How can EMA support GP organisations’ efforts to stimulate independent research?

EMA interaction with healthcare professionals

Presented by Ivana Silva on 5 September 2016
Public Engagement Department / Stakeholders and Communication Division
Regulatory authorities need to continuously monitor, and investigate as necessary, the benefit/risk profile of medicines

High quality information on clinical use of medicines is needed:

- Population exposure
- Utilisation patterns
- Safety
- Efficacy/effectiveness
- Effectiveness of risk minimisation measures and their determinants.
Data sources that regulators/ EMA can use to obtain data on clinical use of medicines

• Voluntary contributions: ENCePP network, other networks, registry holders, academics, patients and HCPs’ associations, ...

• Use of data sources owned or contracted
  • EMA: THIN & IMS, MHRA: CPRD, AEMPS: BIFAP, ...

• Commissioned studies (e.g. EMA framework contract)

• Institutional programmes (e.g. Horizon 2020)

• Studies requested to industry
Some examples

In the context of a safety referral, the EMA conducted a drug utilisation study using IMS Health and THIN electronic health records and Nordic registries, aimed at further determining the utilisation of codeine in real-life practice in the EU to treat cough and colds in children and adolescents. [http://www.encepp.eu/encepp/openAttachment/fullProtocol/8637](http://www.encepp.eu/encepp/openAttachment/fullProtocol/8637)

The EMA commissioned a drug utilisation study using Danish health and administrative registries and the UK Clinical Practice Research Datalink (CPRD). The aim was to assess the use and safety of metformin in patients with and without renal insufficiency in current clinical practice in at least two EU Member States, to add evidence to help reassess and unify the guidelines for use of metformin in patients with renal insufficiency.

ENCePP: European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

ENCePP guiding principles and tools

Transparency
- EU PAS Register
- Registration of studies
- Publication of protocols and results

Independence
- Clear roles and responsibilities of all parties involved for public health benefit
- Code of Conduct

Standards
- Methodological Standards Guide
- Checklist for Study Protocols
- Stimulate consideration of important principles in study design

Who are the ENCePP partners?

Centres (>150)
- Public (university, hospital, government, charities)
- Others (CROs, consultants)

Networks (>20)
- International
- National
- Special interests: psychiatry, rheumatology, respiratory, effectiveness, teratology, pharmacogenetics, congenital abnormalities, women’s health, paediatrics, psoriasis, severe cutaneous adverse reactions to drugs;

Data sources (>50)

ENCePP: European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

14th ENCePP plenary meeting – November 2015

Brainstorming on funding mechanisms for post-authorisation studies

‘The emerging consensus was that in the interest of public health it would not be appropriate to exclude industry from the process of observational research. However, the public need to be re-assured that the academics doing the study are in control, and are independent.’

ENCePP Work plan 2017-2019

• Paper on central mechanism for voluntary industry funded studies and paper on potential governance models

• Draft business case for EU public funding for benefit-risk studies post Horizon 2020
Studies funded by EMA via public procurement

Calls for tender subject to the rules of Directive 2014/24/EU on public procurement

<table>
<thead>
<tr>
<th>Topic</th>
<th>Year</th>
<th>EU PAS Register ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/H1N1 pandemic vaccines and pregnancy outcomes</td>
<td>2010</td>
<td>5304</td>
</tr>
<tr>
<td>Impact of risk minimisation in patients treated with rosiglitazone-containing products</td>
<td>2010</td>
<td>2236</td>
</tr>
<tr>
<td>Isotretinoin and the effectiveness of the Pregnancy Prevention Programme in Europe</td>
<td>2011</td>
<td>4654</td>
</tr>
<tr>
<td>Patterns and determinants of use of oral contraceptives in the EU</td>
<td>2011</td>
<td>3520</td>
</tr>
<tr>
<td>Monitoring the effectiveness of risk minimisation in patients treated with pioglitazone-containing products</td>
<td>2011</td>
<td>3221</td>
</tr>
<tr>
<td>Risk of cardiac valve disorders associated with the use of biophosphonates</td>
<td>2011</td>
<td>7967</td>
</tr>
<tr>
<td>Association between anxiolytic or hypnotic drugs and total mortality</td>
<td>2012</td>
<td>1062</td>
</tr>
<tr>
<td>Metformin use in renal impairment</td>
<td>2013</td>
<td>7492</td>
</tr>
</tbody>
</table>
Framework of collaboration with Academia under development

EMA is already providing support to research and innovation via the scientific advice/protocol assistance procedures, the Innovation Task Force, the Science and Innovation Support Office, the SME Office, the PRIME scheme, and the qualification advice on novel methodologies

• Focus on pre-authorisation, clinical trials, hospital setting
• Users are mainly companies, university based academic groups and hospital based clinical research groups

Need for regulatory support to research in post-authorisation, falling outside traditional format of clinical trials, covering primary care

For endorsement by EMA Management Board in December 2016
How can EMA provide regulatory support to research in primary care?

• Promote convergence between regulatory authorities’ needs to continuously monitor and investigate the benefit/risk profile of medicines and GPs’ research community interests
  • EMA workshop April 2016: expert group of general practitioners/ family physicians
  • Further collaboration with EFPC/ WONCA/ UEMO
  • Explore links to the European General Practice Research Network (EGPRN) and other existing networks

• Explore opportunities provided by ENCePP
  • Explore possibility for EFPC to become an observer
  • Promote ENCePP to primary care research networks/ GP-led initiatives

• Other ideas?
Thank you for your attention

Further information

HCPsecretariat@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Follow us on @EMA_News