CMDh statistics

2017
### Finalised Procedures

#### New Active Substances - DCP

<table>
<thead>
<tr>
<th>DCP</th>
<th>ozenoxacin</th>
</tr>
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**MRP/DCP New applications - 2017**
FINALISED Procedures – MRP/DCP

Total: 310 MRP and 1205 DCP (regarding 569 and 2417 products respectively)
MRP/DCP New applications - 2017

FINALISED Procedures – MRP/DCP per RMS

[Bar chart showing the number of MRP/DCP new applications by RMS for different countries such as NL, DE, UK, PT, DK, SE, ES, AT, HU, CZ, MT, FI, PL, EE, NO, IS, SK, BE, HR, SI, FR, IE, LV, IT, LT, RO, BG, CY, EL, LU. The chart indicates the number of MRP and DCP applications for each country.]
MRP/DCP New applications - 2017

FINALISED Procedures – MRP/DCP per CMS

4 CMDh statistics 2017
FINALISED Procedures – MRP/DCP per type of procedure

Total: 310 MRP and 1205 DCP (regarding 569 and 2417 products respectively)
FINALISED Procedures – MRP per legal basis

Total: 310 MRP (regarding 569 products)
FINALISED Procedures – DCP per legal basis

Total: 1205 DCP (regarding 2417 products)
FINALISED Procedures – MRP/DCP per type of product

Total: 310 MRP and 1205 DCP (regarding 569 and 2417 products respectively)
FINALISED Procedures – MRP/DCP per prescription status (as approved by RMS)

Total: 310 MRP and 1205 DCP (regarding 569 and 2417 products respectively)
STARTED Procedures – MRP/DCP
Total: 300 MRP and 1180 DCP (regarding 525 and 2426 products respectively)
STARTED Procedures – MRP/DCP per RMS

Total: 300 MRP and 1180 DCP (regarding 525 and 2426 products respectively)
STARTED Procedures – MRP/DCP per CMS

Total: 300 MRP and 1180 DCP (regarding 525 and 2426 products respectively)
MRP/DCP New applications - 2017

STARTED Procedures – MRP/DCP per type of procedure

Total: 300 MRP and 1180 DCP (regarding 525 and 2426 products respectively)
STARTED Procedures – MRP per legal basis

Total: 300 MRP (regarding 525 products respectively)
STARTED Procedures – DCP per legal basis

Total: 1180 DCP (regarding 2426 products respectively)

- 823 applications
- 1180 DCP

- 30 MRP/DCP New applications
- 9 Full dossier
- 9 Generic
- 41 Hybrid
- 2 Fixed combination
- 2 Traditional Herbal
- 75 Well established use
- 8 Similar biological
- 2 Informed consent
STARTED Procedures – MRP/DCP per type of product

Total: 300 MRP and 1180 DCP (regarding 525 and 2426 products respectively)
MRP/DCP New applications - 2017

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

Total: 300 MRP and 1180 DCP (regarding 525 and 2426 products respectively)
Variations - 2017

Worksharing procedures

![Bar chart showing variations from 2010 to 2017]
CMDh 60-day Referral Procedures - 2017

MRP/DCP finalised vs referred to CMDh
CMDh 60-day Referral Procedures - 2017

MRP/DCP finalised vs referred to CMDh (%)
CMDh 60-day Referral Procedures - 2017

MRPs finalised vs referred to CMDh

- CMDh statistics 2017
CMDh 60-day Referral Procedures - 2017

MRPs referred to CMDh (%)
CMDh 60-day Referral Procedures - 2017

DCPs finalised vs referred to CMDh

![Graph showing DCPs finalised vs referred to CMDh from 2006 to 2017]
CMDh 60-day Referral Procedures - 2017

DCPs referred to CMDh (%)
CMDh 60-day Referral Procedures - 2017

Variations (Type II&WS) finalised vs referred to CMDh


Variations  WS  CMDh Referral

<table>
<thead>
<tr>
<th>Year</th>
<th>Variations</th>
<th>WS</th>
<th>CMDh Referral</th>
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<tbody>
<tr>
<td>2010</td>
<td>2361</td>
<td>0</td>
<td>9</td>
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<td>2011</td>
<td>49</td>
<td>884</td>
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</tr>
<tr>
<td>2012</td>
<td>5</td>
<td>537</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>6</td>
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<td></td>
</tr>
<tr>
<td>2014</td>
<td>3</td>
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</tr>
<tr>
<td>2015</td>
<td>2</td>
<td>384</td>
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</tr>
<tr>
<td>2016</td>
<td>1</td>
<td>435</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>1</td>
<td>475</td>
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</table>

CMDh statistics 2017
CMDh 60-day Referral Procedures - 2017

Variations (Type II & WS) referred to CMDh (%)
CMDh 60-day Referral Procedures - 2017

Procedures referred to CMDh in 2017
Status per Type of Procedure (MRP/DCP/Type II/Renewal/WS)

Procedure Type by Status

- Ongoing
- Agreement
- Withdrawn
- Arbitration

Referrals

Status per Type of Procedure:
- MRP
- DCP
- Type II
- Renewal
- WS
Procedures referred to CMDh in 2017
Per Type of Procedure

- New application: 83%
- Variation: 8%
- Repeat use: 8%
Procedures referred to CMDh in 2017
Per Legal Basis

- 50% Generic
- 33% Well established use
- 8% Full dossier
- 8% Hybrid

CMDh 60-day Referral Procedures - 2017
Procedures referred to CMDh in 2017
Per Ground

- Bioavailability/bioequivalence: 36%
- Efficacy: 7%
- Safety and efficacy: 36%
- Quality: 21%
CMDh 60-day Referral Procedures - 2017

Procedures referred to CMDh - Overview
Per Outcome at Day 60

Agreement Reached (or withdrawals)  CHMP Arbitration

<table>
<thead>
<tr>
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<tbody>
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<td>23</td>
<td>8</td>
<td>4</td>
<td>6</td>
<td>12</td>
<td>16</td>
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</tbody>
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Arbitrations to CHMP for procedures referred to CMDh

Per Outcome at Day 60

CMDh 60-day Referral Procedures - 2017
Rapporteurs in the Paediatric Worksharing

Rapporteurs for Art. 45 procedures – Waves 1-36
Rapporteurs in the Paediatric Worksharing

Number of Art. 45 procedures started/year


AT  BE  BG  CZ  DE  DK  EE  EL  ES  FI  FR  HU  IE  IS  IT  LV  MT  NL  NO  PL  PT  RO  SE  SI  SK  UK
Rapporteurs in the Paediatric Worksharing

Art. 46* Worksharing per Number of Studies – 2008-2017

* Art.46 Rapporteurs appointed by the CMDh Secretariat according to the BPG Art.46
Explanatory note

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’.