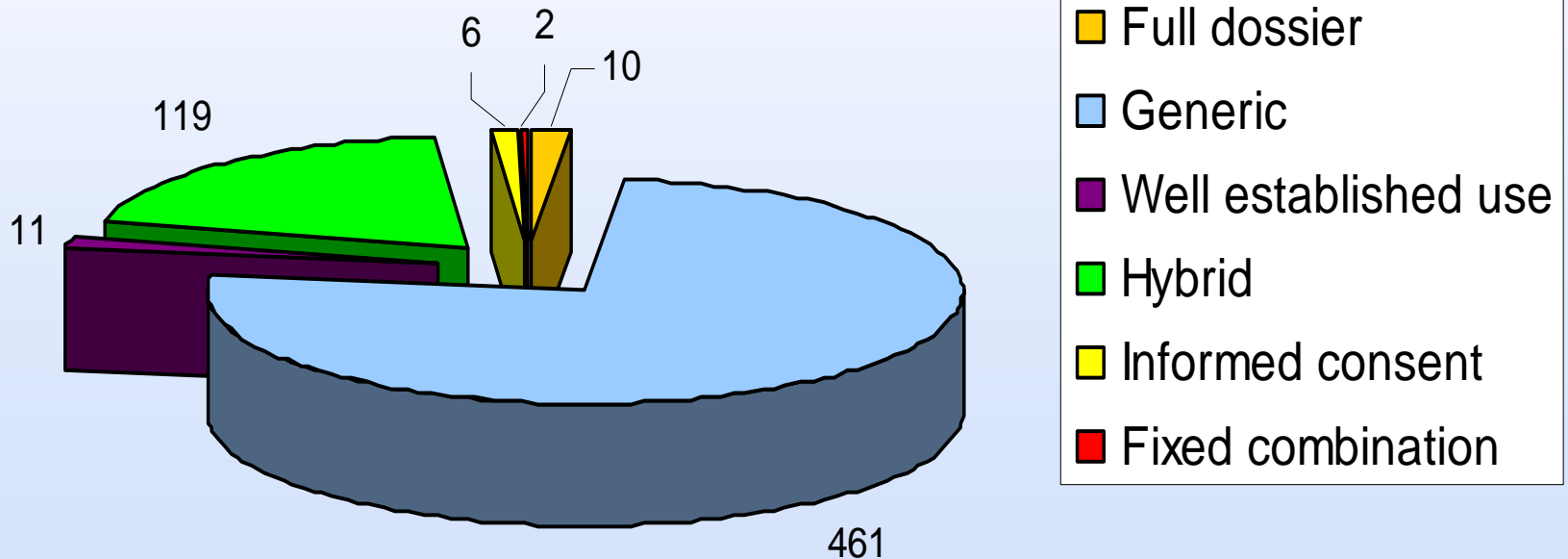


- Full dossier
- Generic
- Well established use
- Hybrid
- Fixed combination

*\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised'*

### **FINALISED Procedures - DCP per legal basis\***

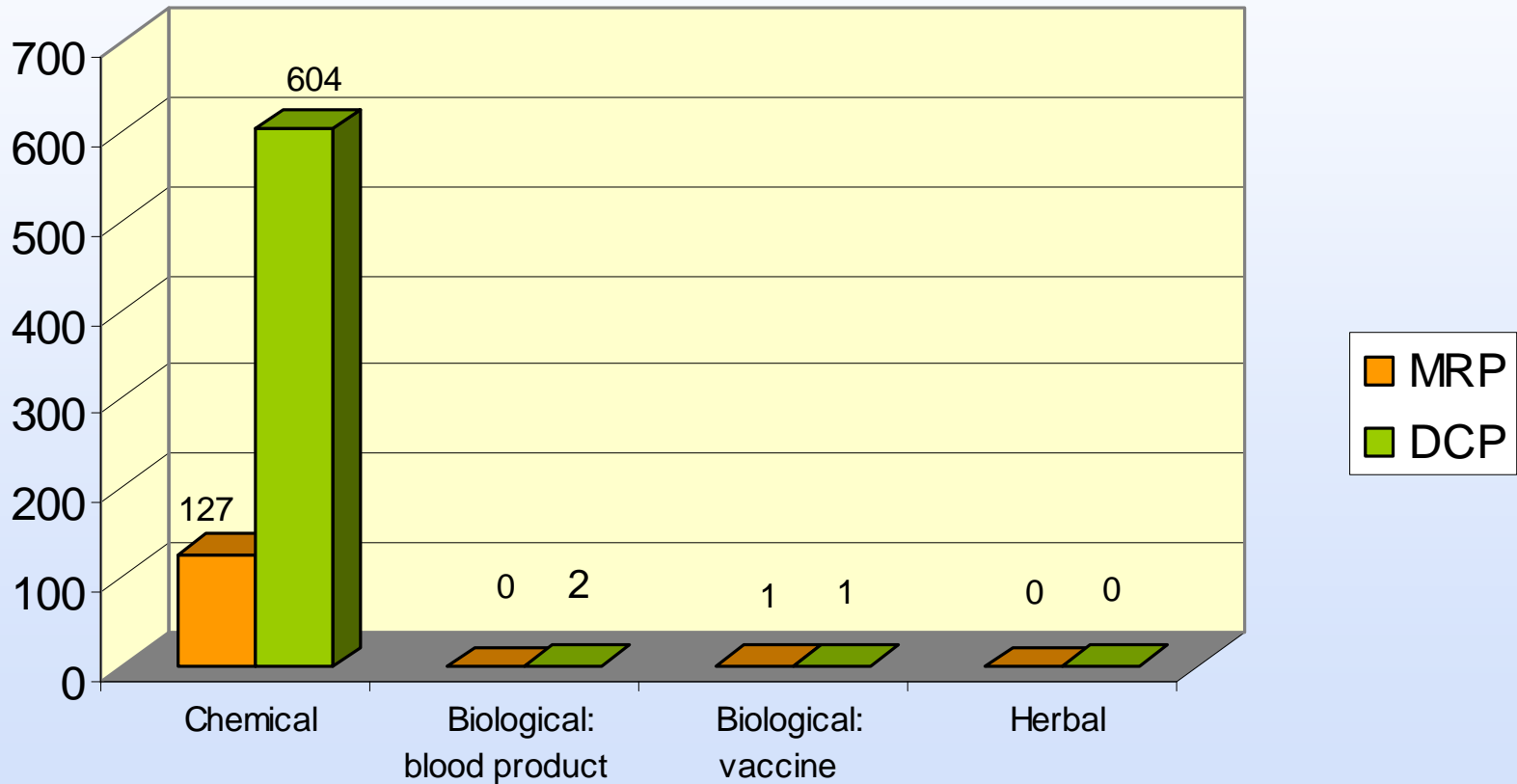
Total: 609 DCP (regarding 1254 products)



\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised'

# MRP/DCP New applications 1<sup>st</sup> January to 30<sup>th</sup> June 2011

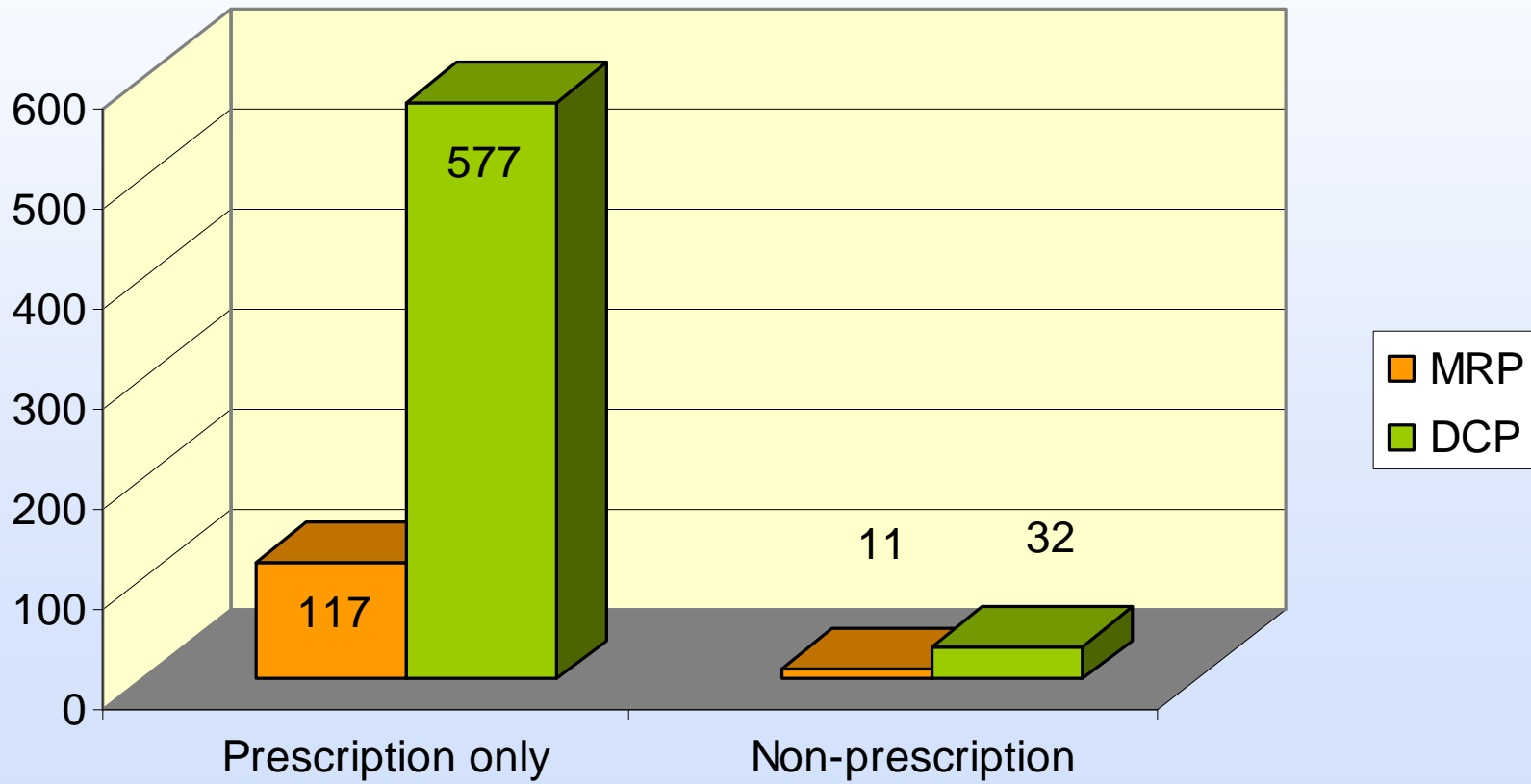
## FINALISED Procedures – MRP/DCP per type of product\*



\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised'

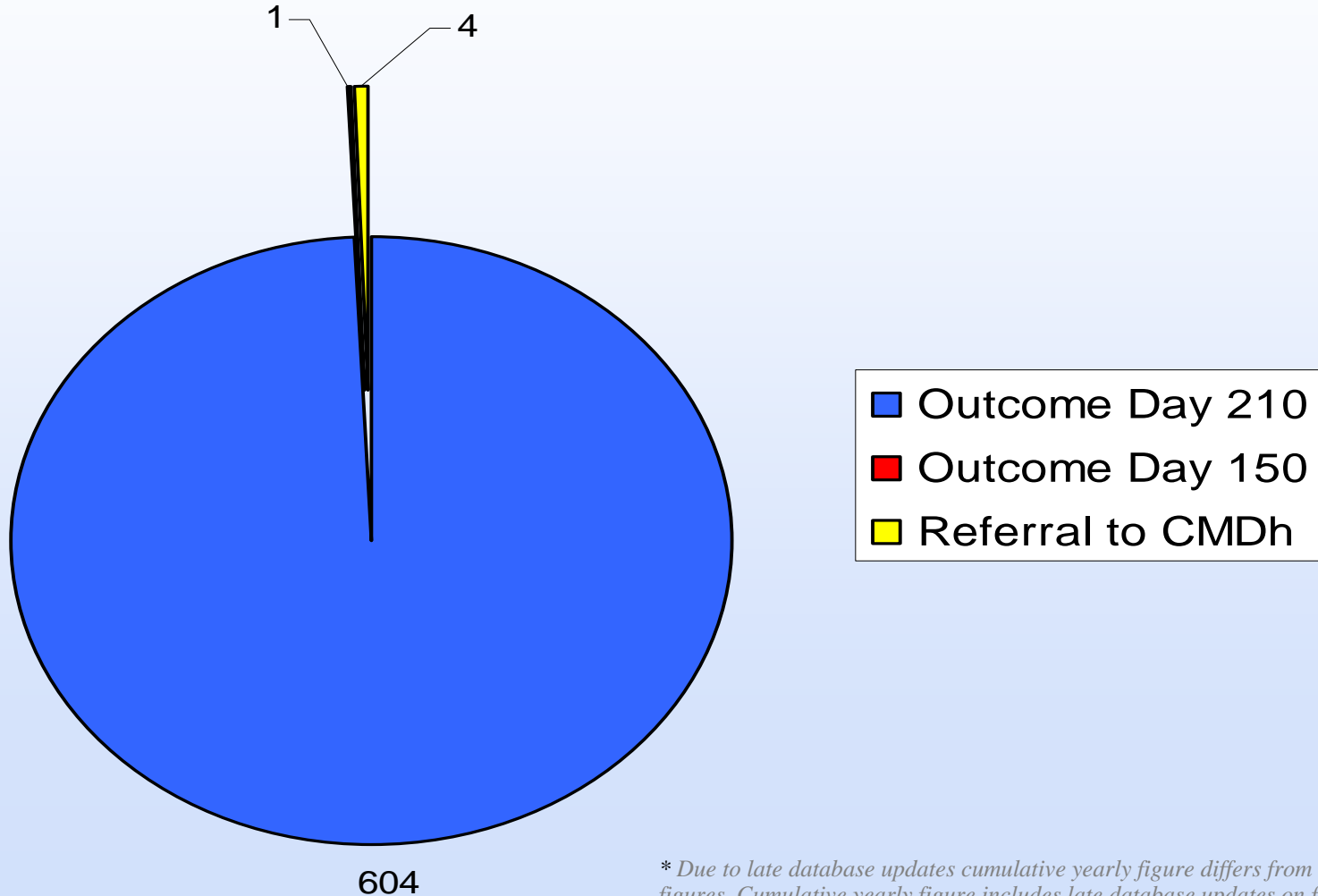
# MRP/DCP New applications 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## FINALISED Procedures – MRP/DCP per prescription status\* *(as approved by the RMS)*



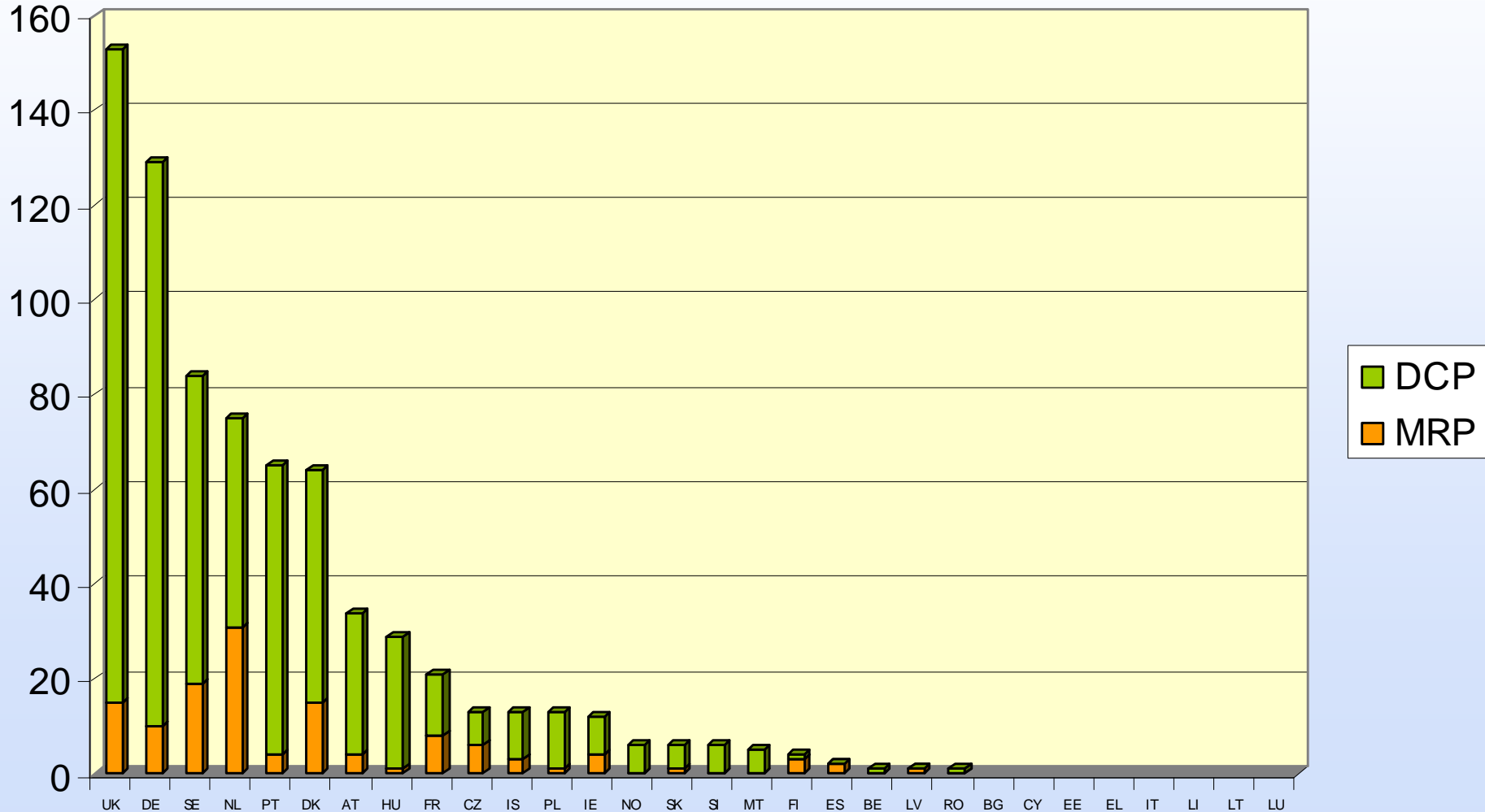
\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised

## FINALISED Procedures – DCP per day of outcome\*



\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised'

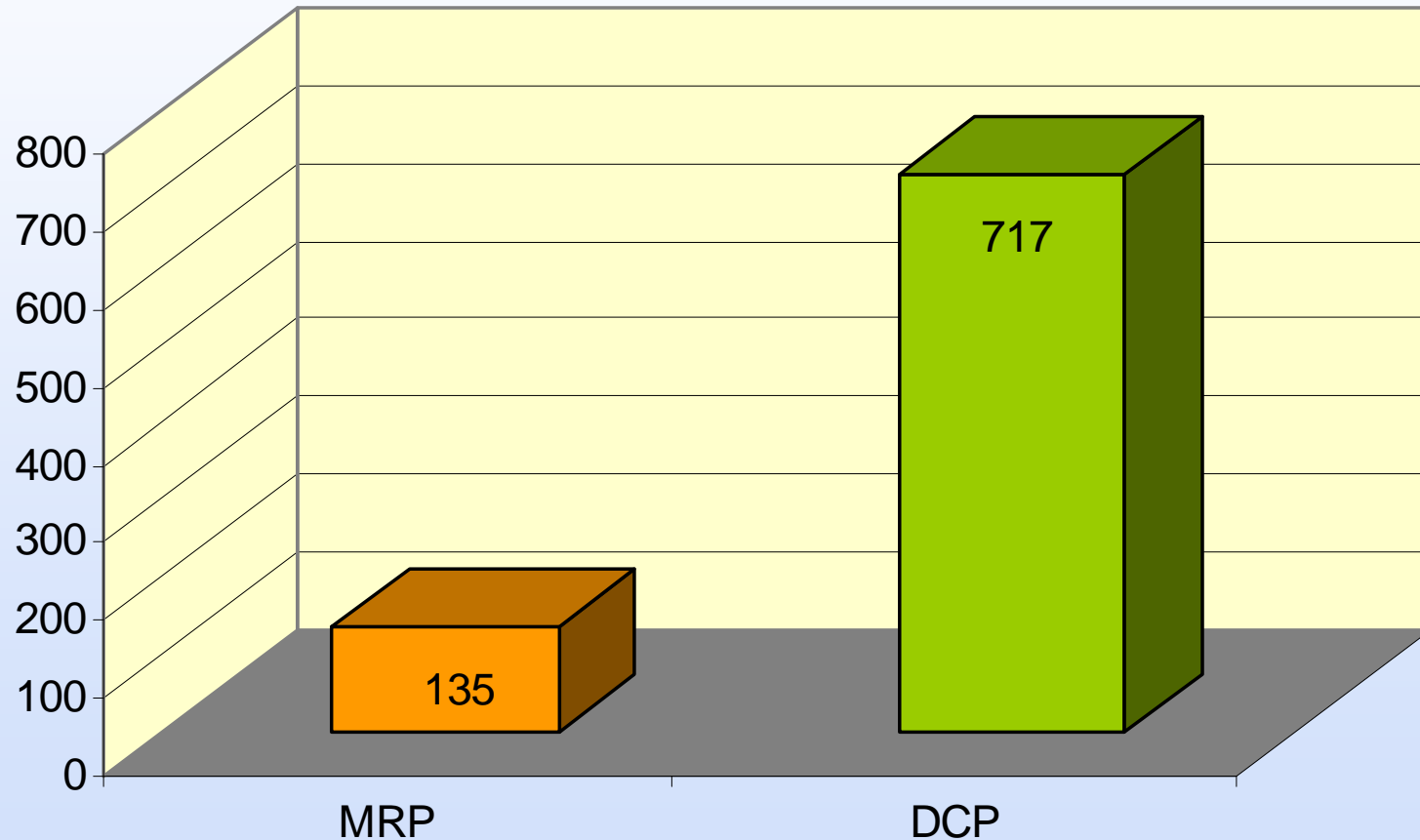
### **FINALISED Procedures – MRP/DCP per RMS**



# MRP/DCP New applications 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## STARTED Procedures\*

*Total: 135 MRP and 717 DCP (regarding 283 and 1410 products respectively)*

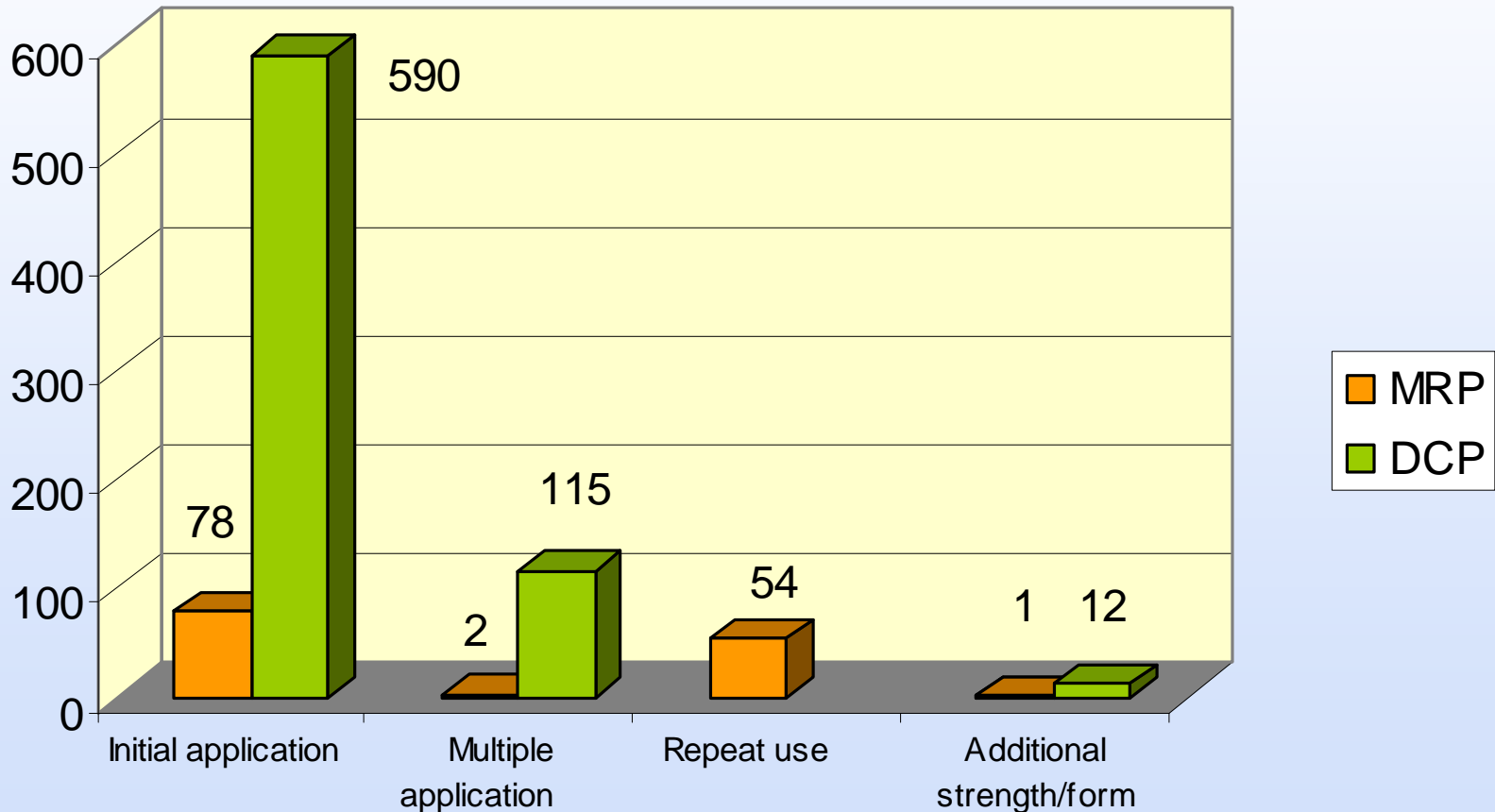


*\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised'*

# MRP/DCP New applications 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## STARTED Procedures – MRP/DCP per type of procedure\*

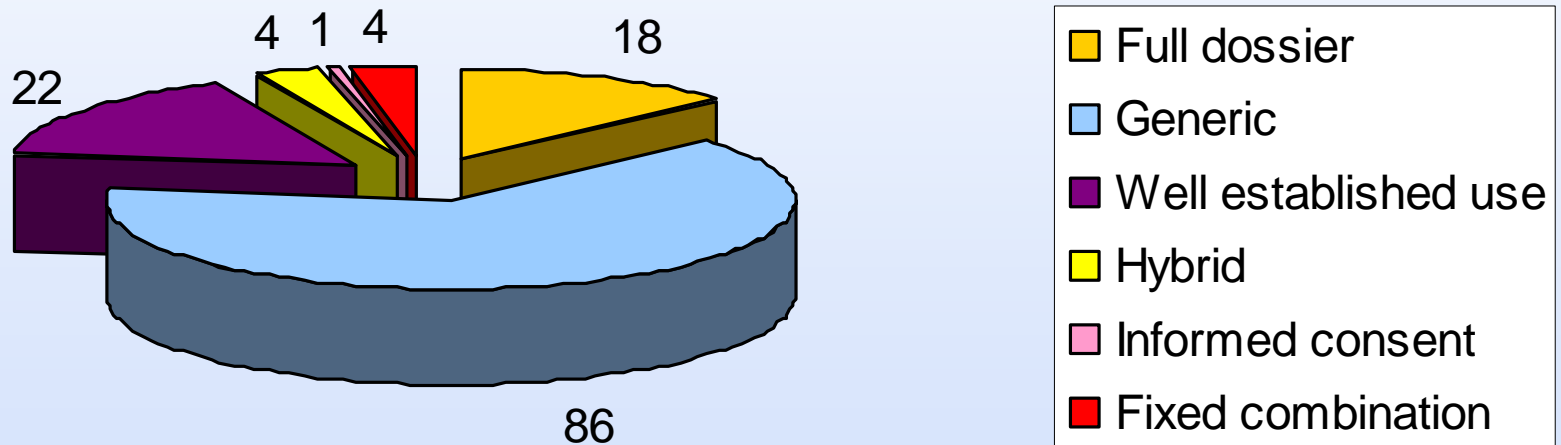
Total: 177 MRP and 709 DCP (regarding 283 and 1410 products respectively)



\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised

### STARTED Procedures – MRP per legal basis\*

Total: 177 MRP (regarding 283 products)

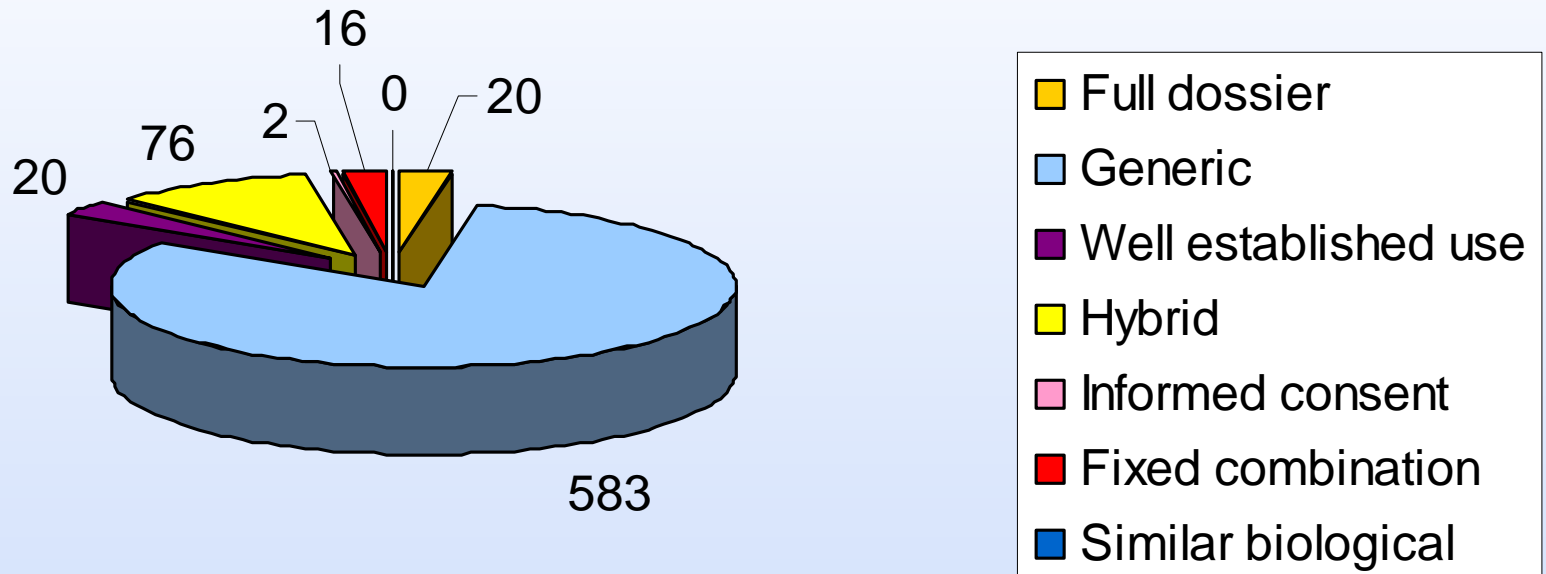


\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised

# MRP/DCP New applications 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## STARTED Procedures – DCP per legal basis\*

Total: 709 DCP (regarding 1410 products)

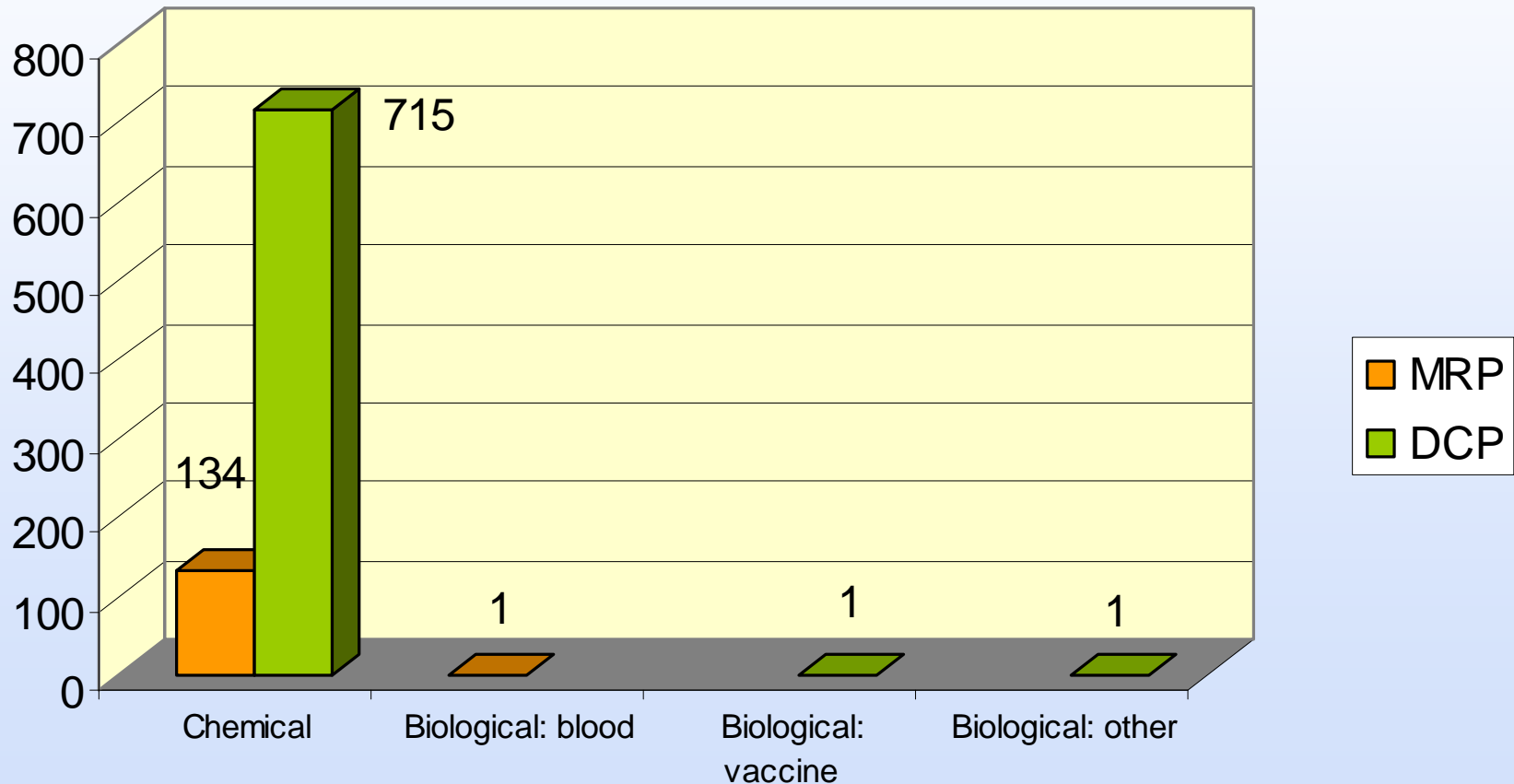


\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised'

# MRP/DCP New applications 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## STARTED Procedures – MRP/DCP per type of product\*

*Total: 177 MRP and 709 DCP (regarding 283 and 1410 products respectively)*

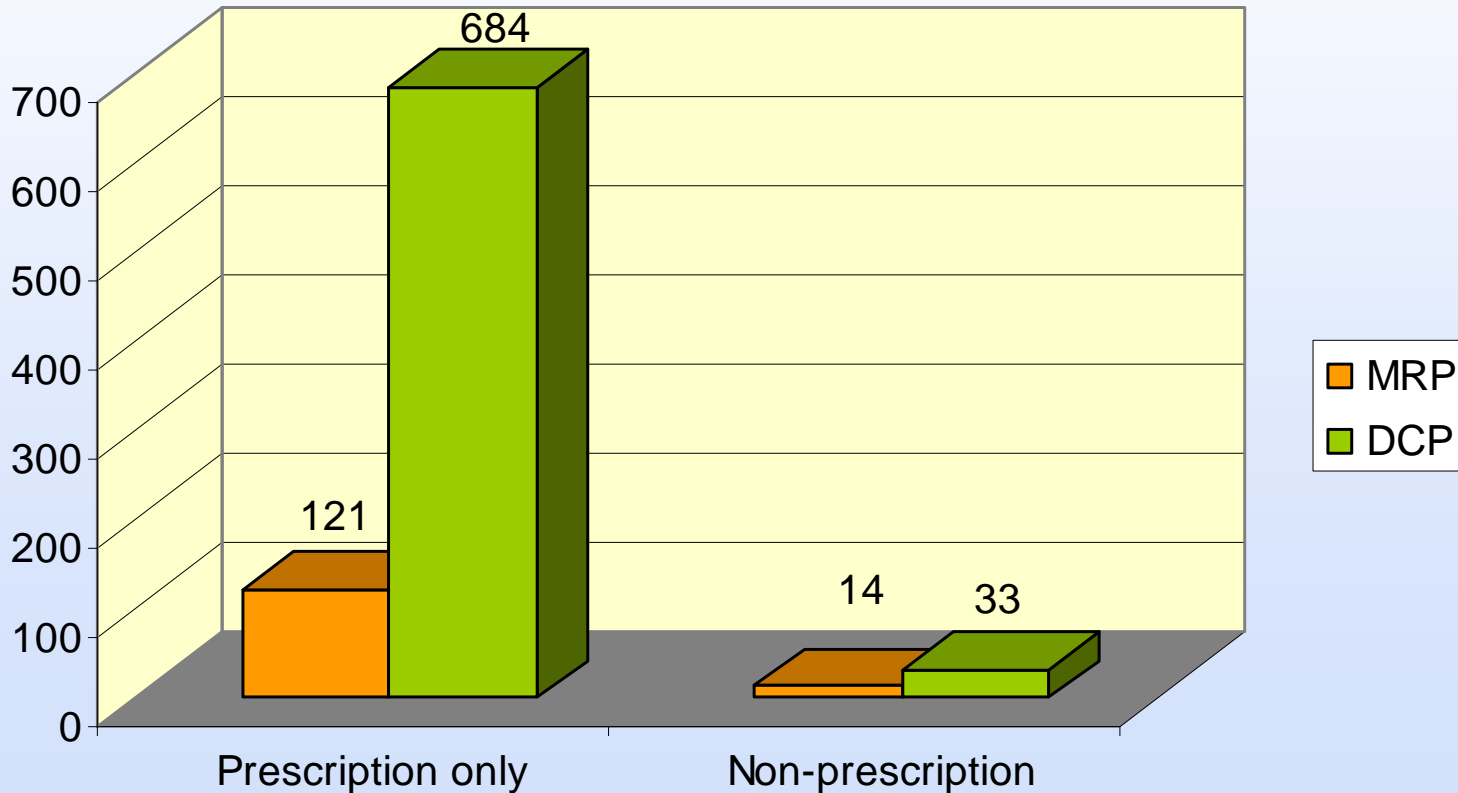


*\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised'*

# MRP/DCP New applications 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## STARTED Procedures – MRP/DCP per prescription status\* (as approved by the RMS)

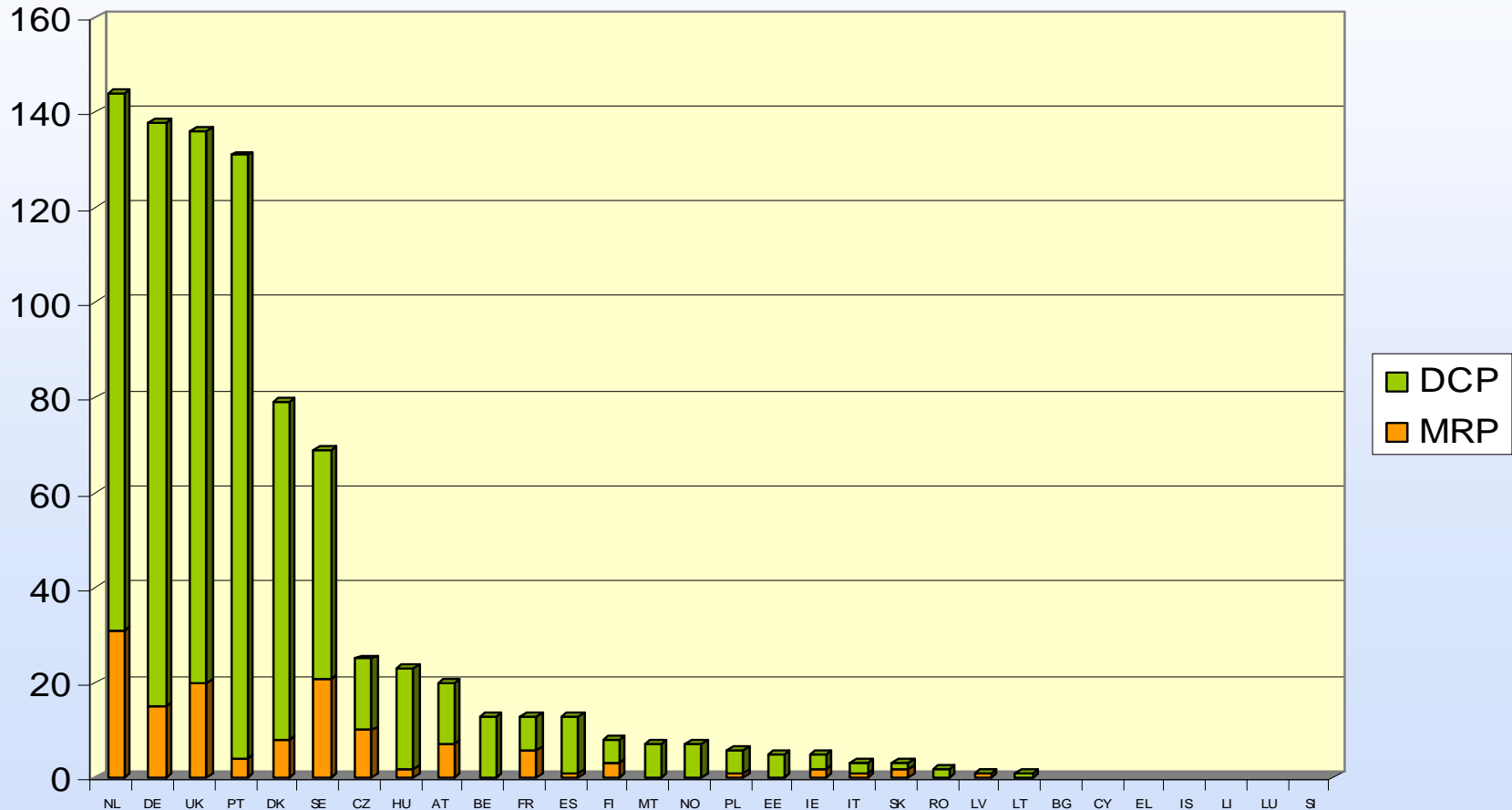
Total: 177 MRP and 709 DCP (regarding 283 and 1410 products respectively)



\* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised

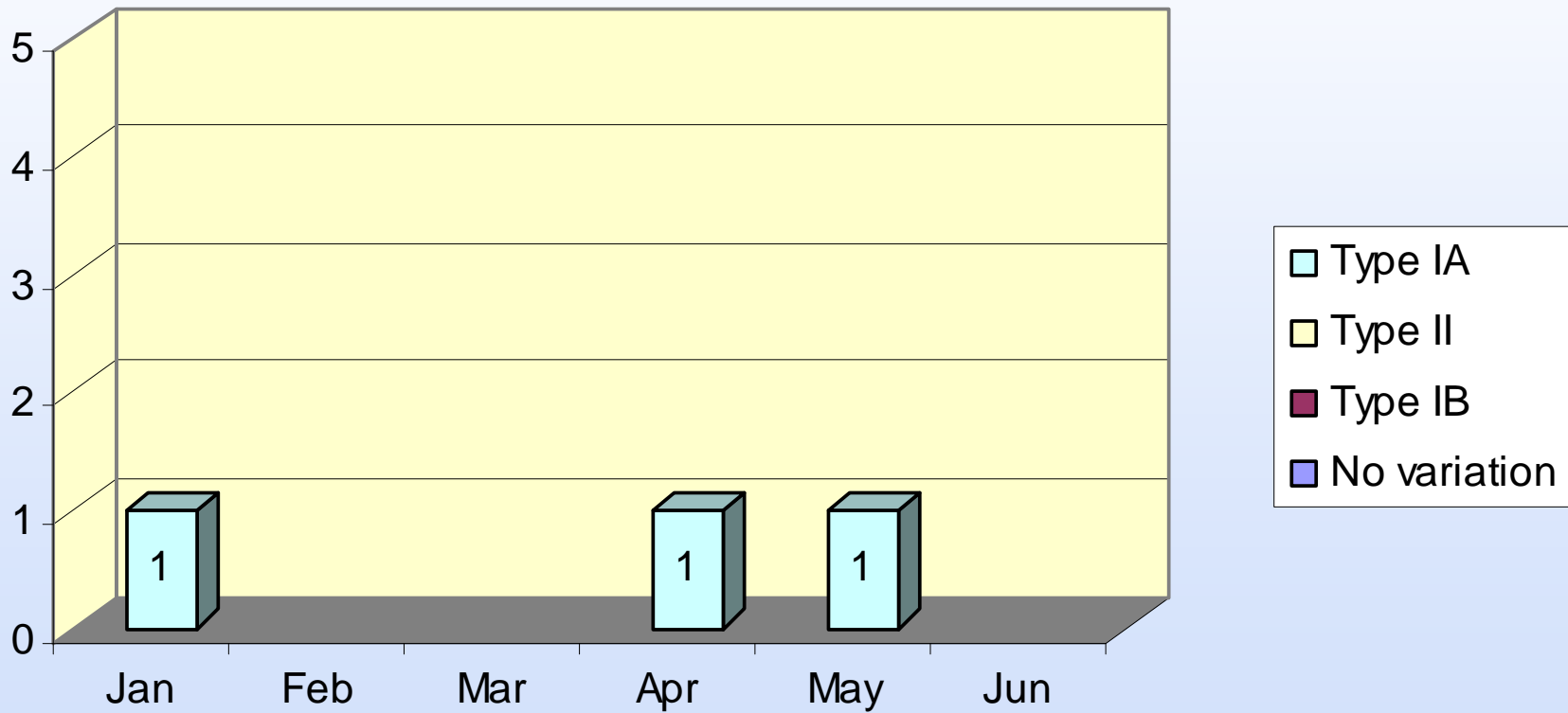
# MRP/DCP New applications 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## **STARTED** Procedures – MRP/DCP per RMS



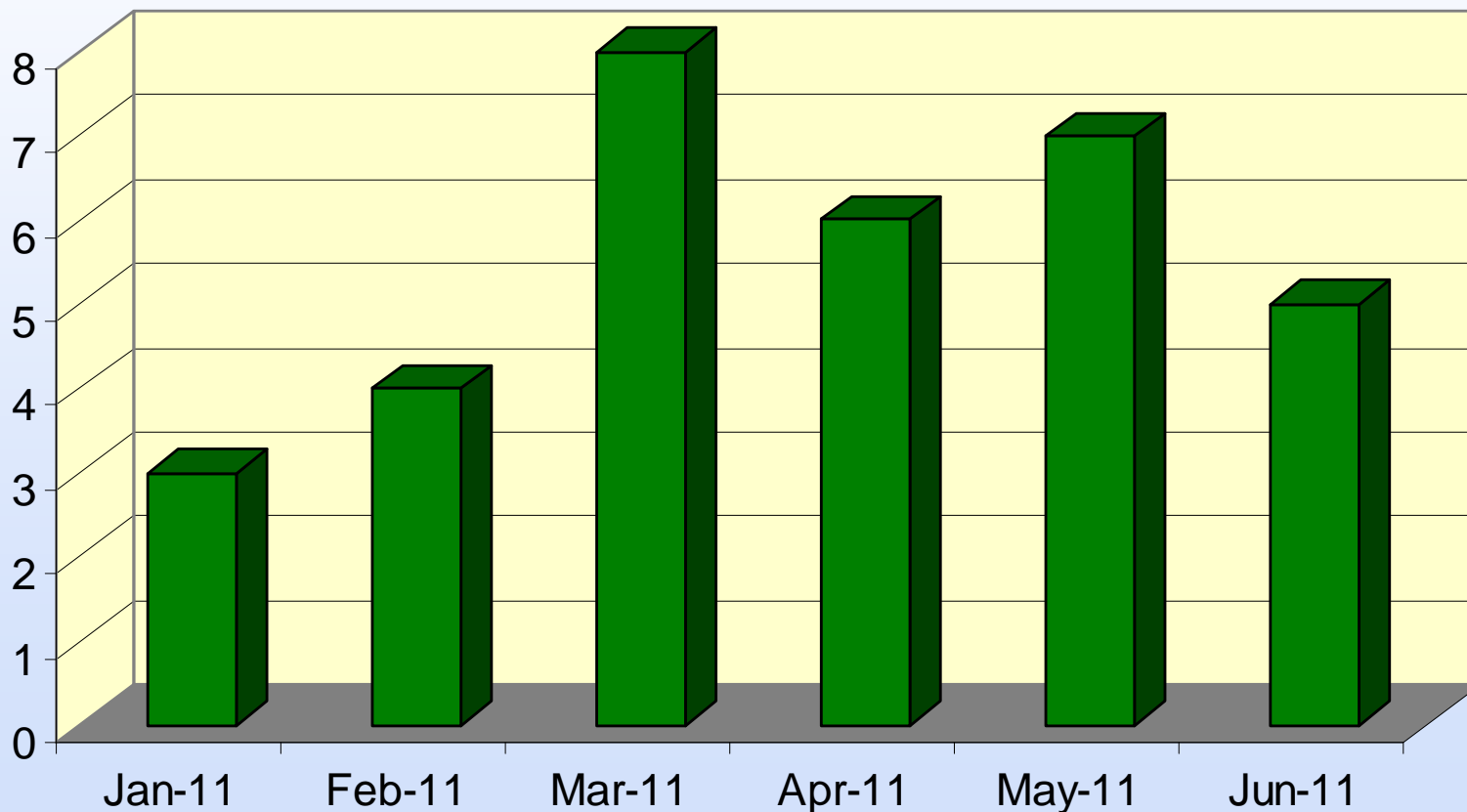
# Implementation of variation regulation 1st January to 30th June 2011

## Art.5 recommendations on variation classification – Per outcome



# Implementation of variation regulation 1st January to 30th June 2011

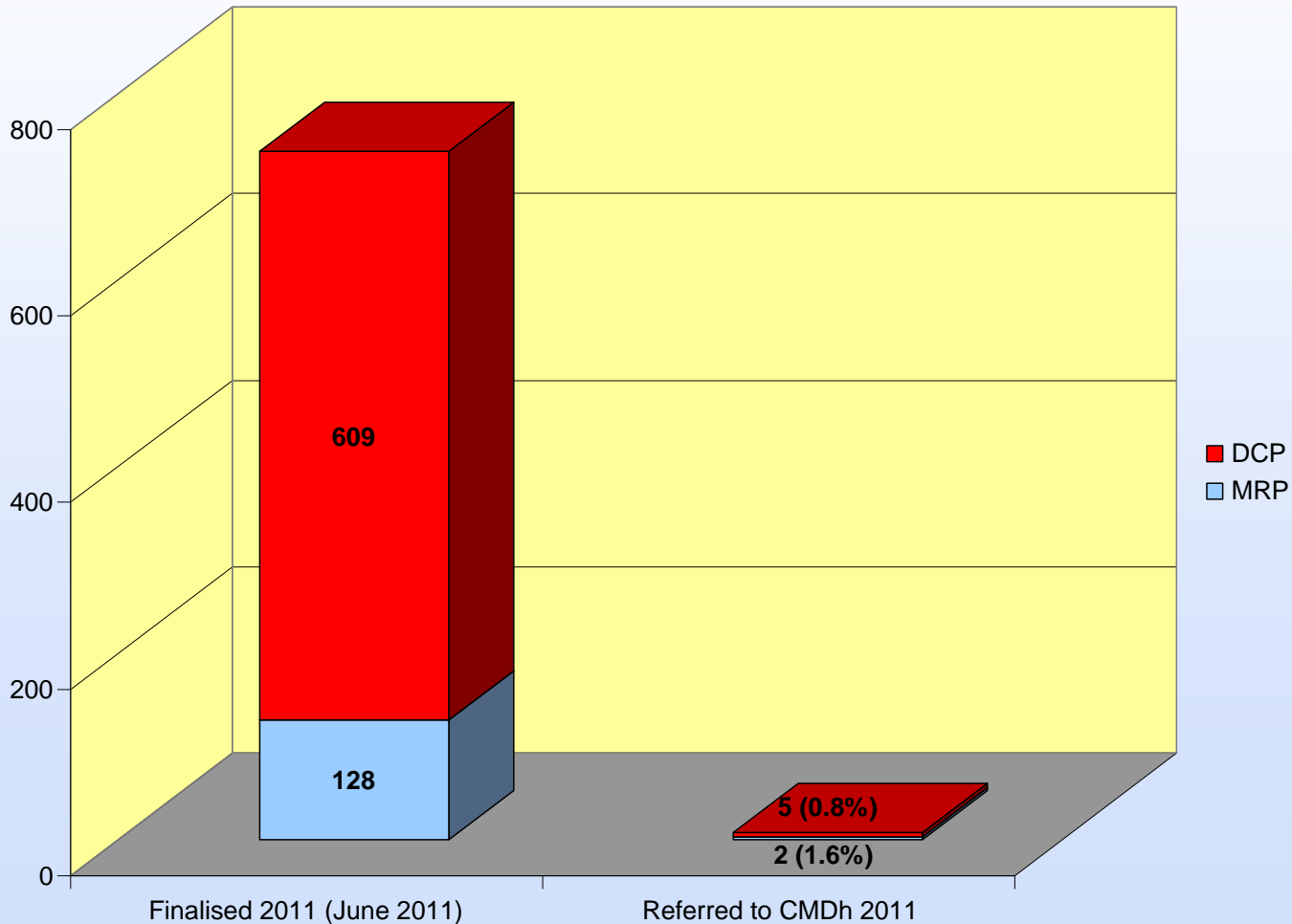
## Letters of intent received for Worksharing involving MRP/DCP only *(per date of discussion at CMDh meetings)*



# CMDh 60-day Referral Procedures

## 1<sup>st</sup> January to 30<sup>th</sup> June 2011

### Overview Finalised vs. Referred to CMDh in 2011 Per Type of Procedures (MRP/DCP)

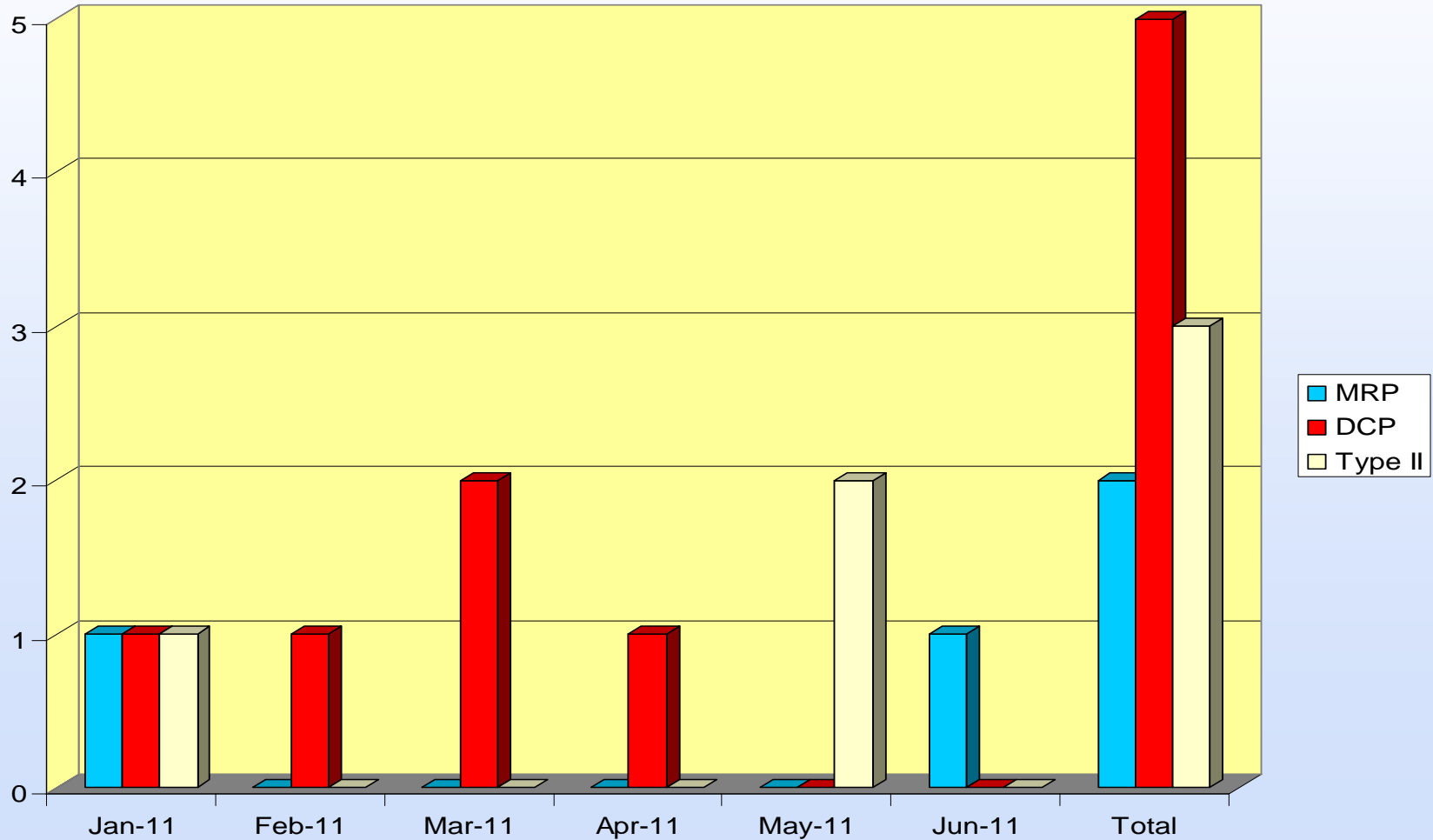


# CMDh 60-day Referral Procedures

## 1<sup>st</sup> January to 30<sup>th</sup> June 2011

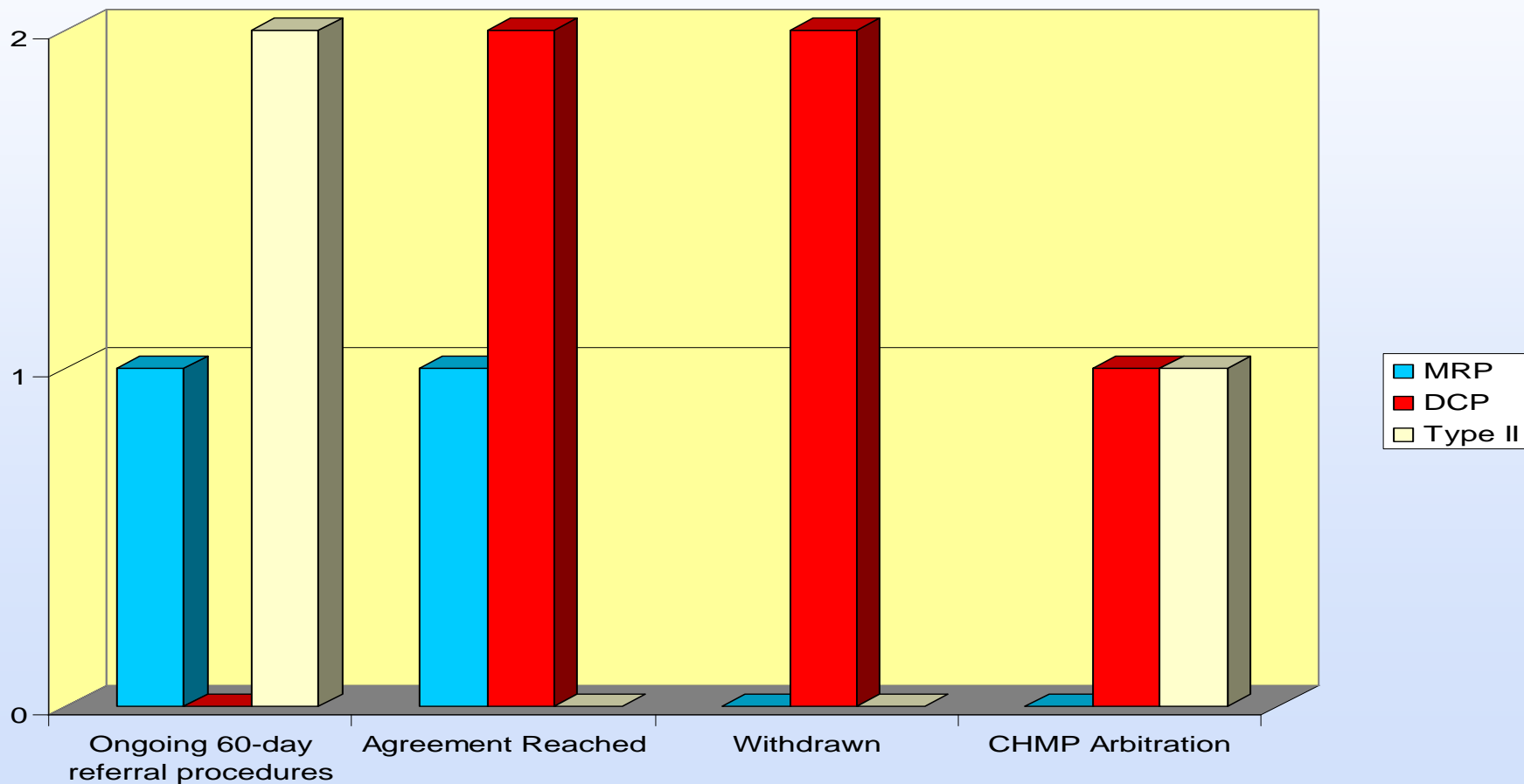
### Procedures referred to CMDh in 2011

#### Per Type of Procedures (MRP/DCP)



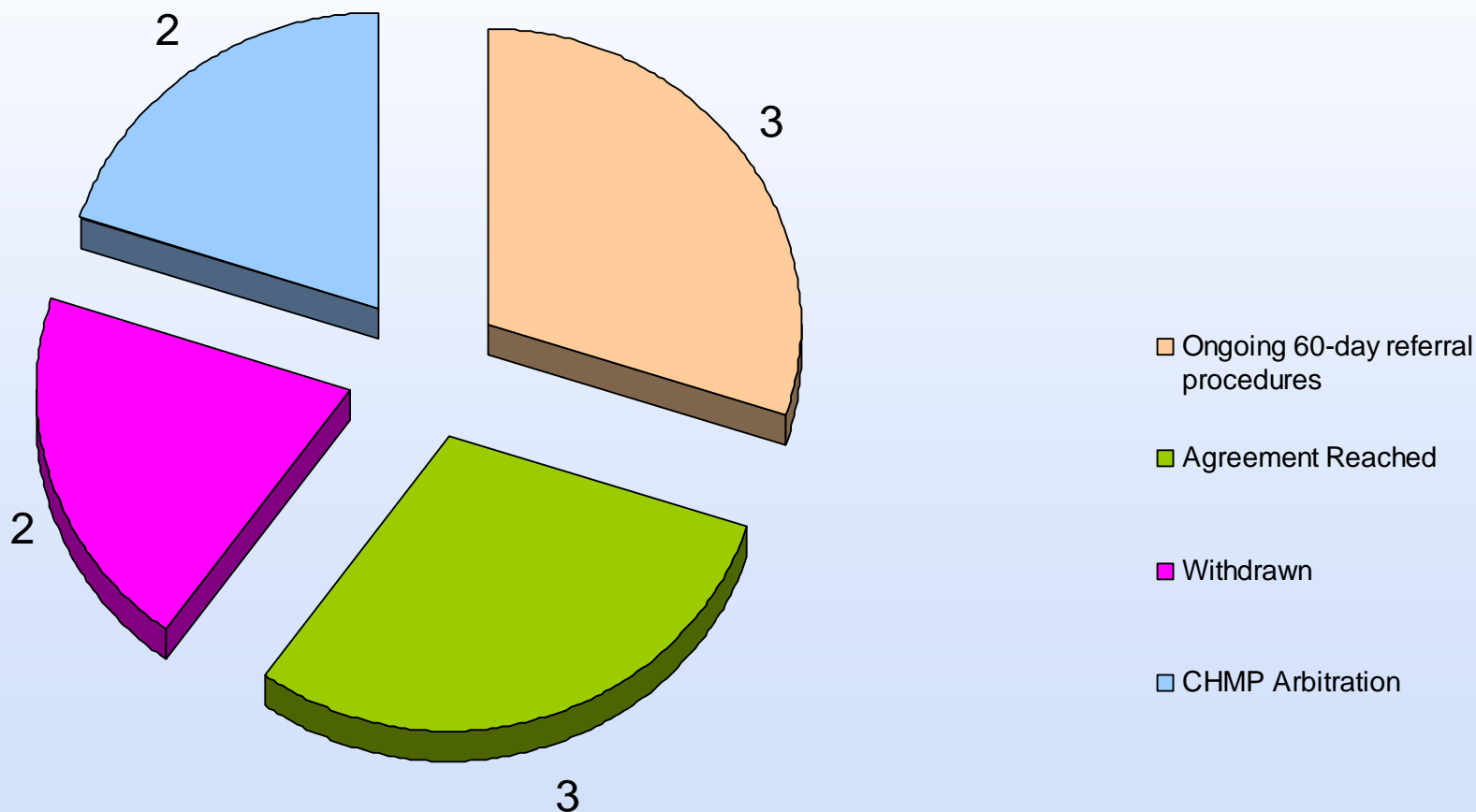
### Procedures referred to CMDh in 2011

#### Status per Type of Procedures (MRP/DCP)



# CMDh 60-day Referral Procedures 1<sup>st</sup> January to 30<sup>th</sup> June 2011

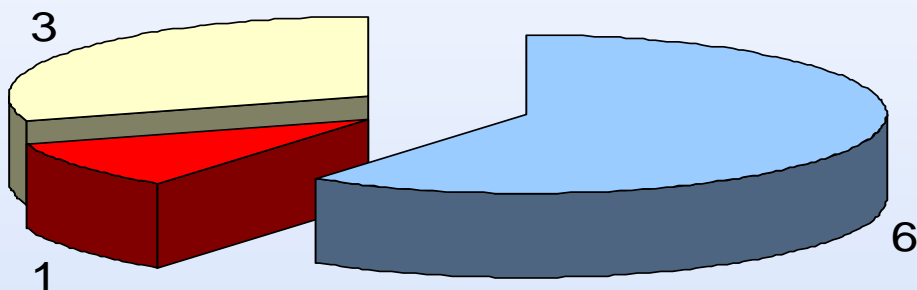
## Procedures referred to CMDh in 2011 – Status overview



# CMDh 60-day Referral Procedures

## 1<sup>st</sup> January to 30<sup>th</sup> June 2011

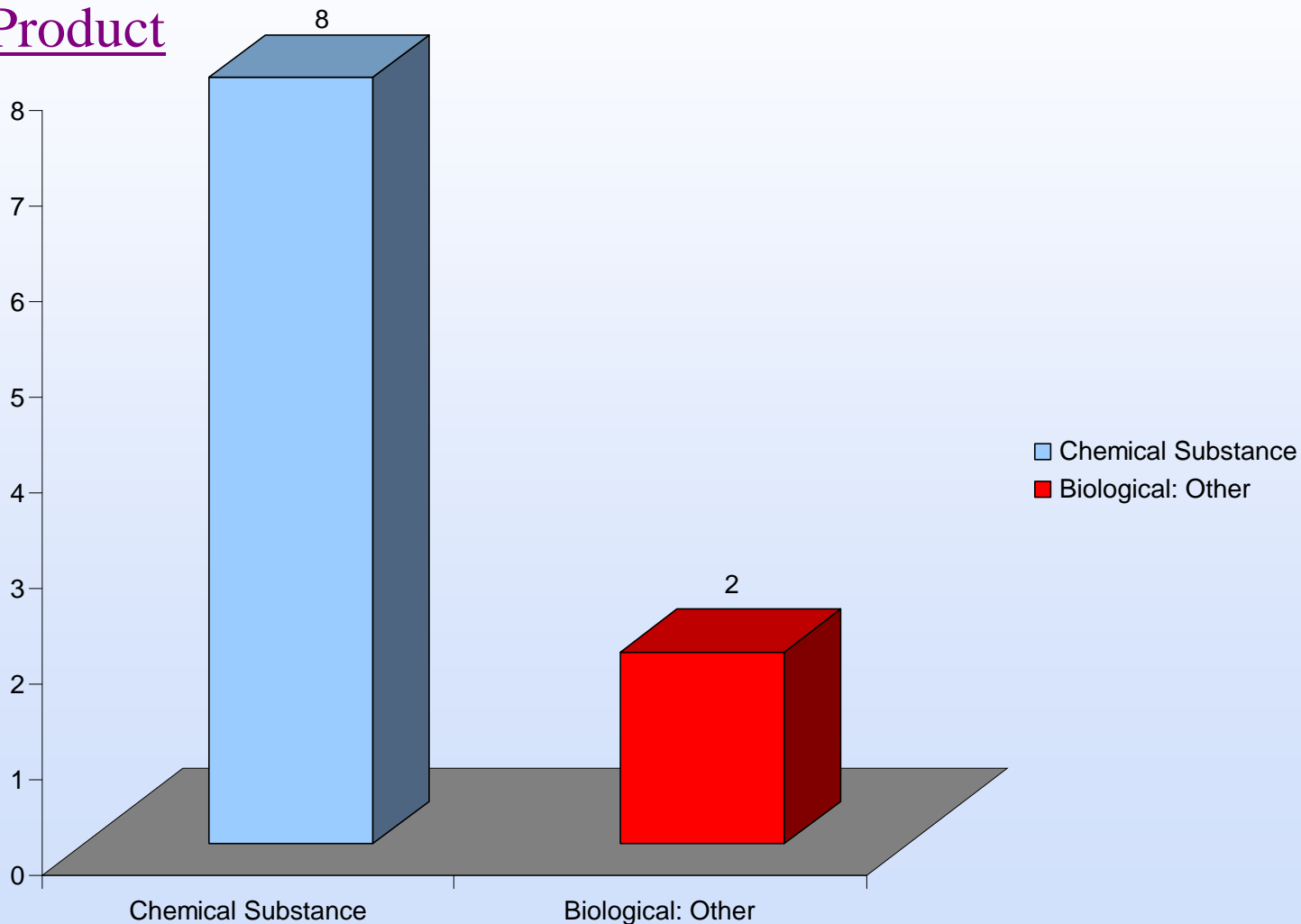
### Procedures referred to CMDh in 2011 Per Type of Procedures (MRP/DCP)



- New Application
- Repeat-Use
- Type II

# CMDh 60-day Referral Procedures 1<sup>st</sup> January to 30<sup>th</sup> June 2011

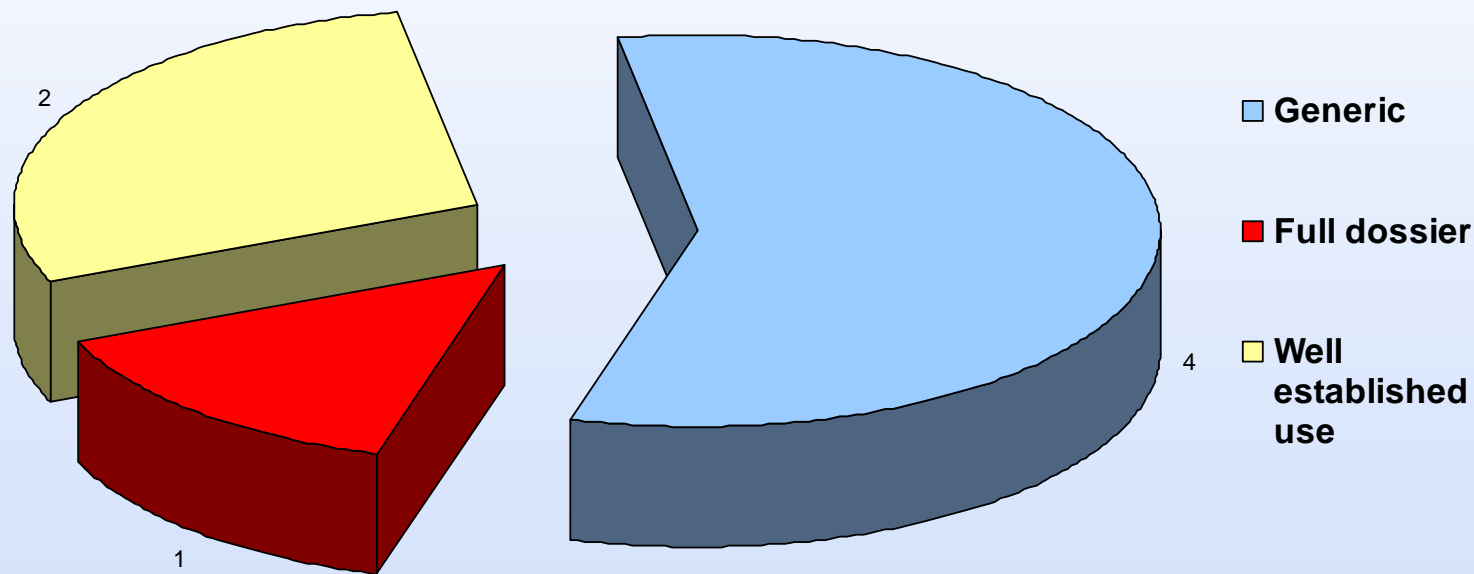
## Procedures referred to CMDh in 2011 Per Type of Product



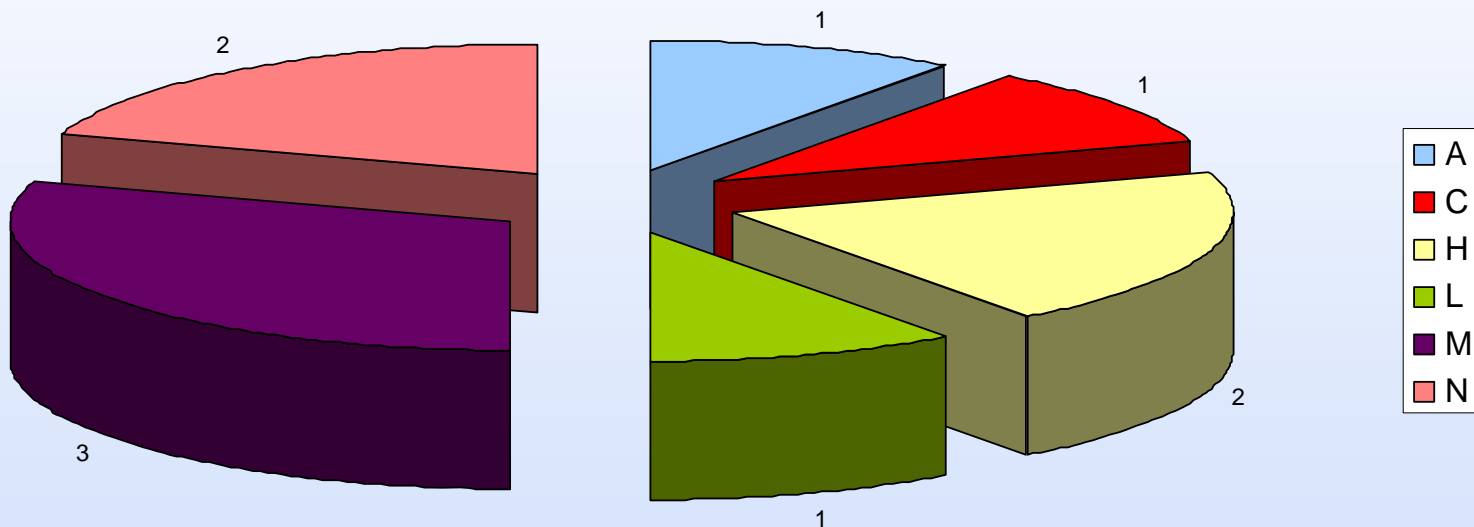
# CMDh 60-day Referral Procedures 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## Procedures referred to CMDh in 2011

Per Legal Basis (excluding referrals for type II variations)



## Procedures referred to CMDh in 2011 Per Therapeutic Area



A: Blood and blood forming organs

C: Cardiovascular system

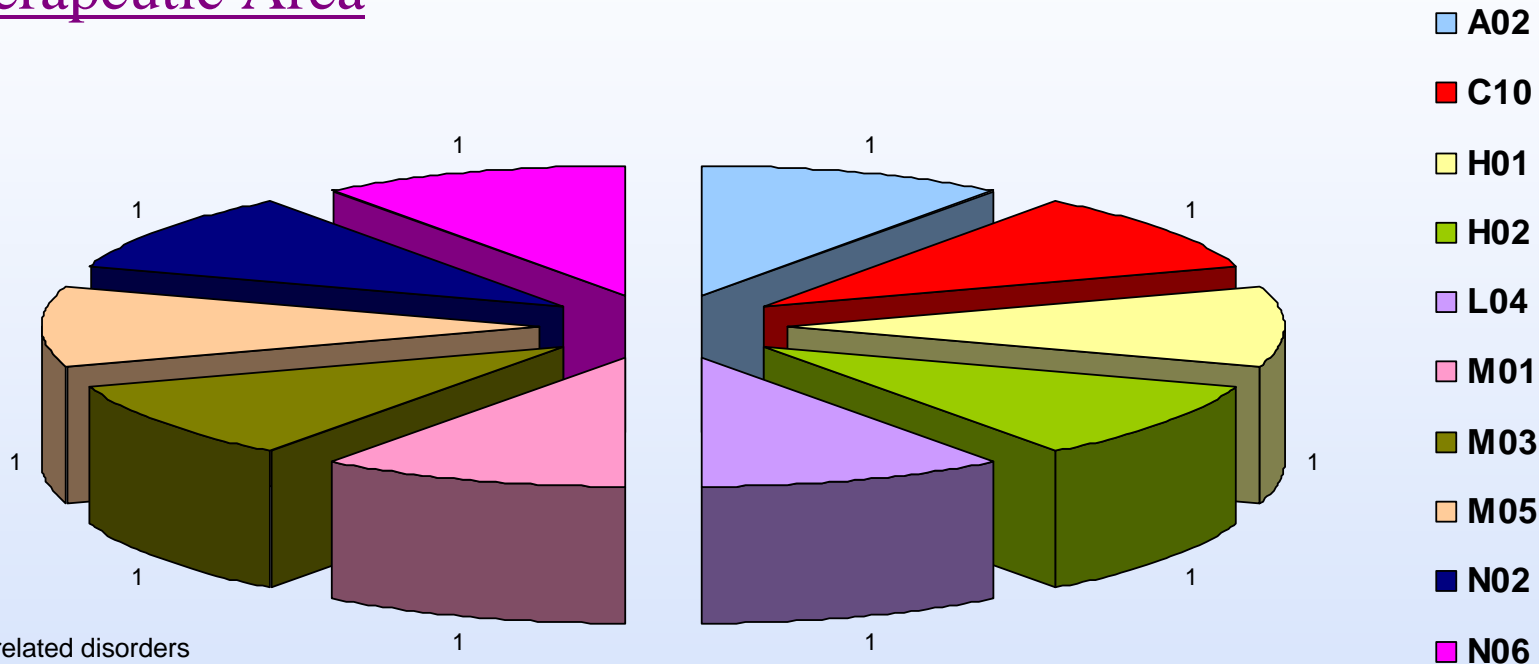
H: Systemic hormonal preparations

L: Antineoplastic and immunomodulating agents

M: Musculo-skeletal system

N: Nervous system

## Procedures referred to CMDh in 2011 Per Therapeutic Area



A02 Drugs for acid related disorders

C10 Lipid modifying agents

H01 Pituitary and hypothalamic hormones and analogues

L04 Immunosuppressants

M01 Anti-inflammatory and antirheumatic products

M03 Muscle relaxants

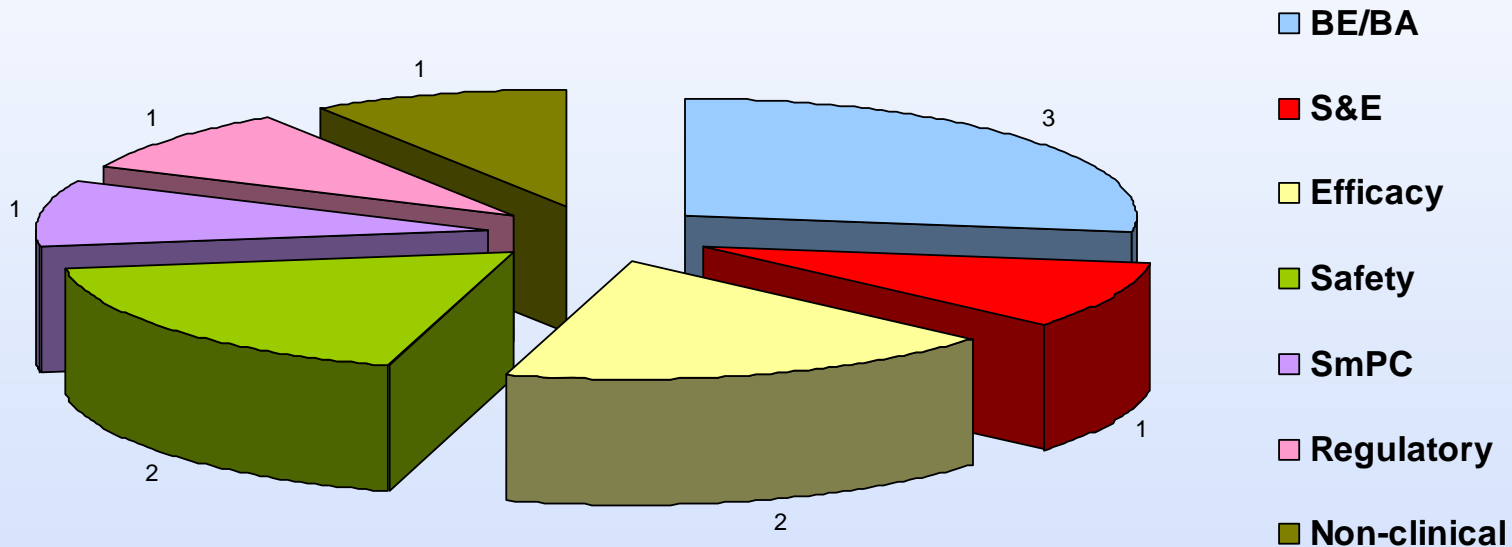
M05 Drugs for treatment of bone diseases

N02 Analgesics

N06 Psychoanaleptics

# CMDh 60-day Referral Procedures 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## Procedures referred to CMDh in 2011 Per Grounds

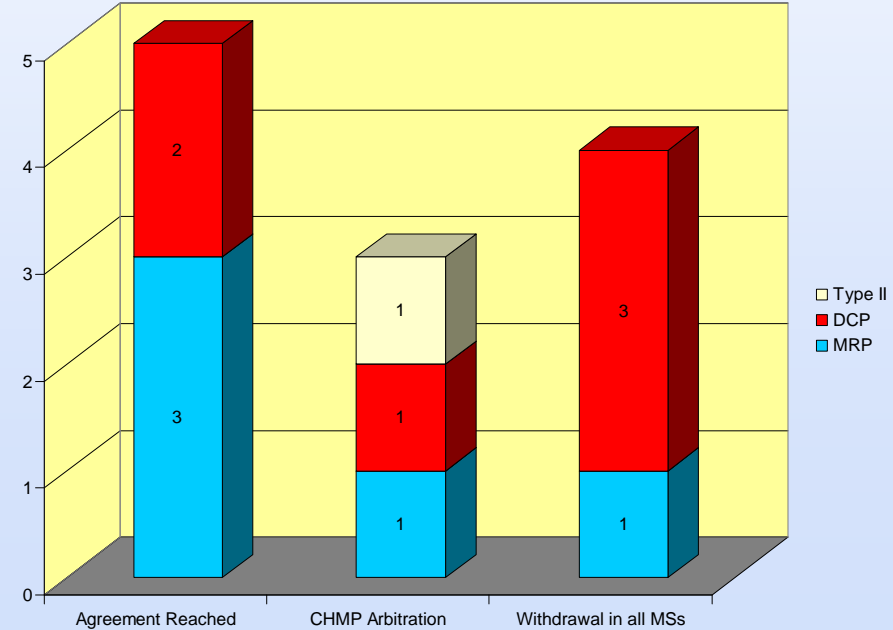
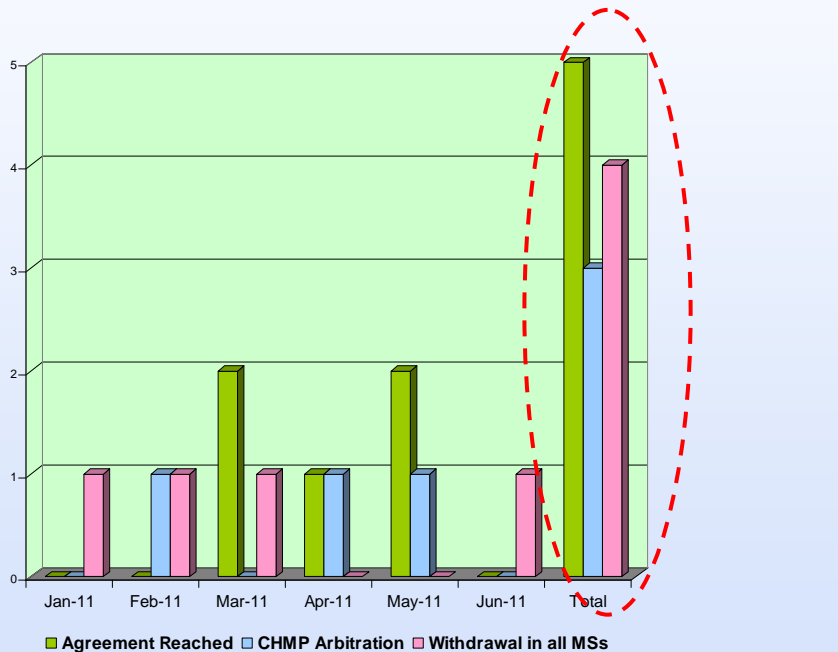


# CMDh 60-day Referral Procedures 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## Procedures referred to CMDh in 2010 & 2011 - Overview\* Per Outcome at Day 60\*\*

\* The numbers include 1 procedures (MRP) referred to the CMDh on identical grounds

\*\* Scientific discussions take place at every monthly CMDh meeting. However Day 60 may fall at the beginning of the following month.

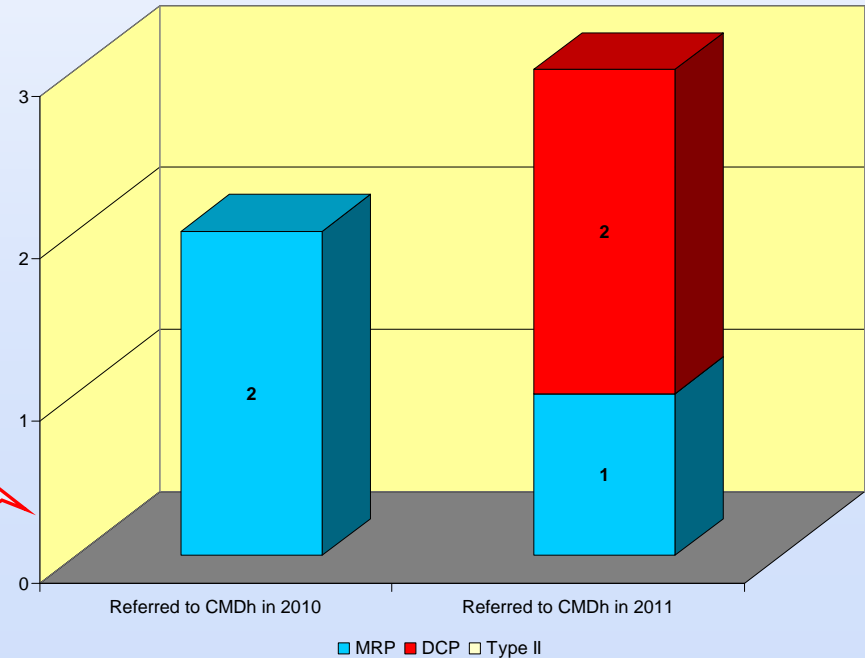
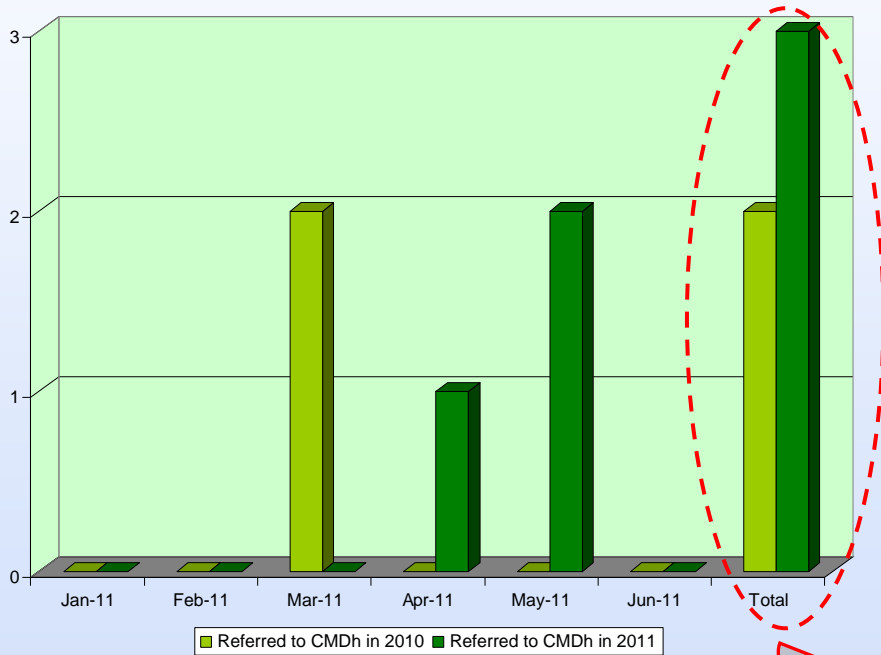


# CMDh 60-day Referral Procedures 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## Agreement Reached in 2011 (procedures referred to CMDh in 2010 & 2011)\* Per Outcome at Day 60\*\*

\* The numbers include 1 procedures (MRP) referred to the CMDh on identical grounds

\*\* Scientific discussions take place at every monthly CMDh meeting. However Day 60 may fall at the beginning of the following month.



# CMDh 60-day Referral Procedures 1<sup>st</sup> January to 30<sup>th</sup> June 2011

## CHMP Arbitration (procedures referred to CMDh in 2010 & 2011)\* Per Outcome at Day 60\*\*

\* The numbers include 1 procedure (MRP) referred to the CMDh on identical grounds

\*\* Scientific discussions take place at every monthly CMDh meeting. However Day 60 may fall at the beginning of the following month.

