Reliance to facilitate access to medicines

4th Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA IV) - Victoria Falls, Zimbabwe

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International Affairs, European Medicines Agency
EMA Tools supporting access to medicines

- EU-M4all Art.58
- Collaborative Registration Procedure
- P R I M E
- Inspections Trainings
- Scientific Advice
- Assessment Reports, Certificates
- Patient

Reliance to facilitate access to medicines - EMA
EU-Medicines4all (Article 58)

• Benefit-risk assessment targeted at non-EU population
• Evaluation supported by experts and regulators from target countries (through WHO)
• Working to have simultaneous Centralised Procedure and Article 58
• Regulators in target country remain in charge of the Licensing decision
EU-Medicines4all (Article 58)

Vaccines or medicines used to prevent or treat public health priority diseases:

• Vaccines used in the WHO Expanded Programme of Immunization;
• Medicines for protection against diseases such as HIV/AIDS, malaria and TB;
• Products of global public health interest (innovative, chemicals and biologicals, biosimilars, vaccines and generics)
One medicine approved
Two medicines approved
Three medicines approved
Four medicines approved
Expected approvals

62 approvals
Scientific Advice

Scientific advice - a platform to seek EMA’s views on scientific questions concerning quality, non-clinical and clinical aspects of medicines intended for markets outside the EU (experts from target countries invited to SAWP discussions)

22 applicants  40 requests
PRIME 1/2

PRIME

• enhanced support for medicines development that targets unmet medical needs;
• based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so these medicines can reach patients earlier;
• to be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data.

**Accelerated assessment** - product of major interest for public health and therapeutic innovation

• Unmet medical needs
• Reduced assessment time to 150 days or less (standard is 210 days), including for Article 58 applications
PRIME  2/2

Requests received: 246
Granted: 55%

• Therapeutic areas:
  • Oncology
  • Neurology
  • Haematology-haemostaseology
  • Infectious diseases

Fee exemption for scientific advice requests and follow-ups for products eligible to PRIME for Small Medium Sized Enterprises and Academics
WHO-EMA Collaborative Registration Procedure

• Accelerate national approval in countries where resources may be limited, based on the assessment work already carried out by the SRA/WLA

• Allows participating national authorities to retain their regulatory responsibilities and make own decisions

• Collaborative Registration for products assessed and pre-qualified by WHO

• Extended to medicines authorised by WHO Listed Authorities with a WHO-EMA pilot launched by end of 2014
Reliance to facilitate access to medicines - EMA

- **5 products**
- **13 countries**
- **23 approvals**

The map illustrates the number of approvals for medicines in different countries across Africa. The colors indicate the number of medicines approved:
- Light yellow: One medicine approved
- Light orange: Two medicines approved
- Dark orange: Three medicines approved
Sharing Assessment Reports

• Pilot launched July 2014
• Uses EU decentralised procedure as model for sharing assessment reports during scientific assessment
• Shared by the EU agencies in real time with participating non-EU authorities
• For generics in the pilot
• Upon request from the company applying for marketing authorisation
• Receiving authorities benefit from the EU assessments but maintain their own regulatory responsibilities for decision-making
EMA proposal for a pilot parallel assessment of both centralised procedure and EU-M4all (Article 58)

- Minimise duplication of assessment work
- Concluded with decision for CAP, and separate opinion for Art. 58
- WHO and LMIC countries’ experts still involved

<table>
<thead>
<tr>
<th>Product</th>
<th>Intended use</th>
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<tbody>
<tr>
<td>Lamivudine ViiV, (ViiV)</td>
<td>Special version of EU-approved HIV oral treatment, developed especially for LMICs</td>
</tr>
<tr>
<td>Lamivudine/Zidovudine ViiV</td>
<td>Special version of EU-approved HIV oral treatment, developed especially for LMICs</td>
</tr>
<tr>
<td>Aluvia (Abbvie)</td>
<td>Special version of EU-approved HIV oral treatment, developed especially for LMICs</td>
</tr>
<tr>
<td>Pyramax (Shin Poong)</td>
<td>Oral treatment for artemisinin-resistant malaria</td>
</tr>
<tr>
<td>Hemoprostol (Linepharma)</td>
<td>Oral treatment for post-partum haemorrhage</td>
</tr>
<tr>
<td>Hexaxim (Sanofi Pasteur)</td>
<td>Vaccine for infants and toddlers from six weeks to 24 months of age against DTP, hepatitis B, poliomyelitis and invasive diseases caused by <em>Haemophilus influenzae</em> type b</td>
</tr>
<tr>
<td>Tritanrix HB (GSK)</td>
<td>Vaccine for infants from 6 weeks onwards against DTP and hepatitis B</td>
</tr>
<tr>
<td>Mosquirix (GSK)</td>
<td>Vaccine for children aged 6 weeks up to 17 months against malaria caused by <em>Plasmodium falciparum</em> and against hepatitis B</td>
</tr>
<tr>
<td>Umbipro (GSK)</td>
<td>Gel to prevent infection of the umbilical cord in newborn infants</td>
</tr>
<tr>
<td>Fexinidazole Winthorp</td>
<td>Oral treatment of human African trypanosomiasis (HAT)</td>
</tr>
</tbody>
</table>

= Also approved for use in the EU
EMA support tools

ACADEMIA

Scientific Advice

PRIME

NATIONAL EXPERTS, WHO

SCIENTIFIC OPINION

Accelerated assessment

EUM4all (Art 58)

Collaborative registration procedure

Certificates, assessment reports

National authorisation

Scientific Advice

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Conclusions

EUM4all – Art.58

Intercontinental Networking,
Use of local expertise
WHO Prequalification List

PRIME

Unmet needs,
Faster approval

Capacity building,
Sharing knowledge and best practices,
Joint assessment

Trainings: observed inspections,
in preparation web page with trainings overview

Saving resources

Scientific Advice

Good use of existing resources

Adjustment to local conditions and needs

Collaborative Registration Procedure

Reliance to facilitate access to medicines - EMA
Useful links

Medicines for use outside the European Union


Obtaining and maintaining a scientific opinion on a medicine for use outside the European Union


EMA procedural advice for medicinal products intended exclusively for markets outside the European Union under Article 58 of Regulation (EC) No 726/2004 in the context of co-operation with the World Health Organisation (WHO)


Support for applications on Article 58


Prime

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