Update on Pharmacovigilance legislation

EMA Stakeholder meeting
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Health and Consumers

European Commission

2010 Legislation - Key achievements

- Clear tasks and responsibilities for all parties
- Improved EU decision-making procedures
- Proactive and proportionate risk management
- Higher quality of safety data
- Stronger link between safety assessments and regulatory action
- Strengthened transparency, communication and patient involvement

The 2010 legislation – not the last word on pharmacovigilance

- 'Stress test' of the 2010 legislation detected certain areas where legislation could be further strengthened

- 25 October 2012 new amending legislation adopted:
  - *Directive 2012/26/EU of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance*
  - *Regulation (not yet published in the Official Journal)*

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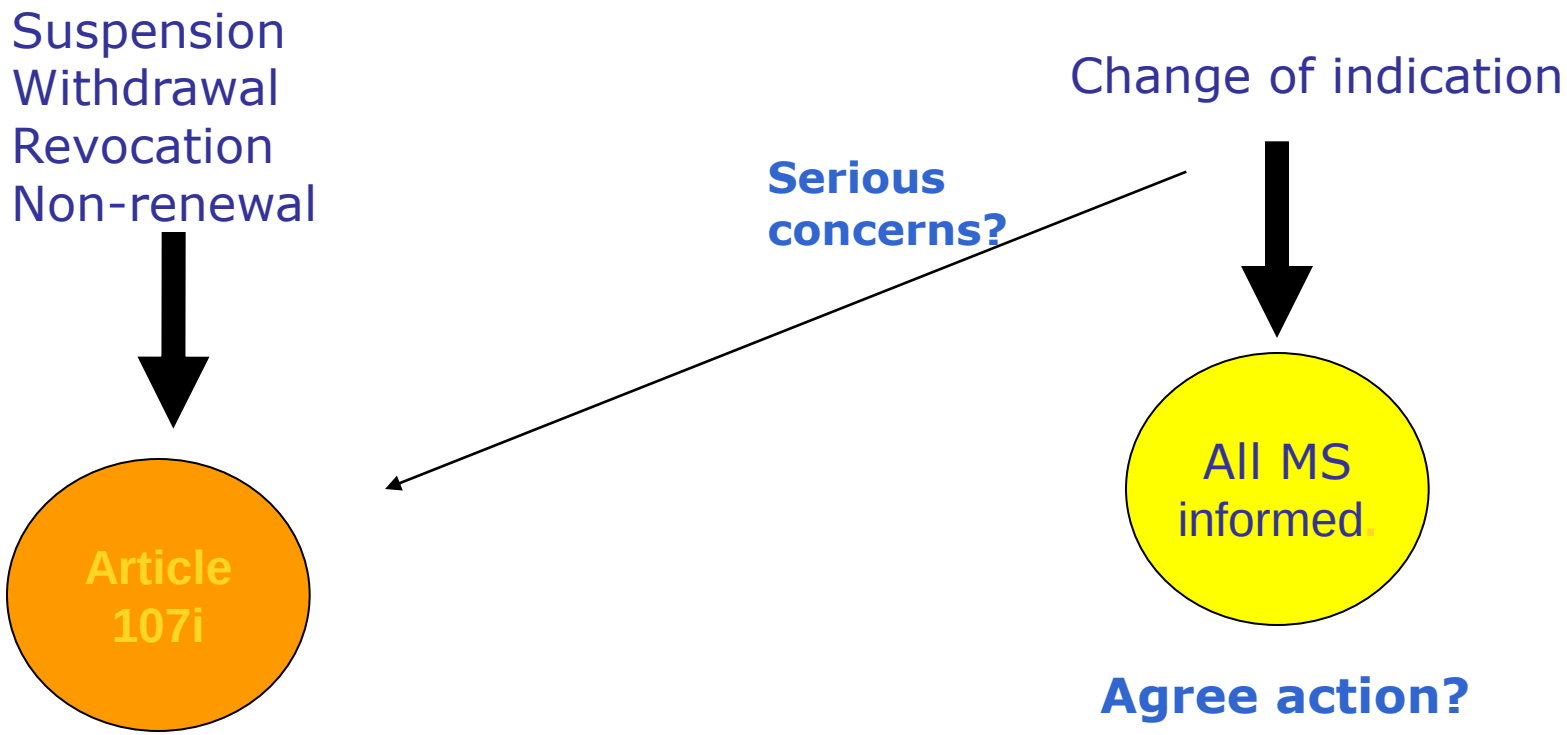
Pharmacovigilance II – Filling Gaps

- Clarification of scope of 'referral' procedures and events that will lead to the initiation of the procedures (especially Urgent Union procedure)
- Modified Union interest procedure will allow Member States to take provisional measures
- Voluntary withdrawal – marketing authorisation holder to state reasons
- Increased transparency: List of products subject to additional monitoring

Clarification of referrals

Action based on PhV concerns



Voluntary withdrawal

Companies must explain reasons for:

- *Suspension/ceasing marketing of a product*
- *Withdrawal of the product from the market*
- *Requesting withdrawal of the marketing authorisation*
- *Not applying for a renewal of a marketing authorisation*

On the basis of the explanation received the competent authority may initiate a referral

Withdrawal for safety concerns must not be disguised as commercial activity

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Additional monitoring

- Black symbol - Inverted black triangle (▼)
- Commission Decision (before 2 July 2013)
- 2012 legislation extends obligation for inclusion of black symbol to products with:
  - Conditional or exceptional conditions of marketing
  - Obligation for post authorisation safety studies
  - Stricter reporting of adverse reactions

Implementation: Commission

- Implementing Regulation (EU) No 520/2012
- Nomination of PRAC members
- Delegated act on efficacy studies ("may" provision)
- Reports: readability of product information PIL/SPCs and environmental effect of medicines
- Fees for pharmacovigilance