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2008 Pharmaceutical Package - Impact on Implementation by BfArM

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Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector

1. Making further Progress towards a Single and Sustainable Market in Pharmaceuticals

1.1. Better Access to Medicines for European Patients
1.2. Better Regulation for a More Competitive Industry
1.3. Safer Medicines for Better Informed Citizens
2. Taking on the Opportunities and Challenges of Globalisation
2.1. Tackling Worldwide Health Challenges
2.2. Towards Global Cooperation and Harmonisation
2.3. Towards Global and Fair Competition
3. Making Science Deliver for European Patients
3.1. Supporting Pharmaceutical Research
3.2. Keeping the Pace: New Horizons in Medicine
4. Conclusion

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Counterfeit Medicines

- Identify more easily false representations of medicinal products in particular through safety features ensuring full traceability of each individual package of high-risk products.
- Improving the control at the EU external borders through which false medicinal products could enter; and
- Ensure that the active pharmaceutical ingredients is of high quality standard and not falsified.

Pharmacovigilance

- Providing for clear roles and responsibilities for the key responsible parties;
– Rationalising EU decision-making on drug safety issues;
– Strengthening medicines safety transparency and communication;
– Strengthen companies' pharmacovigilance systems;
– Ensure the proactive and proportionate collection of high quality data;
– Involve stakeholders in pharmacovigilance including through direct patient reporting of suspected adverse reactions;
– Improve the availability of medicines in small Member States.

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HMA/EMEA Status Report 03-09

- EudraVigilance Database
  - Eudravigilance Access Policy
- Review & Learning Project: Experience and Assessment of RMP‘s
  - Update Risk Management Guideline
  - Implementation of RMPs in Member States
  - Recommendations for „best practice“-implementation
- Resource-oriented worksharing of PSUR assessment incl. training of assessors
- Activities to improve methodology for benefit/risk analysis
- Experience of PDCo and CAT
- Pilot-phase of signal-detection-system und EU „Incident Management Plan“
- Promotion of research activities via IMI and 7th Framework Programms of EC
- „Influenza-Pandemic“ activities; core RMP for influenza vaccines in case of pandemia

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„Personalized Medicine“
EU / 3rd Task Force Report

“With the emergence of new technologies like pharmacogenomics and patient-specific modelling and disease simulators, personalised medicine is now on the horizon. In the long term, doctors may be able to use genetic information to determine the right medicines, at the right dose and time. This field is already affecting companies' business strategies, the design of clinical trials and the way medicines are prescribed. Although it is too early to say whether ‘-omics’ technologies will indeed revolutionize the sector, the Commission closely monitors the area and will reflect on how it can support its development.”

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Access to Reliable Information

- Only certain information about prescription-only medicines may be published such as the patient leaflet or a different presentation of its contents.
- Only certain communication channels for the dissemination of information shall be allowed, including Internet and health-related publications as defined by the Member State of publication. TV and radio are excluded.
- Strict quality criteria must be fulfilled.
- Adequate and effective monitoring and control must be ensured.

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Conclusion on Variation Regulation

- Variation Regulation 1234/2008 is very welcome
- Many aspects of the simple German system have been considered
- New variation system is expected to disburden the NCAs from huge workload with variation procedures
- NCAs will be involved in further development of guidance documents through Variation Subgroup and other Committees and working groups
- Art. 4-Guideline and further guidance documents should be finalized asap and well before implementation of the new system

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Conclusion

- Active support for strenghtening national and European Pharmacovigilance Systems
- Support of ressource-oriented worksharing projects
- Support for regulatory oriented research activities
- Extension of information exchange with the public