## Finalised Procedures

**New Active Substances - DCP**

| DCP | • landiolol hydrochloride |

**MRP/DCP New applications**

1st January to 31st December 2016
MRP/DCP New applications
2006 - 2016

FINALISED Procedures – MRP/DCP
Total: 249 MRP and 1133 DCP (regarding 475 and 2337 products respectively)
MRP/DCP New applications
1st January to 31st December 2016

FINALISED Procedures – MRP/DCP per RMS

![Graph showing MRP and DCP applications per RMS for various countries]
FINALISED Procedures – MRP/DCP per type of procedure

Total: 249 MRP and 1133 DCP (regarding 475 and 2337 products respectively)
MRP/DCP New applications
1st January to 31st December 2016

FINALISED Procedures - MRP per legal basis
Total: 249 MRP (regarding 475 products)
MRP/DCP New applications
1st January to 31st December 2016

FINALISED Procedures - DCP per legal basis
Total: 1133 DCP (regarding 2337 products)
MRP/DCP New applications
1st January to 31st December 2016

FINALISED Procedures – MRP/DCP per type of product
Total: 249 MRP and 1133 DCP (regarding 475 and 2337 products respectively)
MRP/DCP New applications
1st January to 31st December 2016

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

Total: 249 MRP and 1133 DCP (regarding 475 and 2337 products respectively)
STARTED Procedures – MRP/DCP
Total: 270 MRP and 1264 DCP (regarding 525 and 2568 products respectively)
MRP/DCP New applications
1st January to 31st December 2016

STARTED Procedures – MRP/DCP per RMS
STARTED Procedures – MRP/DCP per type of procedure
Total: 270 MRP and 1264 DCP (regarding 525 and 2568 products respectively)
STARTED Procedures – MRP per legal basis

Total: 270 MRP (regarding 525 products)
MRP/DCP New applications
1st January to 31st December 2016

STARTED Procedures – DCP per legal basis
Total: 1264 DCP (regarding 2568 products)
STARTED Procedures – MRP/DCP per type of product

Total: 270 MRP and 1264 DCP (regarding 525 and 2568 products respectively)
STARTED Procedures – MRP/DCP per prescription status (as approved by the RMS)
Total: 270 MRP and 1264 DCP (regarding 525 and 2568 products respectively)
Variations 2010 – 2016

Worksharing Procedures
CMDh 60-day Referral Procedures
2006 – 2016

MRP/DCP finalised vs referred to CMDh

![Bar chart showing the comparison between MRP/DCP finalised and referred to CMDh over the years 2006 to 2016. The chart includes data for each year from 2006 to 2016, with the number of referrals and MRP/DCP finalised for each year.](image-url)
MRP/DCP finalised vs referred to CMDh (%)
MRPs finalised vs referred to CMDh

CMDh 60-day Referral Procedures
2006 – 2016
CMDh 60-day Referral Procedures
2006 - 2016

MRPs referred to the CMDh (%)
DCPs finalised vs referred to CMDh
DCPs referred to the CMDh (%)
Variations (Type II & WS) finalised vs referred to the CMDh

CMDh 60-day Referral Procedures
2010 - 2016

Variations (Type II & WS) finalised vs referred to the CMDh
Variations (Type II &WS) referred to the CMDh (%)
Procedures referred to CMDh in 2016
Status per Type of Procedure (MRP/DCP/Type II/ Renewal/WS)

* The numbers include 3 DC procedures referred to the CMDh on identical grounds
Procedures referred to CMDh in 2016*
Per Type of Procedure

* The numbers include 3 DC procedures referred to the CMDh on identical grounds

- New application 86%
- Variation 7%
- Repeat use 7%
Procedures referred to CMDh in 2016
Per Legal Basis

* The numbers include 3 DC procedures referred to the CMDh on identical grounds

[Pie chart showing the distribution of procedures referred to CMDh in 2016, with categories Full dossier (14%), Generic (29%), Hybrid (29%), Fixed combination (21%), N/A (7%).]
Procedures referred to CMDh in 2016

Per Ground

* The numbers include 3 DC procedures referred to the CMDh on identical grounds

** One procedure may be referred on more than one ground
Procedures referred to CMDh - Overview
Per Outcome at Day 60

* The numbers include 5 DC procedures referred to the CMDh on identical grounds
Arbitrations to CHMP for procedures referred to CMDh
Per Outcome at Day 60

* The numbers include 5 DC procedures referred to the CMDh on identical grounds
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’