# Industry perspective: Non-prescription medicines

# Introduction

- Perfect timing for a review
- Comprehensive debate on the financing of the system is on-going
- Good occasion to make adjustments and provide clarifications

# Objectives of the pharmacovigilance (PhV) revision

**AESGP supported the objectives of the PhV revision which were to:**

- **strengthen and rationalise existing pharmacovigilance provisions at Union level**
- **to make requirements "more proportionate to risks"**
- **Important savings were anticipated….**

**AESGP commends the EMA for the regular organisation of stakeholders' workshops on the implementation of the pharmacovigilance legislation**

# Savings were anticipated

***Table 12 Quantification of total economic impacts on the industry***

| **Options** | Potential annual cost increase | Potential annual savings |
|---|---|---|
| Company Pharmacovigilance System Master File | | € 85,900,000 |
| Clear legal basis for risk management plans | € 89,225,945 | |
| ADR Reporting simplification | | € 77,143,723 |
| Literature screening by the EMEA | | € 10,000,000 |
| Removal of routine requirement for PSUR+Worksharing | | € 71,953,732 |
| Increase in fees payable to EMEA | € 10,596,000 | |
| **Total** | € 99,821,945 | **€ 244,997,456** |

EC Impact Assessment on REG 726/2004 and DIR 2001/83

# New PSUR requirements

**AESGP appreciates the relief from routinely PSUR generation for**

- Bibliographic and generic applications
- Registered products

**In the principle of proportionality and consistency….**

- Well-established products authorised on basis of full application before bibliographic application possible should also be exempted

**Question…**

- Would the PRAC feel to be the appropriate forum (resources, time, expertise,..) to evaluate authorised homeopathic and herbal products?

# New requirements for Risk Management Plans (RMPs)

## Situation

- RMPs expected for all new products, including those containing well-established substances.
- GVP focuses on products with new substances and limited feedback received so far on EU-RMPs for non-prescription medicines. Therefore, expectations for older products unclear.
- The workload for MAHs and regulators is not insignificant & the value to patient safety is minimal when there are no risk minimisation measures other than routine.
- For established non-prescription products, an appropriate benefit-risk ratio has already been demonstrated for use without intervention of healthcare professional.

# Risk management plans: proposal

**Target:**

- Concise document, length & structure dictated by relevant content only

**Proposal:**

- Lighter-RMP
- AESGP and EFPIA are working on a joint proposal to be submitted to EMA to make EU-RMP more aligned to the stage of the product in the life cycle (similar to abridged EU-RMP for generics).

# EMA Literature Monitoring

**In general, AESGP supports a central literature monitoring, but**

- No liability of MAH for monitoring carried out by EMA should be made clear
- Limited approach to “selected medical literature”
- Limited/Unknown extent of substance portfolio
- Detailed concept for service is still missing

**MAH still requested to screen the remaining**

- substances of MAH portfolio and
- medical literature

….not covered by the EMA search

# EMA Literature Monitoring

**AESGP proposal:**

- Clarify MAH not liable for EMA literature search
- Otherwise 2 systems to run: defeat anticipated benefits of central monitoring

# Referrals

**Experience gathered within last 12 months**

- 19 PRAC procedures including Urgent Procedures (5)
- Majority: Products marketed for decades (e.g. Tetrazepam)
- Focus: Safety issues already mentioned in the SmPC / leaflets

**Procedural experience**

- Narrow time frame hamper joint industry response
- “Moving targets” (e.g. Codeine, Tetrazepam)
- Only a few recommendations by consensus (CMDh)

# Referrals

**AESGP proposals**

- **PRAC** should focus on evaluation of NEW **RISKS**
- **CMDh/CHMP** should focus on overall **Benefit-Risk** assessment
- In general: no national measures before EC decision
- Time frame of Communication Plan unrealistic when EC decision is necessary

# Signal Assessments

**Issues**

- Involvement of MAH(s) concerned
- Information (often only via PRAC Meeting Minutes)
  - delayed
  - no assessment report provided
- National Implemention of Measures  unclear (justification, timelines, procedure,…)

**AESGP proposal:**

- Better involvement of MAHs
- Improved communication with MAHs
- Further clarity concerning national implementation

# Annual Flat Fee

**Described in the EC proposal to cover**

- EudraVigilance signal detection

  ⇒**limited access for MAH (2015-2016?)**

- IT systems
  - EudraVigilance

    ⇒ **limited access for MAH (2015-2016?)**
  - PSUR repository

    ⇒ **inexistent (2015-2016?)**
  - EU Medicinal Webportal

- EMA literature monitoring

  ⇒**inexistent, in conception phase (2015-2016?)**

## Financing of the future system

- Industry ?
- Community budget ?
- Member States ?

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