Germany – The Reorganisation of the Federal Institute for Drugs and Medical Devices (BfArM)

Concepts, Objectives, Consequences

Deutsche Gesellschaft für Regulatory Affairs (DGRA):

8th DGRA Annual Congress
9th-10th May, 2006. Wasserwerk, Bonn

Prof. Dr. Reinhard Kurth
Reorganisation of the BfArM

Evaluation by:

• German Science Council (Opinion 28th May, 2004)
• Commission "Organisational Structures and Procedural Workflow in the BfArM" (Report January 2004)
• Report and Mission Concept of the Task-Force
  
  For improvement in terms of location and the innovative prospects of the pharmaceutical industry in Germany (June 2004)
• Steering committee "Organisational structures and procedure workflow" (Report October 2004)
Reorganisation of the BfArM

Fundamental objectives:
• Authorisation and registration of medicinal products within an appropriate period of time
• Increase in pharmaceutical drug safety
• Positioning within the European network of NCAs
• Advancement of research in the BfArM
Reorganisation of the BfArM

Cornerstones of the reorganisation:

• Development of leaner and more efficient structures and flat hierarchies
• Definite assignment of competence and responsibility
• Further development of the professional expertise of the assessors
• Installation of a sustainable and continuous change management system (organisation, monitoring, planning)
• Evaluation-orientated research
Reorganisation of the BfArM

Actions include:

• Reduction of the number of departments and of units within the departments

• Interdisciplinary project teams consisting of pharmacologists, physicians and toxicologists responsible for every type of procedure (*national, European, renewals and variations*) for drugs of a given indication

• Immediate processing of medically / scientifically streamlined applications in Department 1

• Processing of outstanding therapeutically significant innovations in fast-track procedures

• Introduction of in-house quality management, change management and control
Tasks of Department 1

- Filter function
- Validation
- Simplified procedures
Structure of Licensing Department 1

Department Head

FG 11 Validation
Fr. Dr. Deicke

- SG 11.1 General Enquiries
- SG 11.3 ATC-Code Dept. 3+5
- SG 11.5 AMIS

FG 12 Simplified Procedures
Dr. Horn

- SG 11.2 ATC-Code Dept. 2
- SG 11.4 ATC-Code Dept. 4
- SG 12.1 Administrative Decision Compilation Procedure Completion

FG 13 Parallel Imports
Fr. Keck

- SG 11.2 ATC-Code Dept. 2
- SG 12.2 ATC-Code Dept. 2
- SG 12.3 ATC-Code Dept. 3+5
- SG 12.4 ATC-Code Dept. 4
Validation/Allocation of Procedures

• Validation of all procedures
  except centralised procedures, parallel imports and registrations

• Allocation of procedures
  Departments 2-5 or in "Simplified Procedures" unit of Dept. 1

• Answering common enquiries
Simplified Procedures

• New Applications, e.g.,
  
  Duplicates
  
  Generic drugs based on core specifications

• Variations, e.g.,
  
  National: variations not requiring consent
  
  Variations: DE = CMS: Type IA, IB
  
  DE = RMS: Type IA

• Renewals
Parallel Imports

All Procedures

• New applications

New:

• Variations

• Renewals
Efficient Drug Approval Based on Efficacy, Safety and Quality

Licensing Departments 2 - 4
# Units according to ATC Code

<table>
<thead>
<tr>
<th>Code</th>
<th>Department</th>
<th>Director</th>
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<tbody>
<tr>
<td>21</td>
<td>Procedure Management</td>
<td>Dr. Brendler-Schwaab, S</td>
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<td>22</td>
<td>Gastroenterology</td>
<td>Dr. Meyer, R.</td>
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<td>Endocrinology</td>
<td>Dr. Weise, M.</td>
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<td>Oncology, Immunology, Blood</td>
<td>Dr. Elbers, R.</td>
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<td>Genetic and Reproduction Tox.</td>
<td>Dr. Olejniczak, K.</td>
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<td>Procedure Management</td>
<td>Dr. Eibenstein, M.A., G.</td>
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<td>Antiinfectives</td>
<td>Matz, S.</td>
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<td>Cardiovascular System</td>
<td>Dr. Limberg, J.</td>
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<td>Skin, Ear/Nose/Throat, Eyes, Respiratory Tract</td>
<td>Dr. Kammler, H.-J.</td>
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<td>Biometry, Biostatistics</td>
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<td>Anaesthesiol./Algesiol.</td>
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<td>45</td>
<td>Pharma, Biotech, Biologics, Insp. Quality</td>
<td>Dr. Brake, B</td>
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Department 5
Special Therapeutic Modalities and Traditional Drugs

FG 51
Procedure Management

FG 52
Herbal and Traditional Medicines – Pharmacological Evaluation

FG 53
Herbal and Traditional Medicines – Preclinical and Clinical Evaluation

FG 54
Homeopathic and Anthroposophic Medicines – Pharmacological Evaluation

FG 55
Homeopathic and Anthroposophic Medicines – Preclinical and Clinical Evaluation
Benefits of the Reorganisation

- Reduced and optimised interfaces
- Acceleration of procedures
- Control of process lines
- Focussing on future relevant procedures
Tasks of Department 5

• Communication and information
• Effectiveness and flexibility
• Contemporary implementation of new procedures and consistency in planning (e.g. traditional drugs, MRP, new applications)
• Reducing "Altlasten" (old markets)
Department 6
"Scientific Services"

- Clinical Trials/GCP
  Dr. C. Steffen
- Scientific Advice
  Dr. P. Dejas-Eckertz
- Commissions
  N.N.
- Legal Services
  E. Domeyer
- Pharmacopoeia / Analytics
  Dr. D. Schnädelbach
- Information Technology
  Dr. M. Plagge*
Clinical Trials/GCP

• Continuous increase in clinical trial applications (CTAs) since August 2004
  Q1/2005 vs. Q1/2006: +40% increase in CTAs
• Good overall performance
• Timelines are strictly met
• Current issues:
  Pharmacovigilance (PV) issues in clinical trials due to “over-reporting” of adverse events without matching the SUSAR definition
Number of Clinical Trial Applications
August 2004 – March 2006

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<tr>
<th>Month</th>
<th>&quot;Old&quot; Notification Procedure</th>
<th>&quot;New&quot; Clinical Trial Application</th>
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<td>2006 January</td>
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<td>February</td>
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</tr>
<tr>
<td>March</td>
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</table>
Scientific Advice

• New simplified national scientific advice procedure established
  
  *Procedure/requirements will be published soon*

• New portfolio/pipeline-meetings established
  
  *Allows pharmaceutical companies to present complete portfolios*

• New scientific advice procedures prior to clinical trial applications
  
  *Discussion of complex trial designs prior to CTA*
Commissions

• Constituent meeting of the new expert groups on "Off-Label Use"
  
  Oncology
  Neurology/Psychiatry
  Infectiology / HIV

• Current Issues:
  
  Lack of financial means to scale up the work of the expert groups

  Currently no appointment of the "Commission A" and the "Paediatric Commission" by the Ministry of Health
Legal Services

- Enormous increase of workload due to end of "Nachzulassungsverfahren" ("Old Market Procedures") and the establishment of five judicial court chambers
  - *Open Legal Cases: >2700*
  - *Open Objection Procedures: >1500*
- Outsourcing of legal cases to external lawyers
- Internal reorganisation to enhance capacities
Pharmacopoeia / Analytics

• Update and maintenance of the German Pharmacopoeia (DAB) and the German Homoeopathic Pharmacopoeia (HAB)

• Cooperation in the European Pharmacopoeia (Ph. Eur.)

• Additional focus on counterfeit drugs and illegal drugs
  
  *Federal cooperation (“Länder”, BKA: Federal Criminal Police Office)*

  *International cooperations (EMEO = European Medicines Enforcement Officers)*
EU and International Affairs

I. Strengthening BfArM presence in the EU and at the international level

II. Processing of EU questions of principle

III. Coordination and evaluation of information management for European and international developments
Strengthening the BfArM Presence

- BfArM in EU (e.g. CHMP, CMD/h, NTA)
- Liaison to the Permanent Secretariat of the Heads of Agencies
- Coordination of cooperation with international committees
- Contact point for EU- and international institutions
- Coordination of cooperation and support for twinning projects in the new EU member states
Questions of Principle

• Early identification of relevant developments at the EU- and international level
• Development of strategies and positions for BfArM
• Coordination with Ministry of Health and other authorities
Management of Information

• Dissemination of information to all units
• Secretariat and "contact point" for BfArM employees participating in EU- und EMEA-committees to support the preparation of opinions
• Contact point for centralised procedures, EMEA
Strategy and Planning

• Goals

  Short-term operative
  Finishing the 'Nachzulassung' (old market), reducing other backlogs

  Medium-term strategic
  business plan, workload processing

• To do list

  Management by objectives
  Control
  Quality management
Quality Management / Change Management

1. Licensing procedures
   • Implementation of the new procedures in the "new" units
   • Backing and coordination of the changes
   • Evaluation of all relevant sub-procedures
Quality Management / Change Management

2. Development of a documented QM System
   • Definition of quality goals and quality policy
   • Development of quality organisation
   • Training of QM employees
   • Documented manual of QM
Quality Management / Change Management

3. Analysis / Optimization of procedures
e.g. Monitoring stakeholders / customers

4. BEMA
Benchmarking of EU Authorities
   Preparation and realisation of self assessment
   Preparation of peer review
Quality Management / Change Management

5. Certification
   DIN EN ISO 9001

6. Business plan
Scientific Quality Assurance

- Consistency of decisions
- Early detection of undesirable developments
- Support for training/education
- Senior experts in clinical, quality and toxicology assessments
- Predefinition of standards
- Questions of coordination
- Management of information
- Active organisation of meetings, conferences and assessor training
- Data maintenance
Electronically supported business processes will promote BfArM as the center of regulatory competence
Requirements for the Staff

• User requirements
  *Easy to use interface*
  *Clear overview on a task list / workflow*
  *Easy availability of relevant information, documents and templates*

• Technical requirements
  *1 GB network*
  *Sufficient storage capacity*
  *Permanent availability*
Requirements for the Applicants

• Requirements regarding processes
  
  * Predictability of timelines
  * Transparency of the process steps
  * Two-way communication

• Technical requirements
  
  * Easy to use electronic formats / templates
  * Single point of entry for upload, support, and information
  * Simple practical tools for e-submission
What has happened in IT since July 2005?

• Revised guideline for electronic submission in preparation
• Requirements for a workflow system have been developed
  - Definition of the processes required for the pilot project
  - Mock-ups for the user interface screens
  - Specifications for interfaces to AMIS, CTS, docuBridge
• Technical requirements have been fulfilled
  - The 1GB network has been installed
  - A server area network has been installed
• Process adjustment
  - Documentation of all current processes have been finished
  - Discussions regarding alignments are ongoing
Thank you for your kind attention!

www.bfarm.de