Federal **A**gency for **M**edicines and **H**ealth **P**roducts
(FAMHP)

Pharmacovigilance: Practical aspects of the implementation

Vanessa Binamé, Director General DG POST **15.05.2012**

TOC

Priorities of the EMA

criteria for prioritisation

- Public health activities
- Transparency and communication activities
- Simplification activities (primarily for pharmaceutical industry)

4 topic areas

- Collection of key information on medicines
- Better analysis and understanding of data and information
- Regulatory action to safeguard public health
- Communication with stakeholders

Collection of Information (1/5)

EMA priorities: Risk management plans	
Deliverable	**Implementation date**
Public consultation on good pharmacovigilance practice (GVP) module	February 2012
New procedure	During 2012
Establishment of effectiveness monitoring system	After 2012

Collection of Information (1/5)

Status 2012 - Risk management plans	
Transitional arrangements	▪ Pending MA applications ▪ Format and content in Implementing Measures?
Procedure	▪ RMP for all new applications, proportionate to risk ▪ PRAC involvement for centrally authorised products; criteria to be defined for nationally authorised products
Format and content	▪ Implementing Measures and GVP (transitional arrangements in IM)
Marketing Authorisation	▪ Key measures RMP = conditions to MA ▪ Summary RMP: format and content under discussion

Collection of Information (2/5)

EMA priorities: Periodic safety update reports	
Deliverable	**Implementation date**
Public consultation on good pharmacovigilance practice (GVP) module	February 2012
New procedure for centrally authorised medicines	During 2012
Publication of list of Union reference dates	During 2012 (currently under public consultation)
Focus on nationally authorised medicines	After 2012

Collection of Information (2/5)

Status 2012 - PSURs	
Transitional arrangements	▪ PSUR repository (Dir. 2010/84 art. 2) ▪ Format and content in Implementing Measures?
Procedure (submission)	▪ GEN, WEU, THMP,..: no routine requirement for PSUR submission ▪ List of Union Reference Dates: will overrule existing submission schedules
Format and content	▪ Implementing Measures and GVP (transitional arrangements in IM)
Marketing Authorisation	▪ PSUR frequency to be mentioned on MA (granted > July 2012)

Collection of Information (3/5)

EMA priorities: Post-authorisation safety and efficacy studies (PAES/PASS)	
Deliverable	**Implementation date**
Public consultation on good pharmacovigilance practice (GVP) PASS module	February 2012
Publication of scientific guideline on PAES	During July 2012
New business process for centrally authorised medicines only: Protocol approval and results management	During 2012
Focus on nationally authorised medicines	After 2012

Collection of Information (3/5)

Status 2012 - PASS	
Transitional arrangements	▪ Non-interventional PASS: protocol approval and results management only for PASS imposed as a condition > 2 / 21 July 2012 (Dir. 2010/84 art. 2) ▪ Format protocol, abstract and final study report in Implementing Measures?
Procedure	▪ New business process for centrally authorised medicines only
Format and content	▪ Implementing Measures and GVP (transitional arrangements in IM)

Collection of Information (4/5)

EMA priorities: electronic submission of information on medicines to EMA	
Deliverable	**Implementation date**
Publication of updated legal notice	5 March 2012 (first published 1 July 2011)
Publication of updated format and detailed guidance	5 March 2012 (first published 1 July 2011 with update 1 September 2011)
Publication of updated XML schema	5 March 2012 (first published 1 September 2011)
Deadline for submission of information by industry	2 July 2012

Collection of Information (5/5)

EMA priorities: Reporting by patients	
Deliverable	**Implementation date**
Provision of information to patients on direct reporting	During 2012

Collection of Information (5/5)

Status 2012 – ADR reporting	
Transitional arrangements	MS may request during transitional period: ▪ Serious non-EU suspected adverse reactions (Article 2 (4) of Directive 2010/84/EU) ▪ Non-serious suspected adverse reactions that occur on their territory (Article 2 (5) of Directive 2010/84/EU)
Procedure	Reporting rules: ▪ HCP / patients -> FAMHP -> EV ▪ HCP / patients -> MAH -> EV (serious) EudraVigilance during the interim period: ▪ all serious reports (EU + non-EU) ▪ no non-serious reports

Better analysis and understanding of data and information

EMA priorities: EudraVigilance and signal detection	
Deliverable	**Implementation date**
Public consultation on good pharmacovigilance practice (GVP) module	February 2012
Revised signal detection process for centrally authorised medicines	From July 2012
Improving quality of EudraVigilance data	During 2012

Better analysis and understanding of data and information

EMA priorities: Additional monitoring	
Deliverable	**Implementation date**
Establishment of list of medicines	During 2012
Agreement on standard wording in SmpC / PIL and black symbol	Ongoing (QRD group)

Better analysis and understanding of data and information

EMA priorities: Information-technology systems to support processing and analysis of data	
Deliverable	**Implementation date**
Development of systems requirements	During 2012
Full development of systems	After 2012

Dia 15

v8 Je suppose qu'il s'agit principalement des modifications à apporter à Eudravigilance???

ou également PSUR repository, RMP repository,...???
vbe, 08/05/2012

Regulatory action to safeguard public health

EMA priorities: Scientific committees and decision-making	
Deliverable	**Implementation date**
First meeting of Pharmacovigilance and Risk Assessment Committee (PRAC)	July 2012
Revised mandate of Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)	From September 2012

PRAC rapporteurships

- Tasks requiring a PRAC Rapporteur
  - RMP (approval, updating and monitoring of effectiveness)
  - PASS (review study protocol/amendments, evaluation of results)
  - Individual PSUR assessment and single PSURs assessment
  - Some Art 31, Art 20 referrals
  - Urgent union procedures (Art 107i)
  - Pharmacovigilance inspections
  - Signal detection responsibilities

  ⇨Activities to be covered by fees (cfr. Fees Regulation revision late 2012):?

- No explicit mandate for the PRAC but other safety risks issues proposed to be discussed such as renewals, annual reassessments, safety type II variations on a case by case basis

PRAC – activities

Activity	Involvement
Risk Management Systems	Agreement on RMPs + monitoring their effectiveness
Periodic Safety Update Reports PSURs	List of harmonised submission frequencies and substances, assessment + recommendation
Eudravigilance + Periodic Safety Update Reports repository	Functional specifications, any substantial changes
Medicines subject to additional monitoring	Addition to/removal from list, extension of timeframe, symbol
Signal Detection	Initial analysis + prioritisation assessment + recommendations

PRAC – activities

Activity	Involvement
Urgent Safety Procedures for the EU	Assessment, public hearings, recommendations
Post Authorisation Safety Studies	Consultations on requests (pre and post MA), assessment of protocols (incl. amendments) + recommendations, assessment of results + recommendations
Literature Adverse Drug Reactions monitoring	Consultation on list of active substances and medical literature subject to monitoring?
Safety announcements	Advice

Regulatory action to safeguard public health

EMA priorities: Strengthening referral procedures	
Deliverable	**Implementation date**
Urgent Union procedure	During 2012

Communication with stakeholders

EMA priorities: Online publishing of information	
Deliverable	**Implementation date**
Agendas and minutes from committees	During 2012
Launch of web portal	After 2012
Coordination of safety messages	During 2012
Public hearings	During 2012

More information on the EMA website:

Home / Regulatory / Human medicines / Pharmacovigilance /2010 pharmacovigilance legislation /Implementation

Implementation in the Belgian legislation

- Amendments to the law of 25/03/1964
- Amendments to the Royal decree of 14/12/2006

Amendments to the law of 25/03/1964

- Council of Ministers of 29/03/2012
- State Council (current status) ⇒ should be adapted to the comments
- Parliament
- Signature of the King
- Publication in the « Moniteur Belge »
- Entry into force planned for 21st July 2012

Amendments to the Royal Decree of 14/12/2006

- Discussion with stakeholders on 27/04/2012
- IF advice
- State of Council
- Signature of the King
- Publication in the « Moniteur Belge »
- Entry into force planned for 21st July 2012

Contribution for the implementation of this new Pharmacovigilance Directive

- Legal act
- Who ?
- How much ?
- How the money will be collected ?

Contributions - Program Law 29/03/2012

- Program law published in the Moniteur Belge on 06/04/2012

- Entry into force 10 days later

  => 17/04/2012

Who will contribute?

- Marketing autorisation holders
- Parallel importators
- Pharmacists
- Wholesalers and distributor wholesalors

How much?

Pharmacists	0.00596 € / packaging
Marketing autorisation holders	58€ / MAD (NAT + CP with a price)
	0.01118 € / packaging NAT only
Parallel importators	58€ / IA
	0.01118 € / packaging NAT only
Wholesalers and Distributor Wholesalers	0,00014 euro / packaging

How the money will be collected ?

Pharmacists – MAH – Parallel importators - Wholesalers and distributor wholesalers:

Contribution by packaging ⇒ use of the current system in place for the Pharmacists

MAH – parllel importators:

once a year / letter to each MAH or importator with the amount to be paid.

Thank you for your attention!!!!