# EU Pharma Package – Industrial View

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DGRA Annual Congress, June 2010

Bundesverband der Arzneimittel-Hersteller e.V. B.A.H

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# Overview

## Presentation of industrial view on

- **Expedited reporting requirements**
- **PSURs**
- **Prospective Risk Management**
- **Web-Portal(s)**

## Leave out many other important issues

- Literature screening performed by EMA
- Referral procedures
- Summary of essential information
- List of intensively monitoring substances
- **...**

# Expedited Reporting Requirements

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# Expedited Reporting: Commissions proposal

## On the one hand ...

### ... much more ICSRs* valid for expedited reporting

- **all serious** ICSRs: **15 days**
- **all non-serious** ICSR occuring in EU: **90 days**

- **No further differentiation for reporting purposes**
  - **expected/unexpected**
  - occuring at normal condition for use
  - **reported by HCPs**or Consumer**

* ICSR: Individual Case Safety Report, ** HCPs: Healthcare Professionals

# Expedited Reporting: Commissions proposal

## On the other hand ...

### ... Simplification of reporting

- **Only electronic** reporting (**E2B**)
- **Single point of data entry: EudraVigilance**
- **no additional national requirements**

# Expedited Reporting: Compromise

- **Member States: keep direct reporting to NCA**

**Reasonable compromise…**

- **Single point of data entry: EV**
- **EV: Routing of ICSRs to NCA immediately**
- **NCA: Approval of the system operability**
- **Transitional phase as short as possible**

# Periodic Safety Update Reports (PSURs)

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# PSURs: Commissions proposal

- Simplication of the requirements
- Single point for PSUR submission: EMA
- Orientation on risk profile of an ingredient
- No further PS URs required for
  - generic products (Art. 10)
  - well established use products (Art. 10a, 10c)
  - registrated homeopathic products (Art. 14)
  - registrated traditional herbals (Art. 16a)
- Exceptions from general waiver remain unclear

# PSURs: Compromise

- **Member States** proposal:

  Keep the **direct PSUR submission to NCA**

**Reasonable compromise…**

- **Single point for PSUR submission: EMA**
- EMA: Establishment of a **PSUR repository** (Access: NCA)
- **NCA: Approval of the system operability**
- **Transitional phase as short as possible**

# What will replace the PSUR ?

**Renewal**

↓

**PSUR**

↓

**?**

**(Prospective Risk Management ?)**

# Prospective Risk Management (RMP, PASS)

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# RMPs, PASS,...

## Criteria for RMP obligation ?

- **Commissions proposal:**

  **"concerns about the risks of an authorised medicinal product"**

  **⇒ no serious concerns ...**

- **Our proposal:**
  **More detailed provisions in the Directive**

# EP proposal: Widening the scope of PASS

**COMPROMISE AMENDMENT 5: Risk / Benefit**

Covers AMs 10, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, IMCO 10

Justification

The compromise doesn't cover amendments 123 - 125, 127 and 128, although these all express concerns about the "added value" of drugs and ability of National Competent Authorities to monitor the efficacy of drugs. By widening the scope of post-authorisation studies, this gives national competent authorities more freedom to determine the kind of study which is most useful. At the moment, most drugs are subject to some kind of PASS as an extra safety precaution. However, although safety monitoring happens throughout the life of a drug, efficacy is only checked once, at the time of authorisation. There should be the possibility to monitor drug efficacy post-authorisation as well - in real world populations and real-life conditions.

***authorisation.***

*scientific advances in the understanding of the disease or in the clinical methodology would significantly change previous efficacy evaluation. For this purpose the Commission shall provide guidelines.*

# Web-Portal(s)

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# Web-Portal(s)

- To be established and maintained by EMA and **Member States**
- **Content (i.a.):**
  - **Members of the various EMA committees**
  - **Details of meetings** (agenda, results, papers)
  - **Referrals** (ingredients, products)
    - reasons, assessment, results
    - information about the hearings
- **Addional content proposed by EP**

# Web-Portal(s)

**COMPROMISE AMENDMENT 7: Web Portal**

(1) risk management systems *and a*

*(1a) the most up-to-date electronic version of the leaflets of the medicines*

*(1b) the most up-to-date electronic version of the summary of the product characteristics and any conditions*

*(1c) assessment reports for medicinal products authorised in accordance with this Directive*

(2) the list of medicinal products referred to in Article 23 of Regulation (EC)

# Web-Portal(s)

## Caveats from industry view

- Enormous **Workload** for both industry and NCA/EMA to establish and maintain the data
- Assurance of **intellectual properties** (RMPs)
- Assurance of **confidentiality** of documents and procedures
- Legal problems: SPC / PIL accessible for general public ?

# Conclusion

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# Conclusion

- **EU Pharma Package will change a lot !**
  - some of the old challenges remain
  - new challenges
- **Strategy to cope: Co-operation of MAHs**
- **Therefor necessary:**
  - Readiness for **co-operation beyond MAHs**
  - **Platforms for coordination** (through industry associations, CROs,… )
  - **Creativity all around …**

# Thank you very much for you attention !

# Any questions ?

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