2008 Pharmaceutical Package

Consequences and Significance for the Pharmaceutical Market in Germany

Priv.-Doz. Dr. Walter Schwerdtfeger
Federal Ministry of Health, Bonn

The Pharmaceutical Package

- 14 meetings in total
- priority ranking according to majority of Member States‘ delegations:

- pharmacovigilance:	docs.	COM(2008) 664/3 COM(2008) 665/3
- counterfeit drugs:		COM(2008) 668
- information to patients:		COM(2008) 662 COM(2008) 663

Proposals on Pharmacovigilance : Key Elements

- definitions
- composition and role of Pharmacovigilance Risk Assessment Advisory Committee
- reporting pathways and access to EudraVigilance database
- information on negative study results
- pharmacovigilance system master file
- key information
- PSURs
- post authorisation safety studies

Proposals on Pharmacovigilance : Comments from Member States (1)

broad support for objective to improve safety, however concern that proposed tools to achieve this might not be fully appropriate

- responsibility of national competent authorities in terms of public health cannot be restricted
- representation of each Member State (at least option) in PRAAC appears crucial
- doubts that full and timely information flow to NCAs will be ensured

Proposals on Pharmacovigilance : Comments from Member States (2)

- If MAH report only to EudraVigilance database, will the incoming data be comprehensively assessed, will double or multiple reports and new quantitative and qualitative tendencies be detected?
- Is it appropriate to largely reduce need for PSURs to medicinal products with new active substances / therapeutic concepts?
- Definition “adverse reaction“: medication errors, misusage by patients - a matter of *pharmaceutical* legislation?

Proposals on Pharmacovigilance - Possible Consequences

Safety gain or safety loss?

- suboptimal and heterogeneous information within EU?
- spontaneous reporting facilitated – assessment more complicated?
- high additional work load by new provisions on PSURs

Proposal on Counterfeit Drugs: Key Elements (1)

- specific obligations for *all* traders
- appropriate measures to be adopted in terms of specific safety-features on the packaging of prescription-only products
- these features must not be manipulated in the distribution chain
- more stringent requirements for import of active substances from third countries
- greater transparency and standardised inspection procedures

Proposal on Counterfeit Drugs: Key Elements (2)

- **MAH**
  - to inform NCA on observed or suspected falsifications
  - to ensure GMP compliance of active substance manufacturer
  - generally liable for damages

- **NCA**
  - to strive for closer cooperation with customs authorities
  - obtains, for imports, written information from third countries on GMP compliance

Proposal on Counterfeit Drugs: Comments from Member States (1)

- introduce appropriate definition for “falsified medicinal products”
- measures introduced to ensure traceability of pharmaceuticals must not be less effective than those already applied in Member States
- safety features should not be restricted to prescription-only drugs
- clarify liabilities of repackers/relabellers

Proposal on Counterfeit Drugs: Positions from Member States (2)

- tighten licensing requirements for wholesalers
- standardize packing and packing sizes
- traders should not only be notified but authorised
- traders should register the source of products received, but are unable to verify validity of MA
- clarify consequences for traders of new definition “trading of medicinal products”
- list of countries to be adopted by Standing Committee
- pharmacists and traders should not be able to assess covert or forensic devices

Proposal on Counterfeit Drugs – Possible Consequences

Positive effects can be expected, due to:

- higher and possibly selective requirements for traders
- greater transparency of the market
- safety features on packaging
- better information on GMP in third countries

However:

- to which extent will NCAs and MAHs be able to fulfil the new obligations as stipulated?

Proposals on Information to Patients: Key Elements

- respecting specific conditions, MAH shall be entitled to provide information directly to the public
- this shall be valid for information already approved by MA authorities and for other product-related information
- defined quality standards for such information
- authorised information channels
- monitoring system and monitoring rules to ensure that standards are complied with

Proposals on Information to Patients: Comments from Member States

- currently stipulated provisions would open ways of communication beyond pure information
- no evidence presented that additional rules would really improve access to information for patients
- control mechanisms are hardly practicable and may cause inappropriate administration efforts
- ex ante control of information might be considered as censorship

Proposals on Information to Patients: Possible Consequences

- demand for intensely advertised medicinal products may be (unnecessarily) increased
- unjustified expenses might by imposed on social security systems
- proposed monitoring systems and mechanisms would be highly cost-intensive
- increased bulk of information provided by single MAHs on single products might rather be confusing than helpful – what patients need is a *comprehensive* and *comparative* survey on information about their disease and available treatments

Status of Proposals, Possible Tendencies

Pharmacovigilance:

tricky in details; needs intense modification to facilitate Member States‘ compliance with their responsibility for public health

support in principle, however general scrutiny reservation by all delegations

Progress Report by Czech Presidency

EP first reading, at the earliest, during autumn 2009

Status of Proposals, Possible Tendencies

Counterfeit Drugs:

somewhat less controversial, but several key elements also critically discussed

support in principle, but scrutiny reservations

Progress Report by Czech Presidency

EP first reading, at the earliest, during autumn 2009

Status of Proposals, Possible Tendencies

Information to Patients:

at least, substantial amendment needed to prevent undesirable options for advertising; no near-term progress to be expected in the Council Working Party

great majority of Member States do not support proposal, priority generally considered lower than that of other proposals

Progress Report by Czech Presidency

EP first reading (theoretically) during autumn 2009