German Competent Authorities as Part of the Network of European Drug Regulators

PD Dr. Walter Schwerdtfeger

BfArM and PEI: General duties

(on the basis of the Federal Health Office Succession Act, June 1994 (BfArM); Establishment Act, July 1972 (PEI); and successive development of legislation)

- performing legally specified tasks and tasks assigned to the authorities by the respective responsible Ministry
- supporting the Federal Government
- performing scientific research within own areas of responsibility
- informing stakeholders and the general public

Federal Drug Authorities - scope of responsibility

PEI

- sera, vaccines (human and veterinary)
- blood preparations, blood components (genetically engineered), bone marrow preparations
- tissues and tissue preparations, allergens
- advanced therapy and xenogeneic medicinal products
- in vitro diagnostics

(**BVL**

- medicinal products for veterinary use, except vaccines)

BfArM

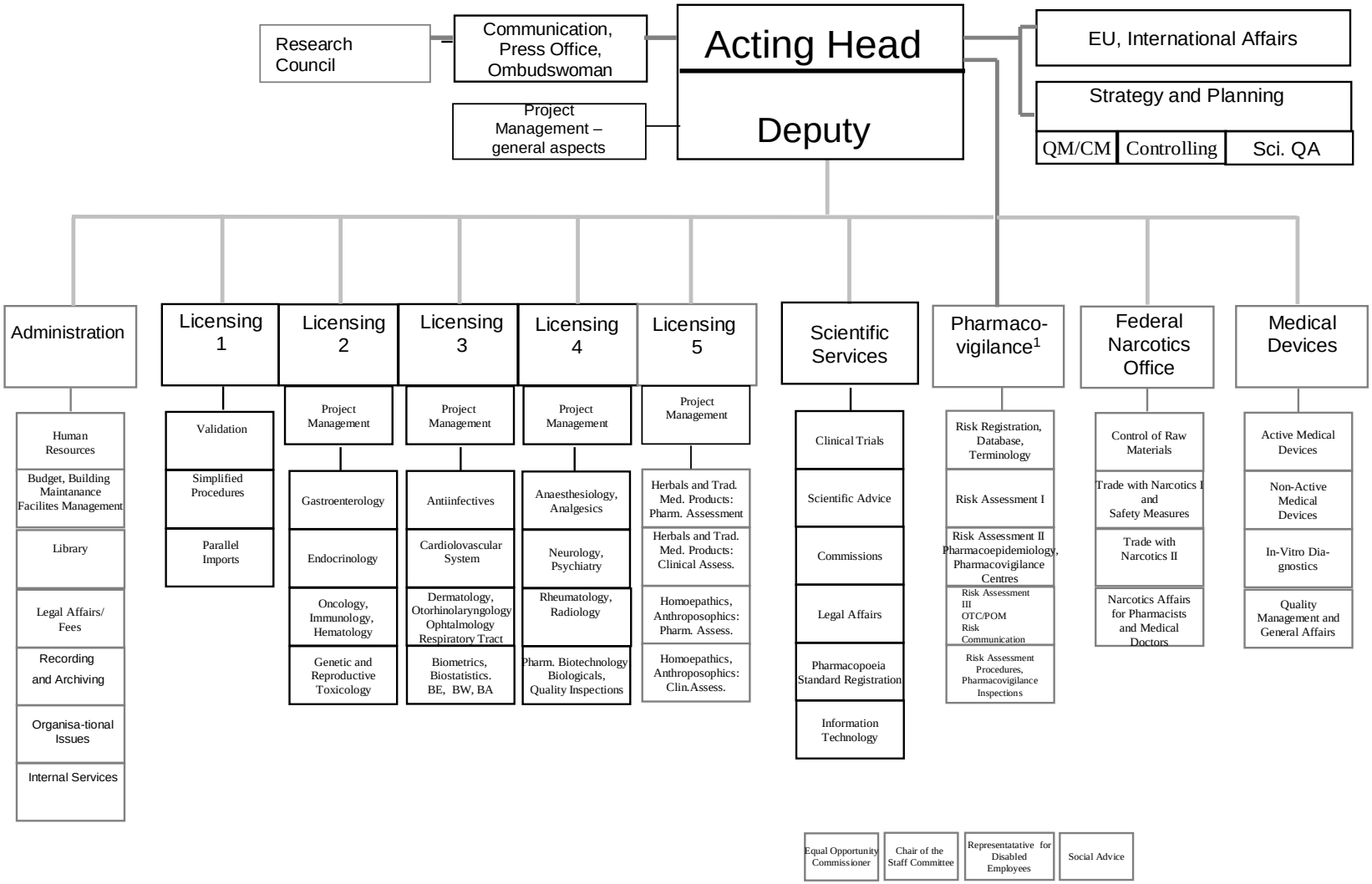
- any medicinal product not regulated by PEI or BVL
- narcotic drugs, psychotropic substances, precursors
- medical devices except in vitro diagnostics

PEI and BfArM: specific duties

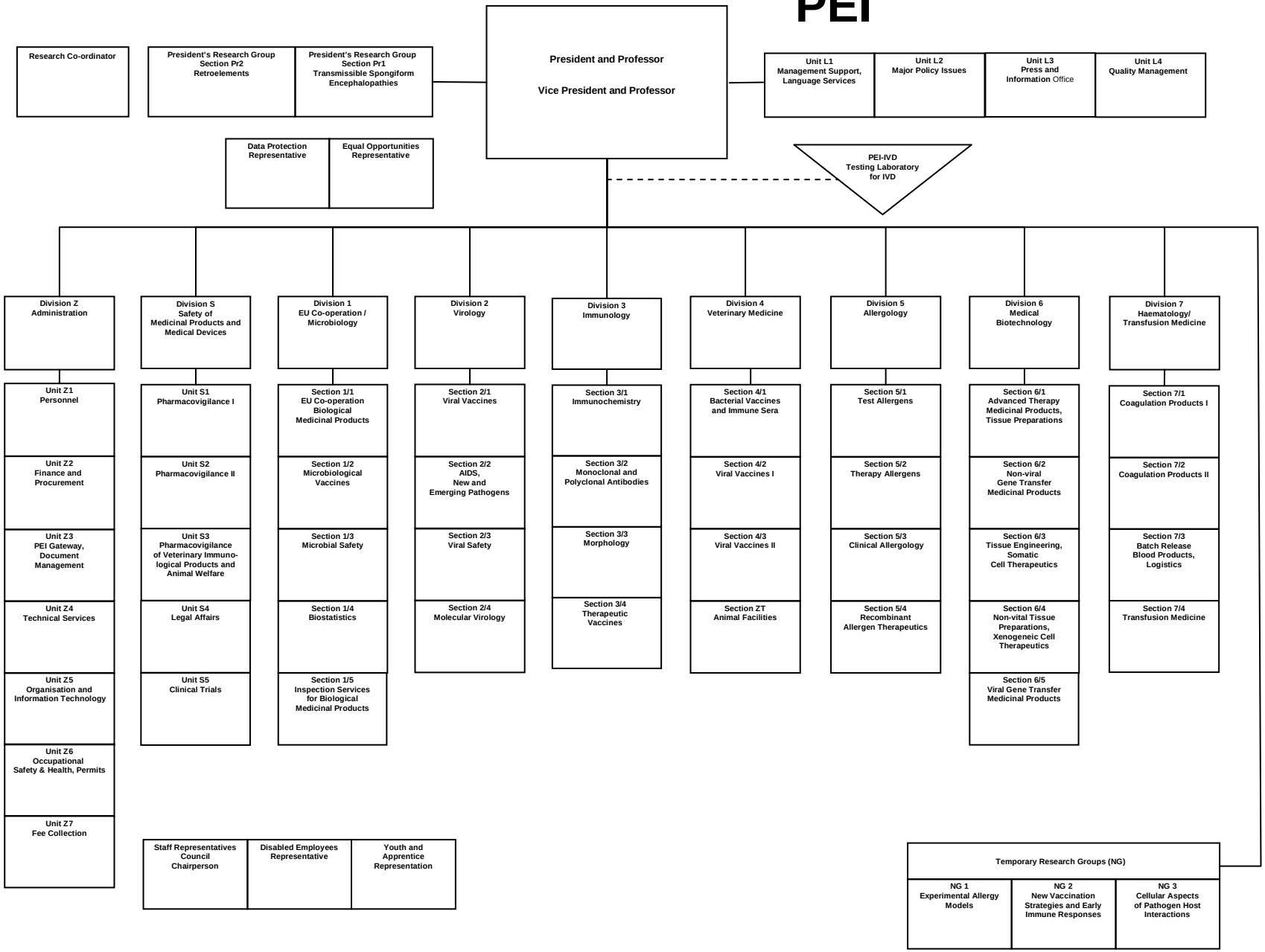
- scientific advice
- approval of clinical studies
- participation in approval of clinical trials (veterinary vaccines)
- authorisation of medicinal products
- registration of homeopathic/anthroposophic and traditional herbal medicinal products
- batch release
- post-marketing activities including pharmacovigilance
- inspections
- monographs for EU- and national pharmacopoeias
- surveillance of legal commerce of narcotics
- medical devices: assessment of the medical and technical safety, vigilance

BfArM

Federal Insitute for Drugs and Medical Devices
(BfArM)
Kurt-Georg-Kiesinger-Allee 3
53175 Bonn
Telefon: (0228) 207 – 30
Telefax: (0228) 207 - 5207



PEI

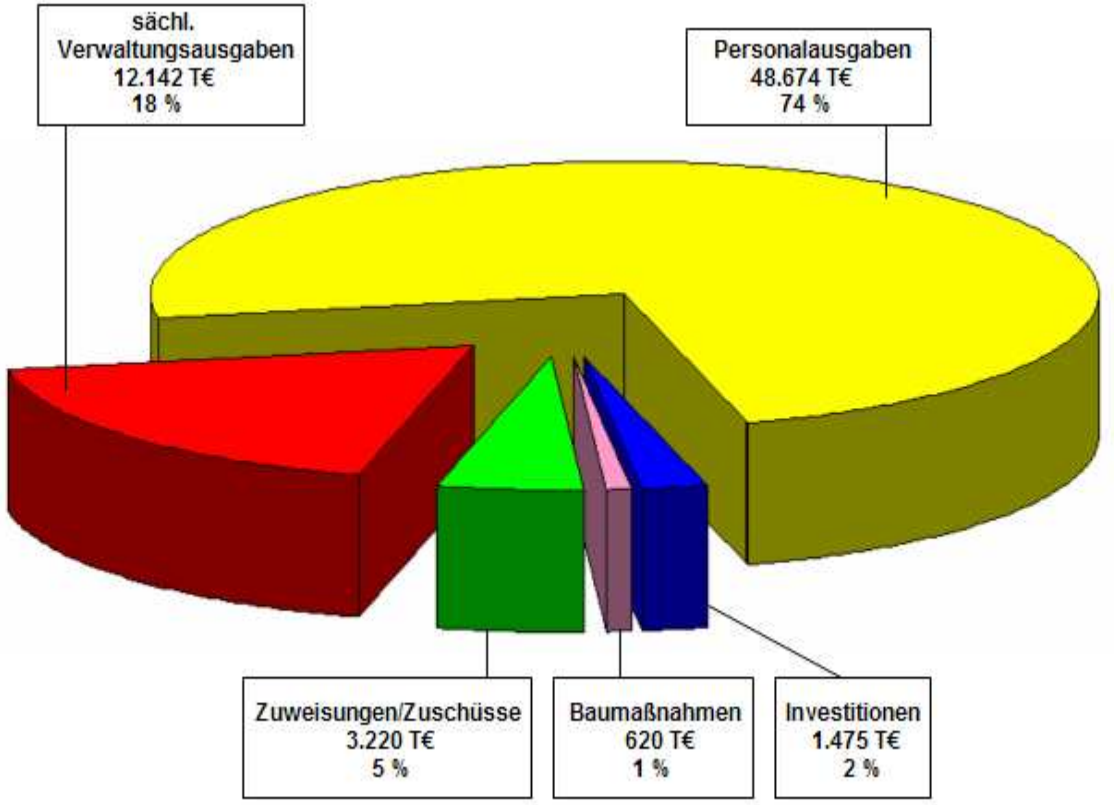

Research Co-ordinator
President's Research Group Section Pr2 Retroelements
President's Research Group Section Pr1 Transmissible Spongiform Encephalopathies
President and Professor
Vice President and Professor
Unit L1 Management Support, Language Services
Unit L2 Major Policy Issues
Unit L3 Press and Information Office
Unit L4 Quality Management
Data Protection Representative
Equal Opportunities Representative
PEI-IVD Testing Laboratory for IVD
Division Z Administration
Division S Safety of Medicinal Products and Medical Devices
Division 1 EU Co-operation / Microbiology
Division 2 Virology
Division 3 Immunology
Division 4 Veterinary Medicine
Division 5 Allergology
Division 6 Medical Biotechnology
Division 7 Haematology/ Transfusion Medicine
Unit Z1 Personnel
Unit Z2 Finance and Procurement
Unit Z3 PEI Gateway, Document Management
Unit Z4 Technical Services
Unit Z5 Organisation and Information Technology
Unit Z6 Occupational Safety & Health, Permits
Unit Z7 Fee Collection
Unit S1 Pharmacovigilance I
Unit S2 Pharmacovigilance II
Unit S3 Pharmacovigilance of Veterinary Immuno-logical Products and Animal Welfare
Unit S4 Legal Affairs
Unit S5 Clinical Trials
Section 1/1 EU Co-operation Biological Medicinal Products
Section 1/2 Microbiological Vaccines
Section 1/3 Microbial Safety
Section 1/4 Biostatistics
Section 1/5 Inspection Services for Biological Medicinal Products
Section 2/1 Viral Vaccines
Section 2/2 AIDS, New and Emerging Pathogens
Section 2/3 Viral Safety
Section 2/4 Molecular Virology
Section 3/1 Immunochemistry
Section 3/2 Monoclonal and Polyclonal Antibodies
Section 3/3 Morphology
Section 3/4 Therapeutic Vaccines
Section 4/1 Bacterial Vaccines and Immune Sera
Section 4/2 Viral Vaccines I
Section 4/3 Viral Vaccines II
Section ZT Animal Facilities
Section 5/1 Test Allergens
Section 5/2 Therapy Allergens
Section 5/3 Clinical Allergology
Section 5/4 Recombinant Allergen Therapeutics
Section 6/1 Advanced Therapy Medicinal Products, Tissue Preparations
Section 6/2 Non-viral Gene Transfer Medicinal Products
Section 6/3 Tissue Engineering, Somatic Cell Therapeutics
Section 6/4 Non-vital Tissue Preparations, Xenogeneic Cell Therapeutics
Section 6/5 Viral Gene Transfer Medicinal Products
Section 7/1 Coagulation Products I
Section 7/2 Coagulation Products II
Section 7/3 Batch Release Blood Products, Logistics
Section 7/4 Transfusion Medicine
Staff Representatives Council Chairperson
Disabled Employees Representative
Youth and Apprentice Representation
Temporary Research Groups (NG)
NG 1 Experimental Allergy Models
NG 2 New Vaccination Strategies and Early Immune Responses
NG 3 Cellular Aspects of Pathogen Host Interactions

Basic budget figures
(M €; official MoH budget 2010)

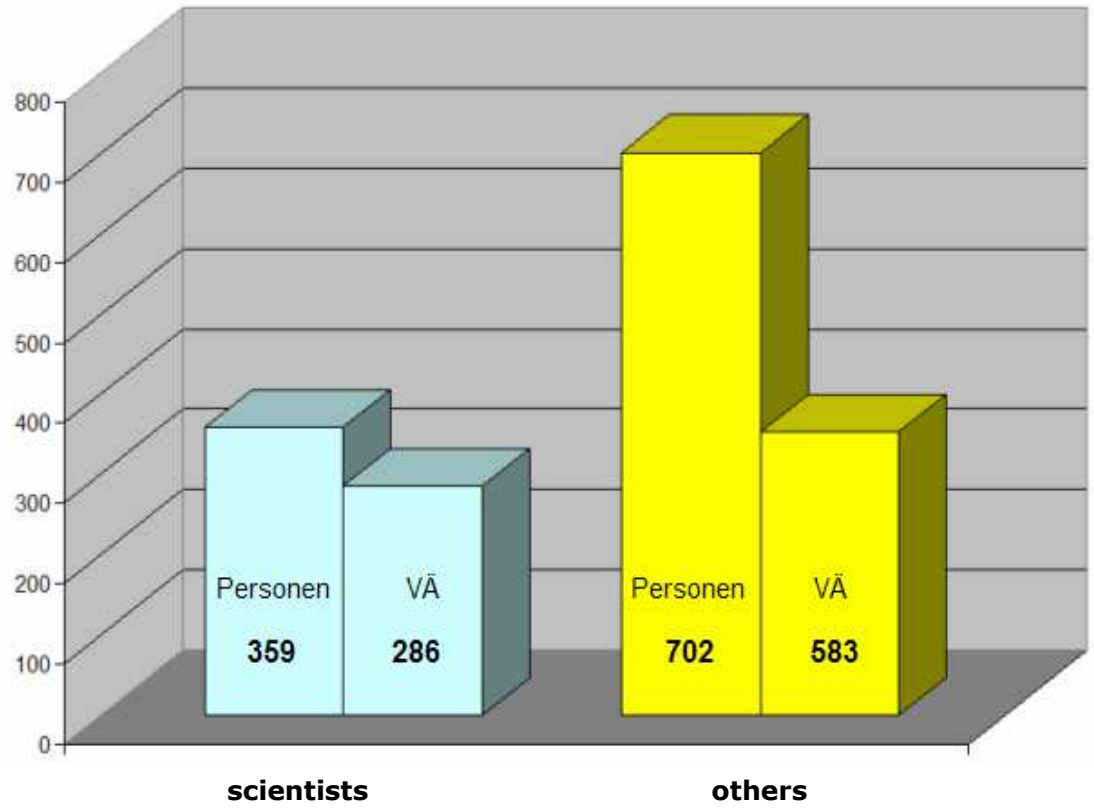
	BfArM	PEI
revenue		
- fees	55.358	13.286
- other	551	1.328
total	**55.909**	**14.614**
expenditure		
- staff	48.674	27.500
- other	17.457	24.048
total	**66.131**	**51.548**
percentage revenue of expenditure	85	28

BfArM: Expenditures 2010

expected total: 66.131 M €

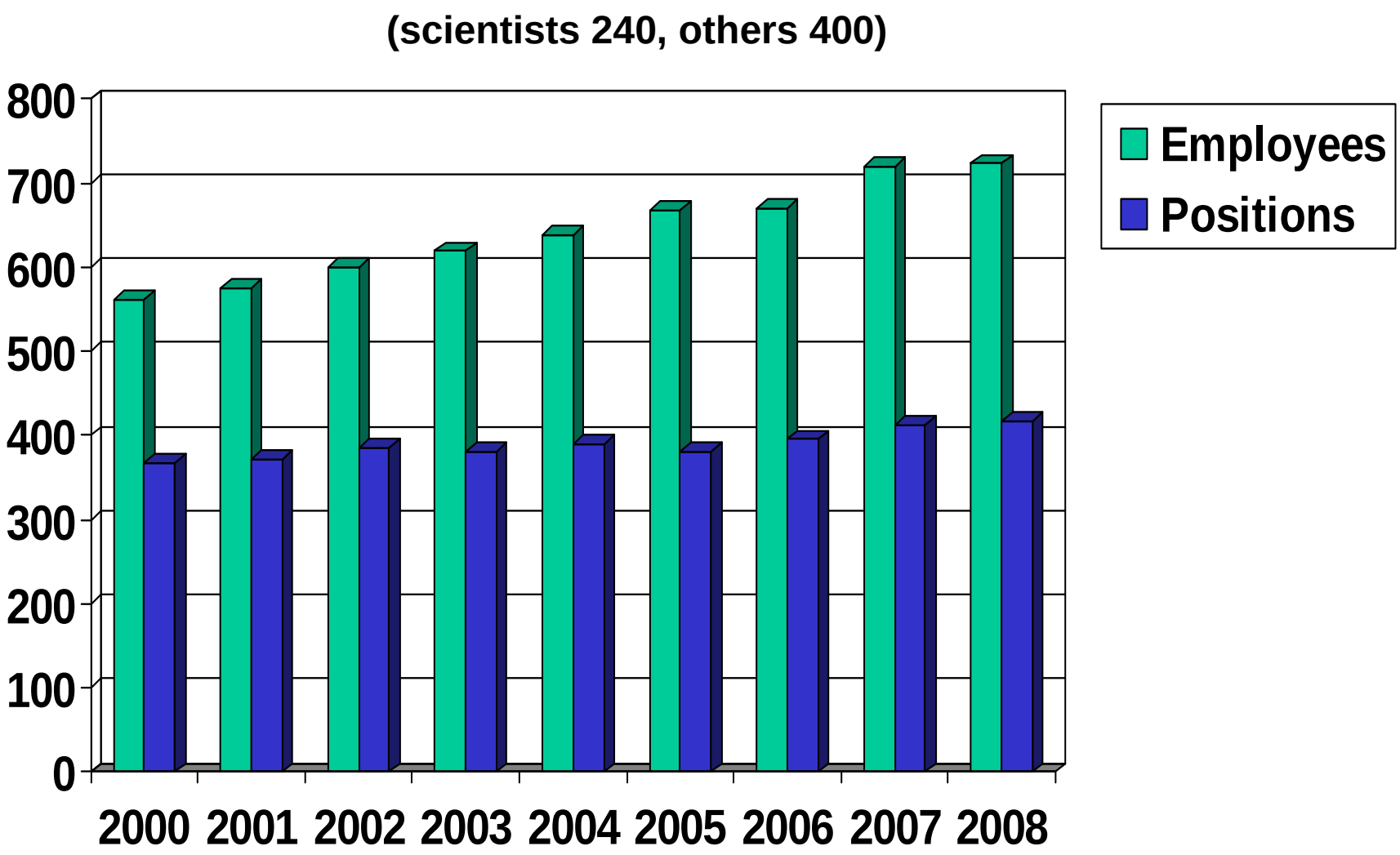


Staff BfArM



VÄ = full-time equivalents

Staff PEI


(scientists 240, others 400)
800
700
600
500
400
300
200
100
0
2000
2001
2002
2003
2004
2005
2006
2007
2008
Employees
Positions

Salaries - how to attract qualified staff

	Marburger Bund			TVÖD	
physician	1st year 3.730	5th year 4.665		1st year 3.075	6th year 3.947
medical specialist	1st year 4.920	11th year 6100		1st year 3.335	10th year 4.730
senior physician	1st year 6.180	4th year 6.530		1st year 3.683	11th year 5.180

What is expected

- fulfill duties correctly and within legal timeframes
- decide using consistent, transparent and plausible criteria
- provide state of the art scientific advice
- communicate openly
- charge fair fees

- give drug safety highest priority
- monitor standards of own performance, participate in benchmarking
- strive towards improving regulatory fundament
- participate in official and scientific networks
- perform task-related scientific research

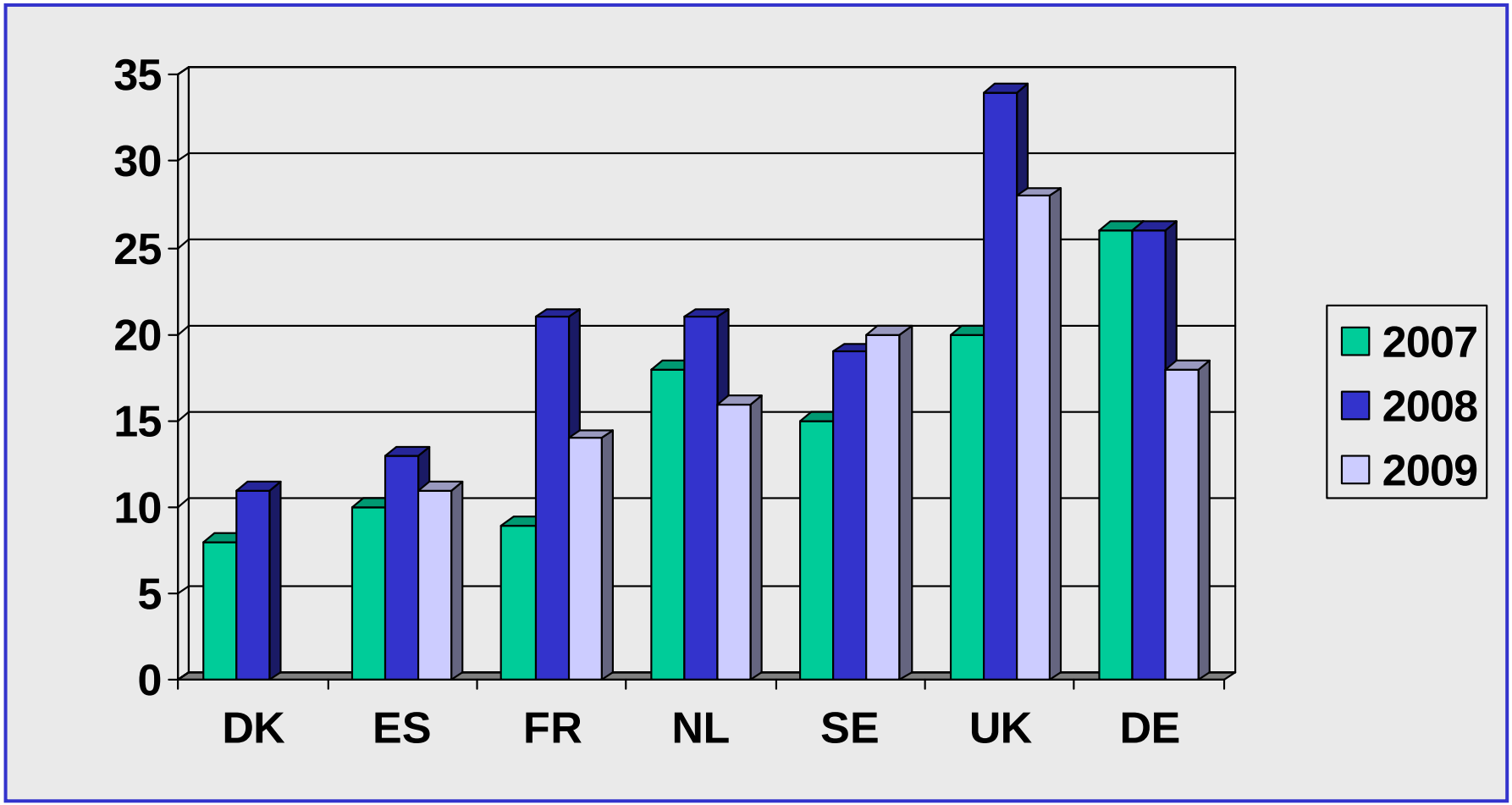
What is necessary

- build up clear operative structures
- assign unequivocal responsibilities
- have concise SOPs for all relevant tasks and procedures
- establish high-performance IT systems
- motivate staff
- think twice when selecting senior staff
- keep in mind that patients, doctors, industry and authorities have closely related interests

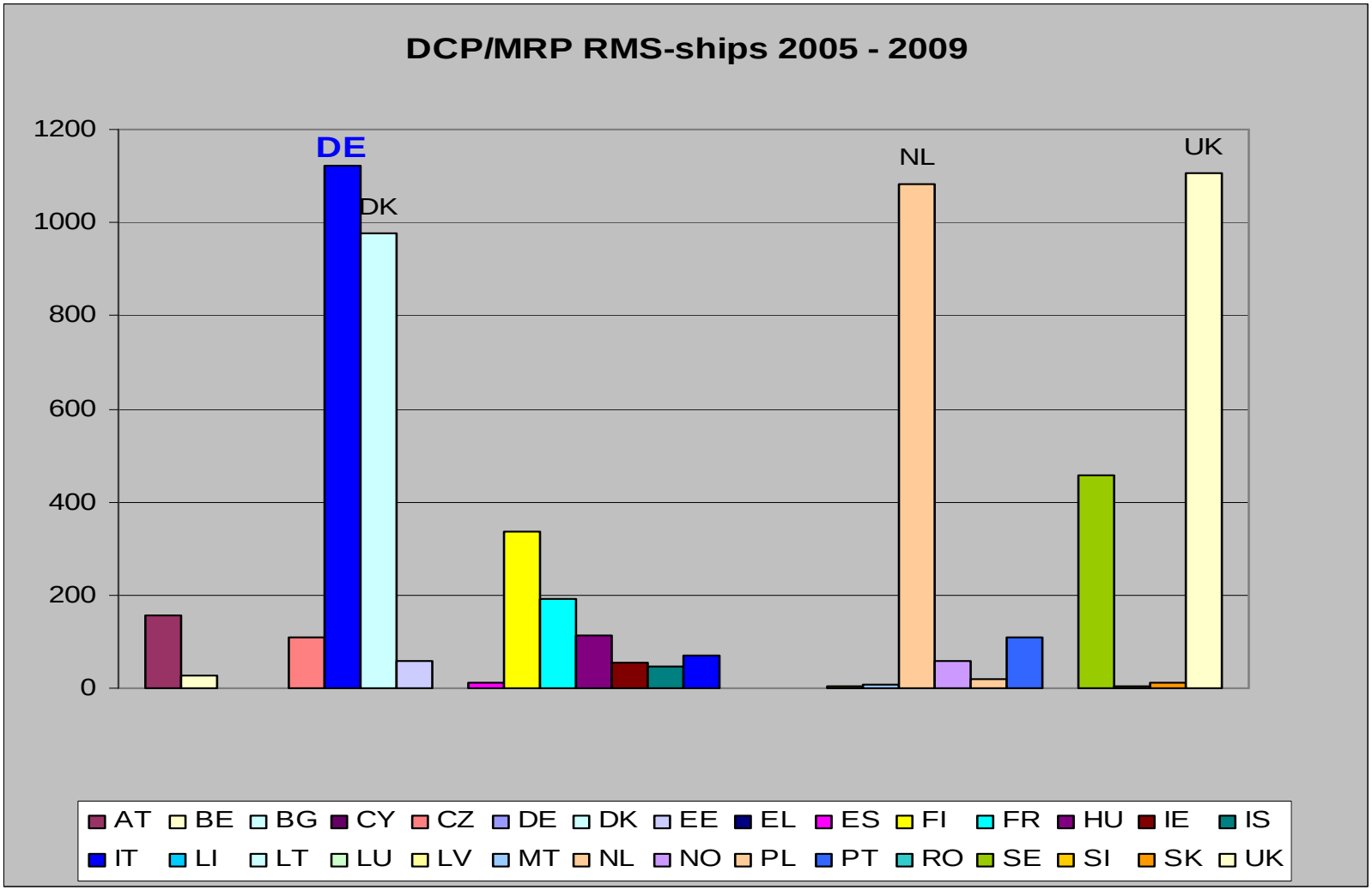
What is fatal

- being unaware of current safety issues
- neglecting safety-related findings when taking decisions
- ignoring the need of continuous performance controlling
- thinking you are the best anyway

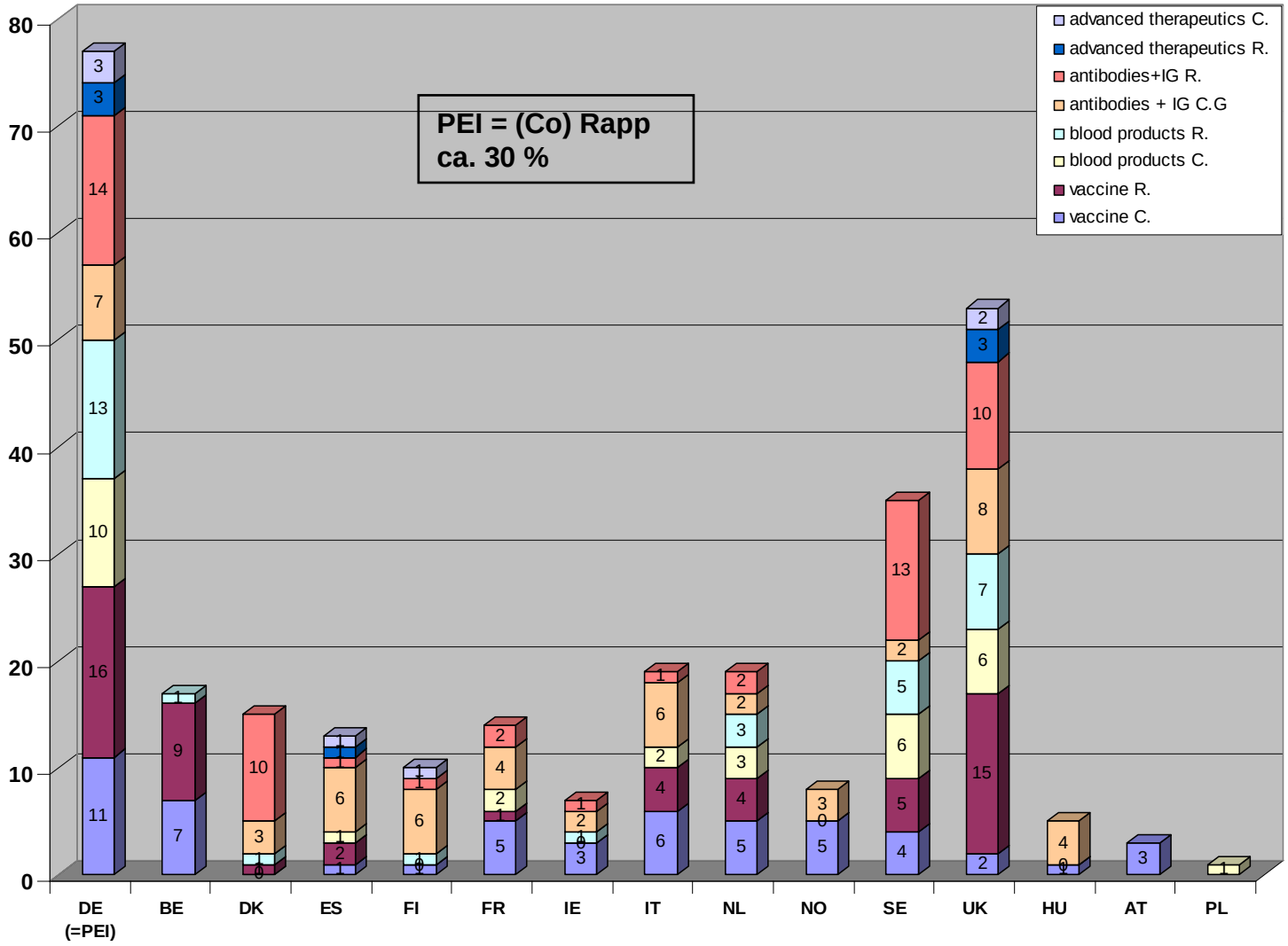
CHMP (co-)rapporteurships, BfArM



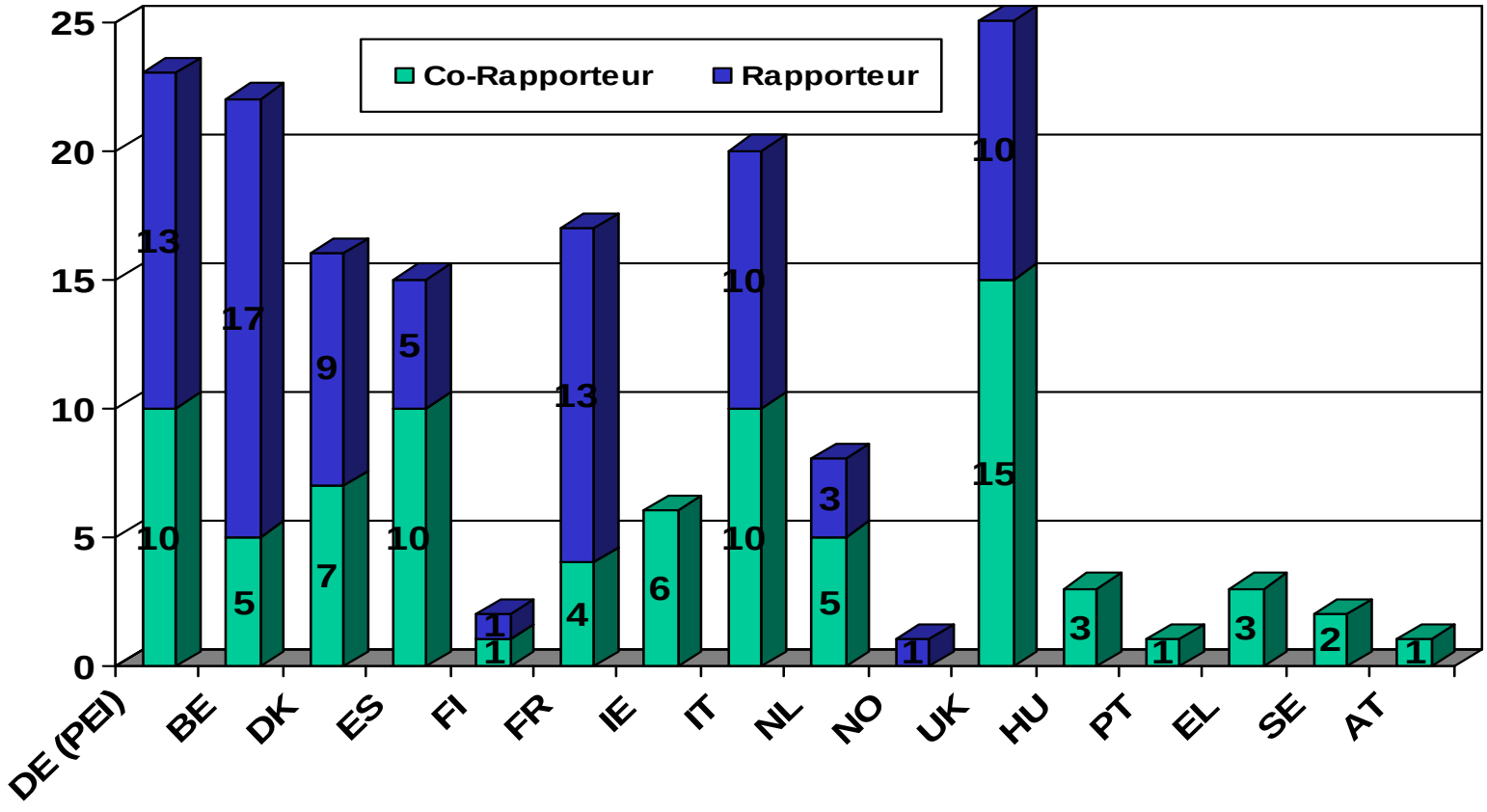
RMS in DCP/MRP-procedures, BfArM



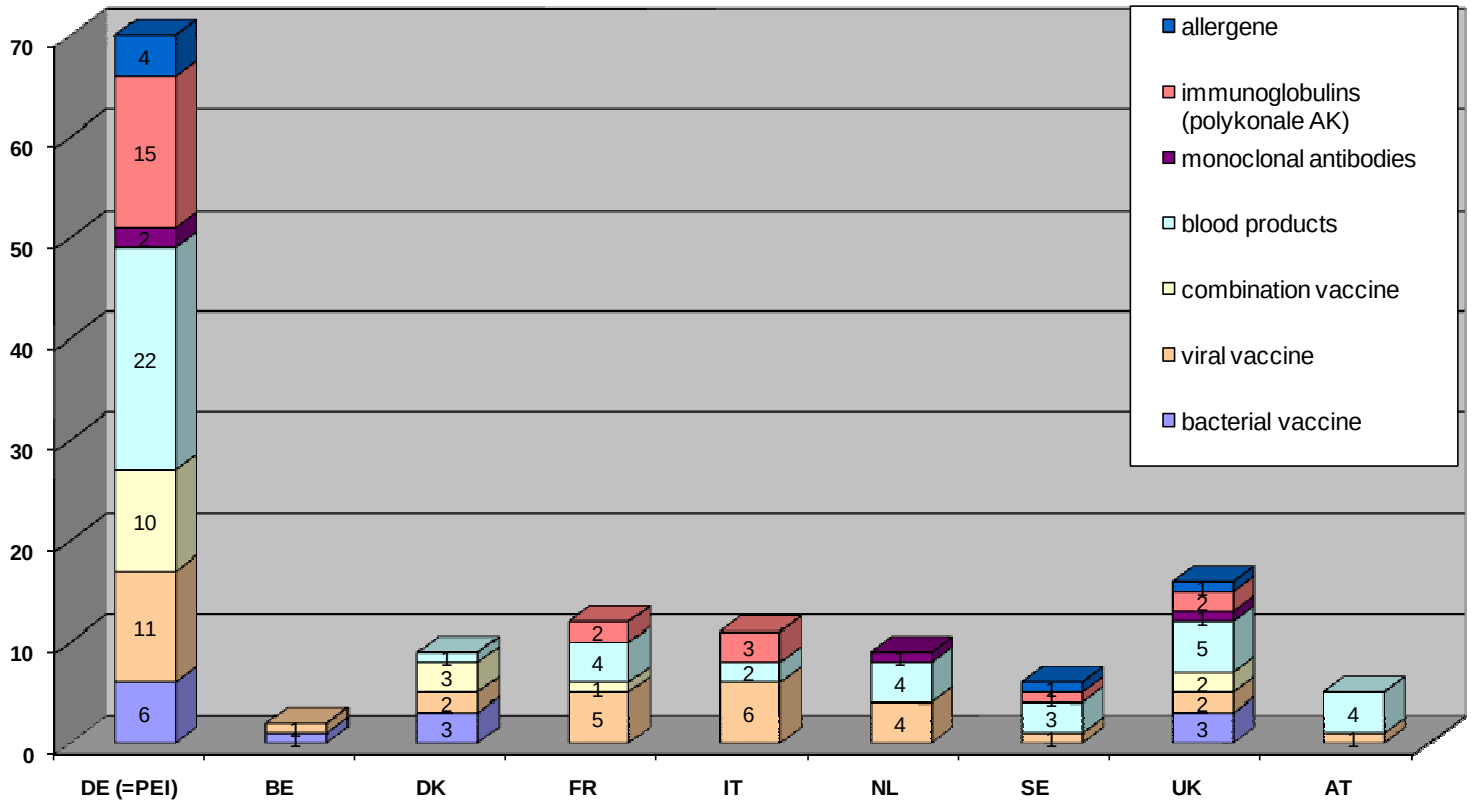
CHMP (co-)rapporteurships, PEI-regulated products [hum.]
1995 - 2009



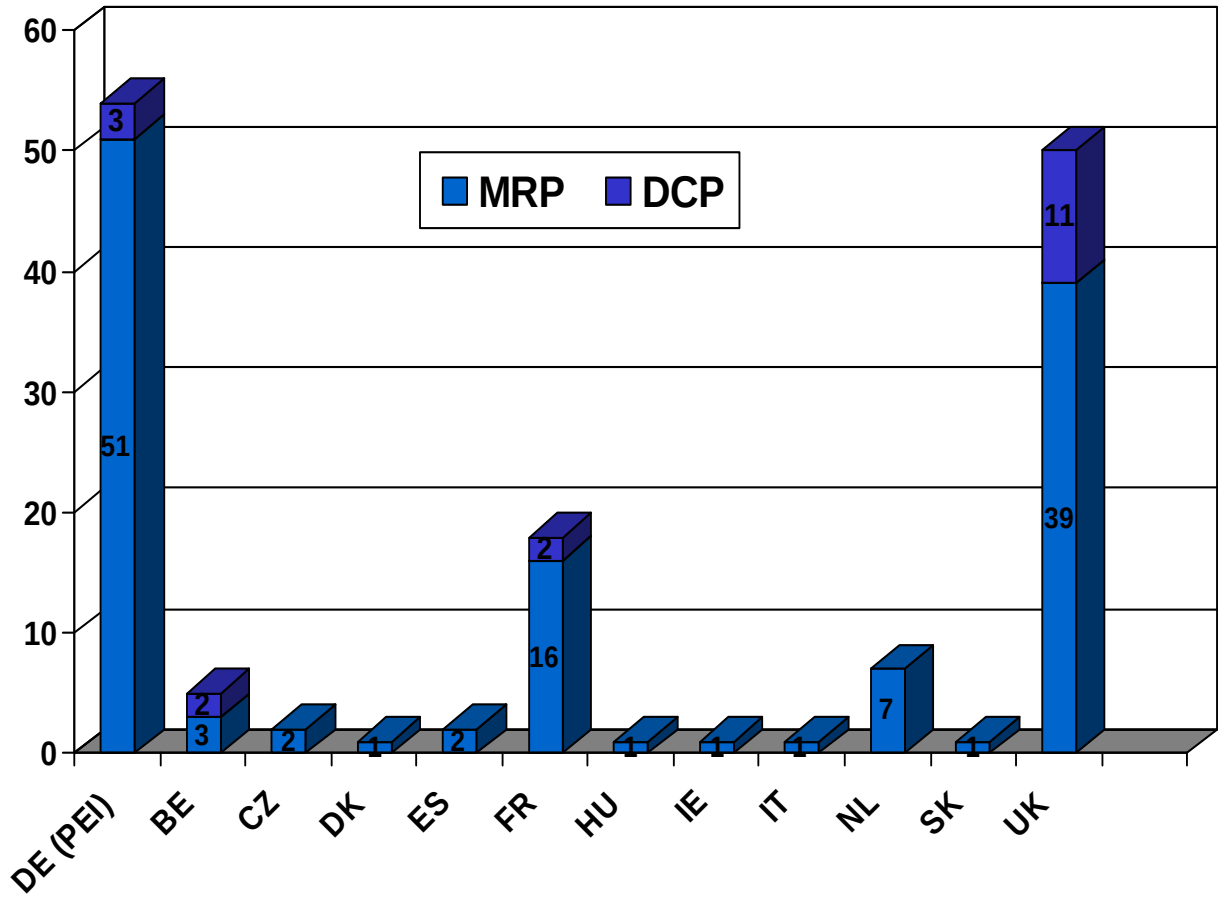
CVMP (co-) rapporteurships, PEI-regulated products [vet.]
1995 - 2009



RMS in MRP/DCP-procedures, PEI-regulated products [hum.] 1995 - 2009



RMS in MRP/DCP, PEI-regulated products [vet.] 1995 - 2009

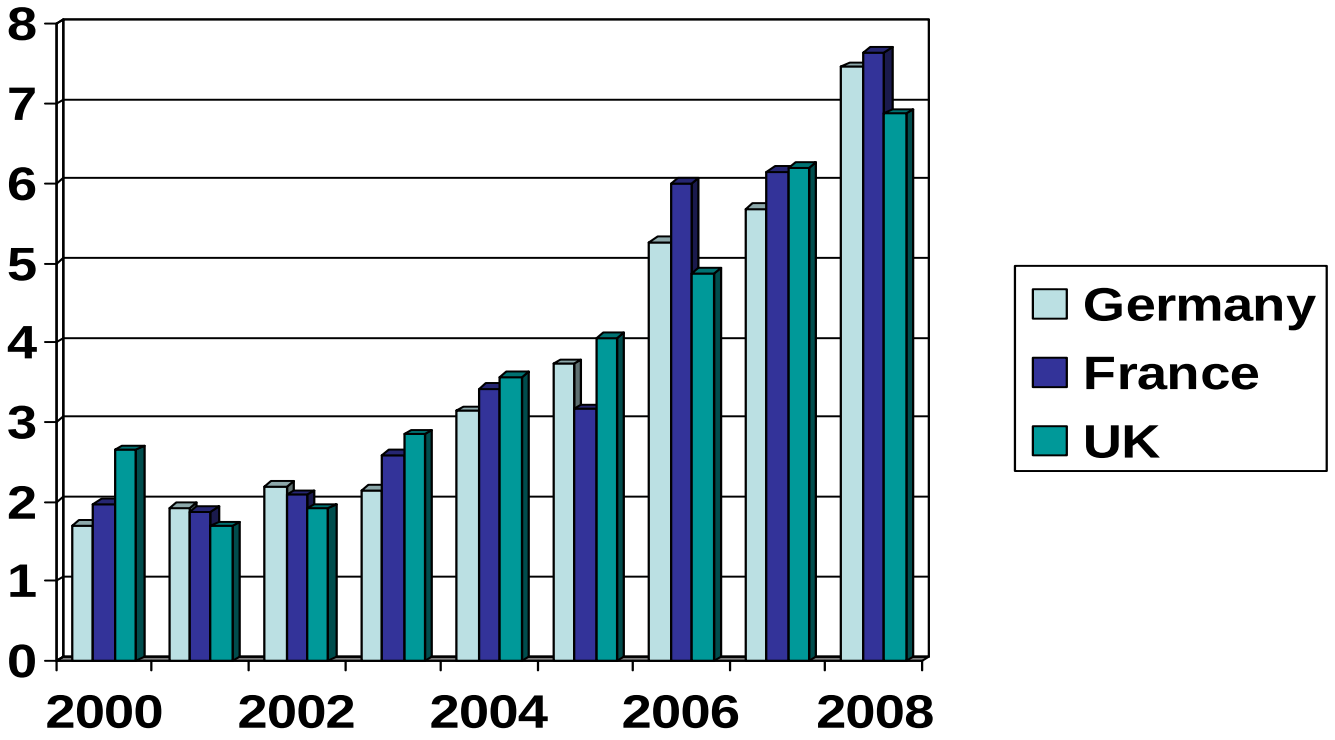


Participation of NCAs in EMA activities, 2009

Number of meeting days

				total
EMA				16.653
Belgium	FAMHP: 684			684
France	AFFSAPS: 705	AFFSA: 179		884
Germany	BfArM: 511	PEI: 526	BVL: 151	1188
Sweden	MPA: 740			740
UK	MHRA: 724	VMD: 124		848

Commitments to NCAs (total, M €)



PEI: Goals

- keep research focussed to task-related topics
- keep position in regulation
  - speed up licensing procedures
  - increase efforts to improve IT systems
  - request external evaluation
- provide to development of advanced therapies

BfArM: Goals

- further improve position in regulation
  - speed up licensing procedures
  - improve quality of assessment reports
  - increase efforts to improve IT systems

- strive towards improving tools and procedures of pharmacovigilance

- improve position in research
  - focus on neurodegenerative diseases
  - expand cooperation with academic environment
  - increase number of research-active senior staff

- generally: apply any available option to attract highly qualified staff