BfArM
Bundesinstitut für Arzneimittel
und Medizinprodukte

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

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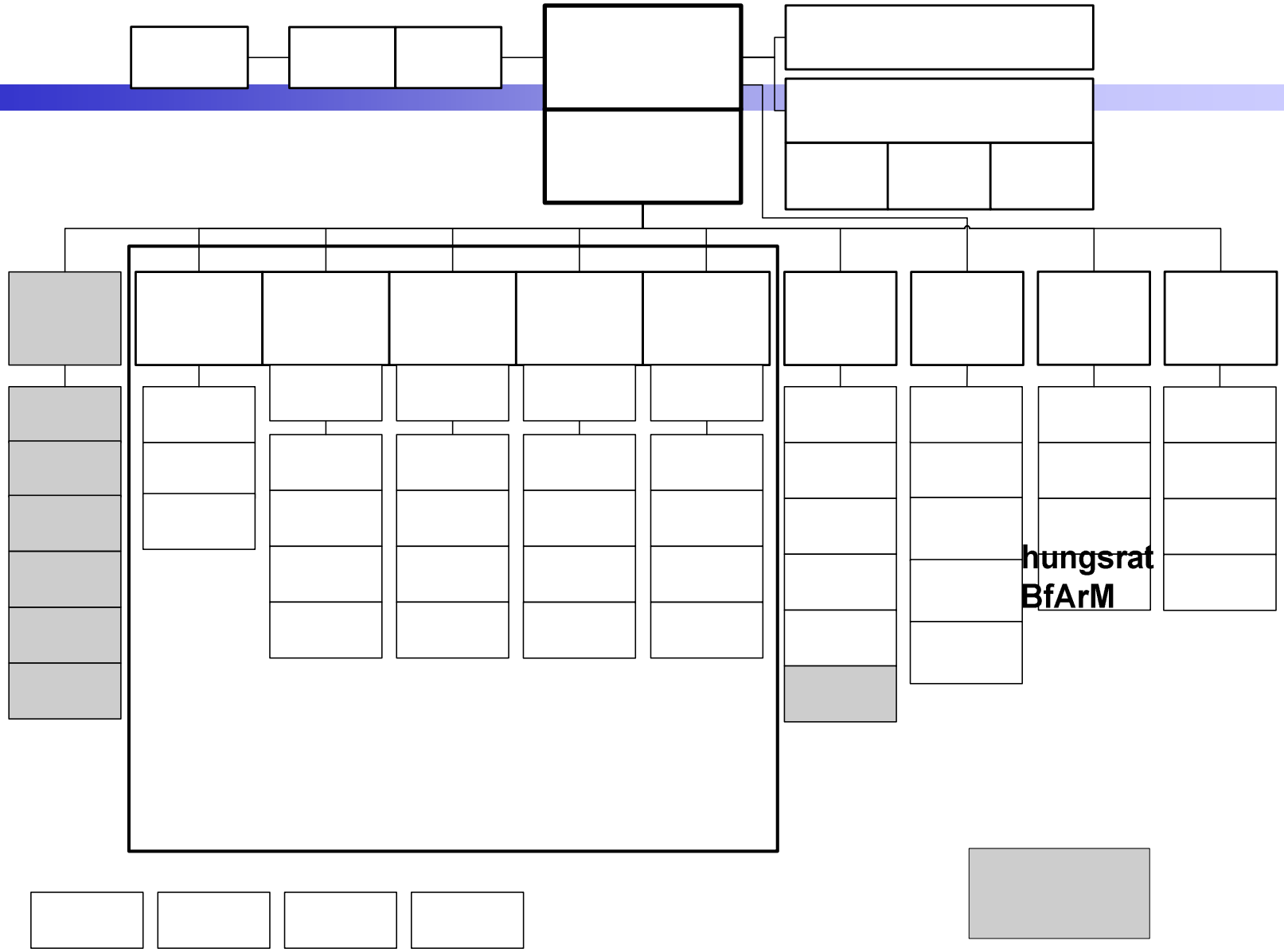
Reorganisation of the BfArM: Status 24.04.2006



P1
Öffentlichk

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

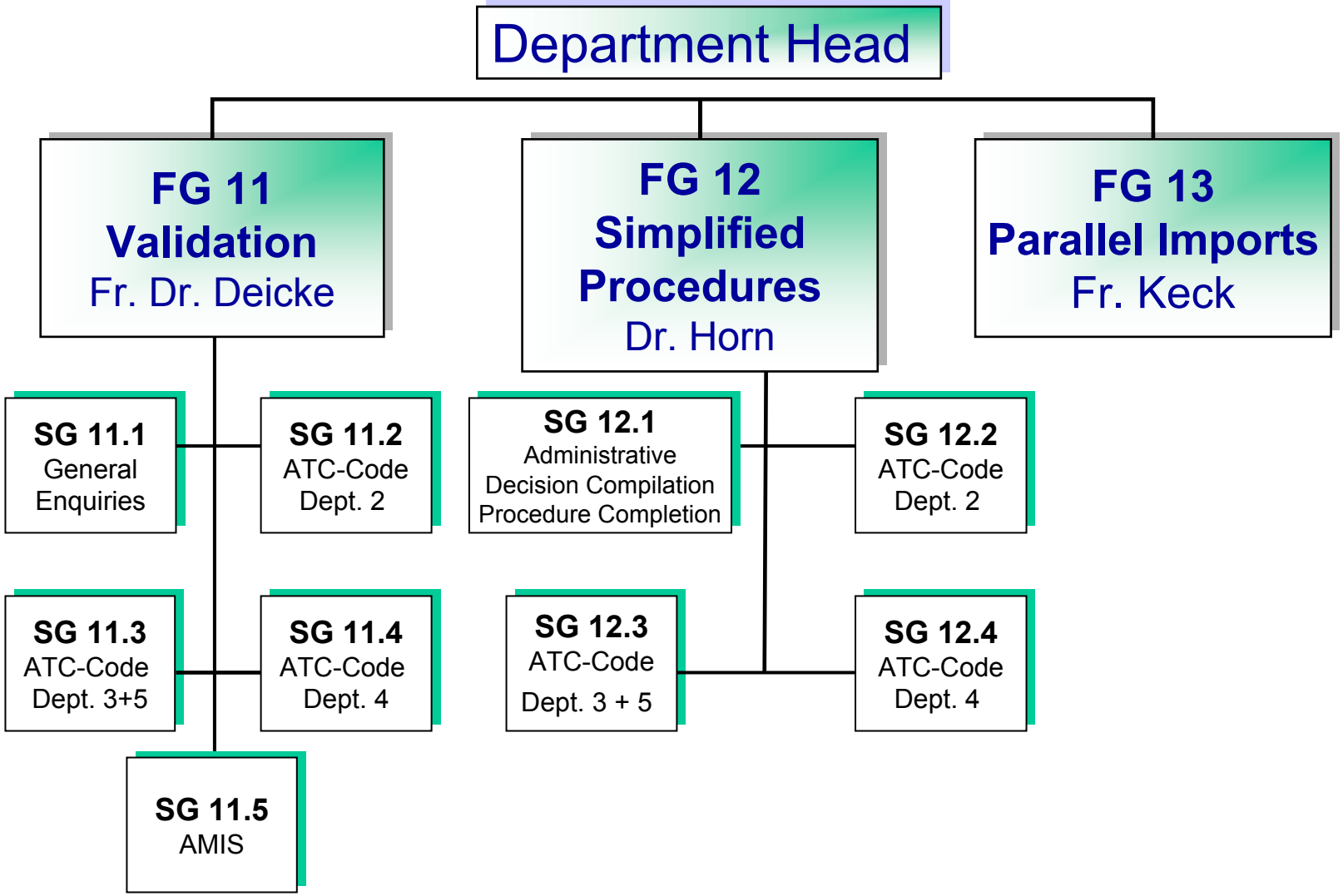
Actions include:

- 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



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

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Efficient Drug Approval Based on Efficacy, Safety and Quality

Licensing Departments 2 - 4

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Units according to ATC Code

21 Procedure Management *Dr. Brendler-Schwaab, S*	**31** Procedure Management *Eibenstein, M.A., G.*	**41** Procedure Management *Winterscheid, S*
22 Gastroenterology *Dr. Meyer, R.*	**32** Antiinfectives *Matz, S.*	**42** Anaesthesiol./Algesiol. *Dr. Cremer-Schaeffer, P.*
23 Endocrinology *Dr. Weise, M.*	**33** Cardiovascular System *Dr. Limberg, J.*	**43** Neurology Psychiatry *Dr. Rieh, B.*
24 Oncology, Immunology, Blood *Dr. Elbers, R.*	**34** Skin, Ear/Nose/Throat, Eyes, Respiratory Tract *Dr. Kammler, H.-J.*	**44** Rheumatology Radiology, Nucl. *Dr. Heim, H.-K.*
25 Genetic and Reproduction Tox. *Dr. Olejniczak, K.*	**35** Biometry, Biostatistics *Dr. Koch, A*	**45** Pharma, Biotech, Biologics, Insp. Quality *Dr. Brake, B*

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)

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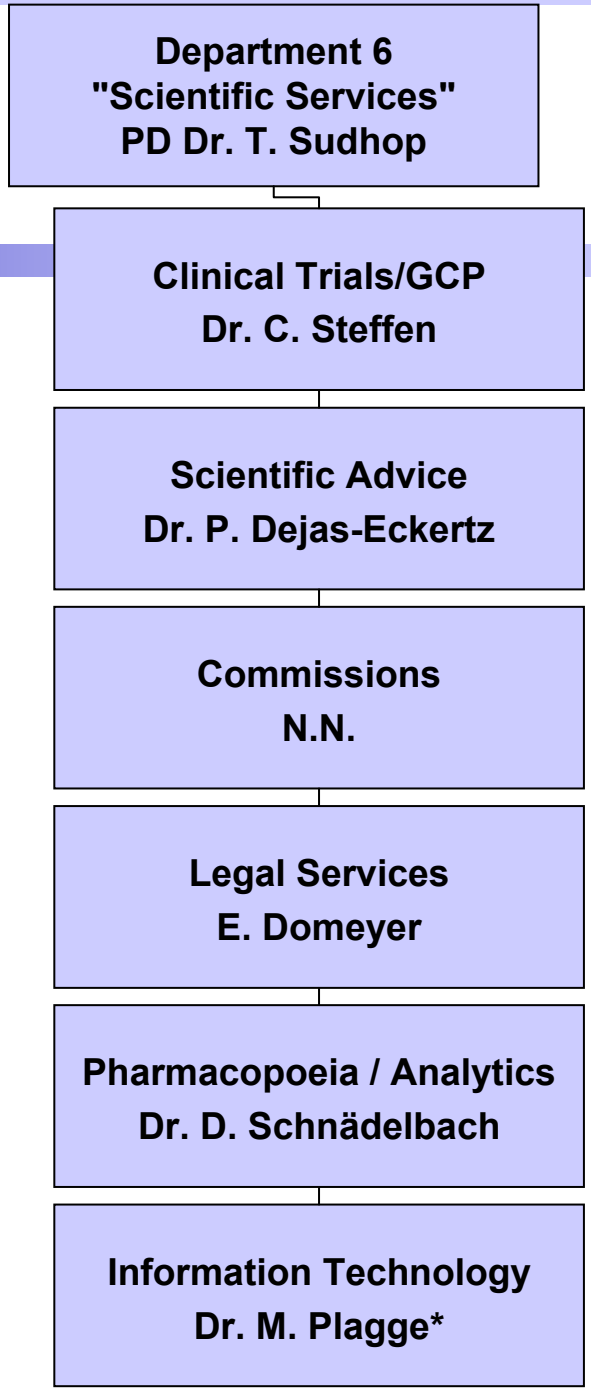
Department 6 "Scientific Services"



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*

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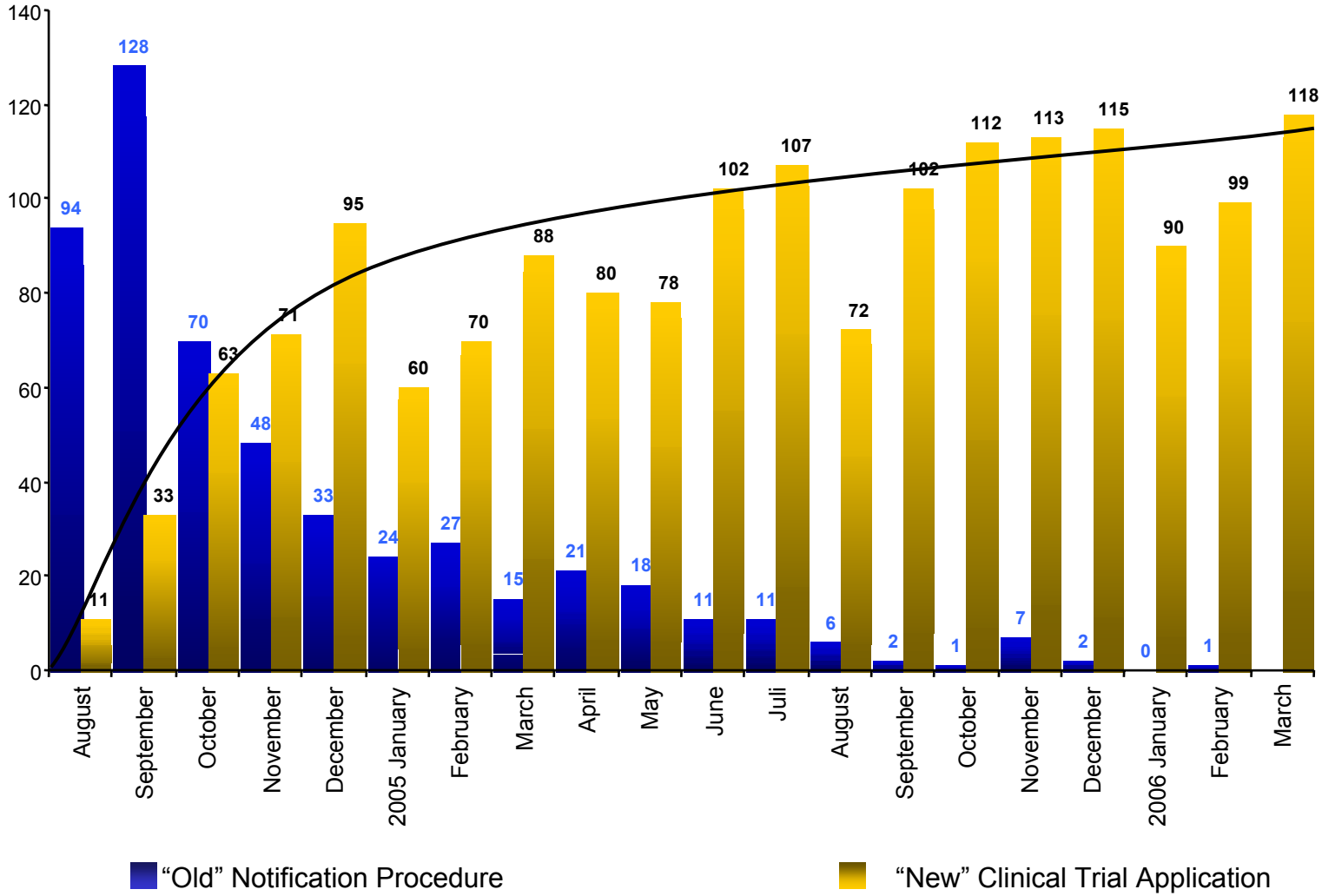
Number of Clinical Trial Applications

August 2004 – March 2006



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

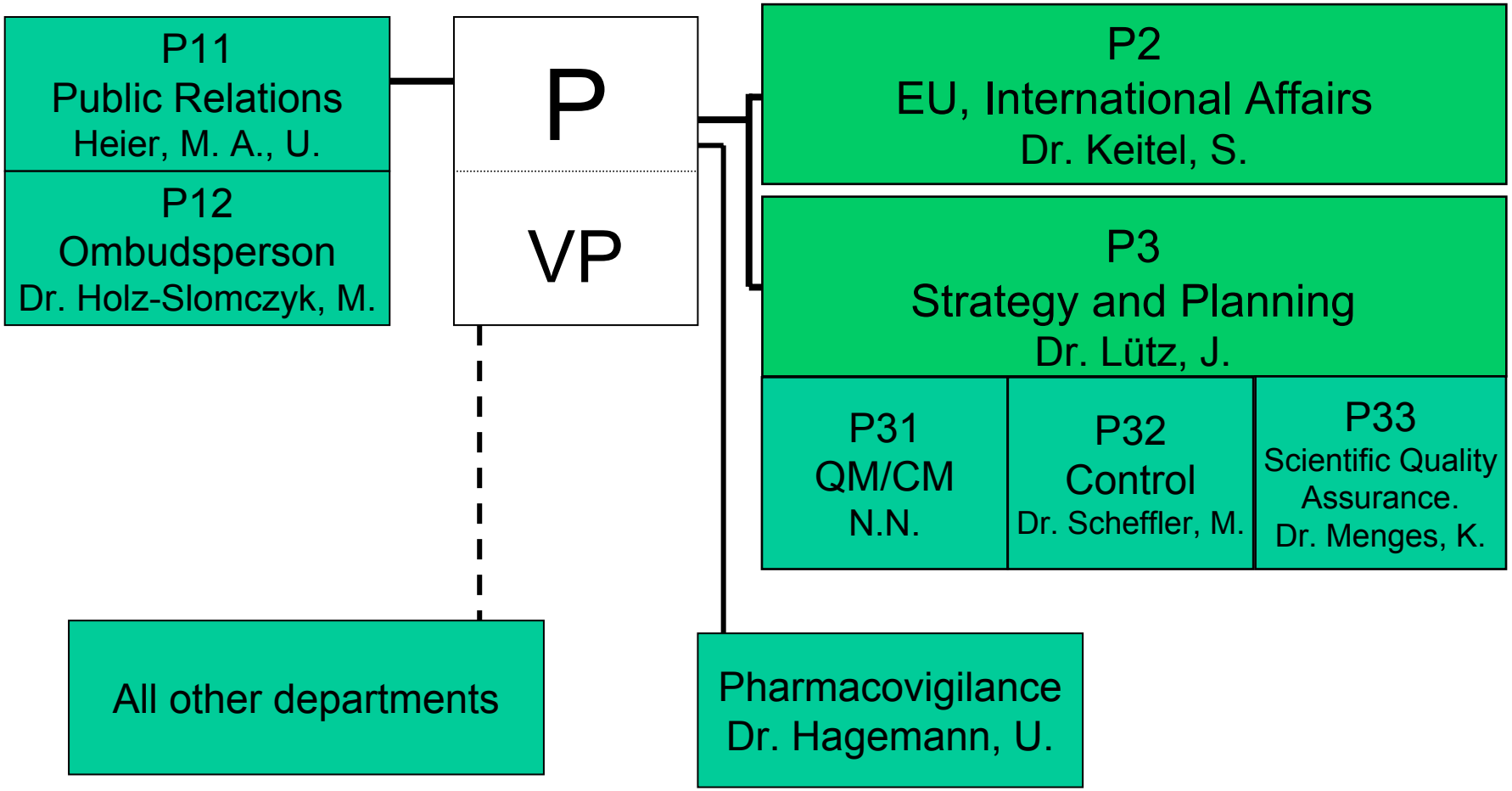
Pharmacopoeia / Analytics

- 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)

Administration/Management



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)
- Laison 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

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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*

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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!

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