BfArM
Bundesinstitut für Arzneimittel und Medizinprodukte

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Federal Institute for Drugs and Medical Devices

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Federal Ministry
of Health

Federal Ministry
of Food, Agriculture
and Consumer Protection

Federal Office of
Consumer Protection
and Foot Safety

BfArM

Paul-Ehrlich-Institut

DIMDI
medicalknowledge
German Institute of Medical
Documentation and Information

History

- The Federal Institute for Drugs and Medical Devices is an independent higher federal authority within the portfolio of the Federal Ministry of Health.
- It was founded June 1994 as successor to the Institute for Drugs founded on 1 July 1975 as part of the now dissolved Federal Health Office.
- The authority's seat was transferred to Bonn in the course of the Government's move to the capital.

Staff

- About 1,100 employees
- Physicians, Pharmacists, Chemists, Biologists, Lawyers, Engineers, Technical Assistants and Administrative Staff

Organisation

- 10 units
  - Authorization (3 units)
  - Special products (homeopthics, herbals)
  - Research
  - Scientific Service
  - Pharmacovigilance
  - Narcotics
  - Medical Devices
  - Administration

Mandate

- Licensing and Registration of Medicinal Products
- Monitoring of Risks due to Medicinal Products
- Controlled Substances (Narcotics, Psychotropics, and Precursors)
- Clinical Trials / GCP Inspections
- Scientific and Regulatory Advice
- Medical Devices

Licensing

- Authorization of finished medicinal products on the basis of the German Medicines Act
- Licenses are limited to five years.
- Renewals are granted upon application and after new evaluation.
- The BfArM must be notified of variations to already licensed medicinal products.
- Major variations can only be implemented after authorization by the BfArM.

Registration

- Homoeopathic drugs are either registered by the BfArM without statement of indications or are licensed with indications
- Complementary and Alternative Medicines (CAM) and Traditional Medicinal Products (TMP) are also registered by BfArM

Responsibilities

- BfArM is responsible for almost all medicinal products for humans
- Special product (blood, vaccines) are under responsibility of Paul-Ehrlich-Institute
- About 95% of all human medicinal products
- Veterinary products are managed by the Federal Office for Consumer Protection and Food Safety or Paul-Ehrlich-Institute

Thank You!

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