

Heading for New Approaches Future of the BfArM in the EU MA System

Johannes Löwer and co-workers

Bonn, 17 June 2008

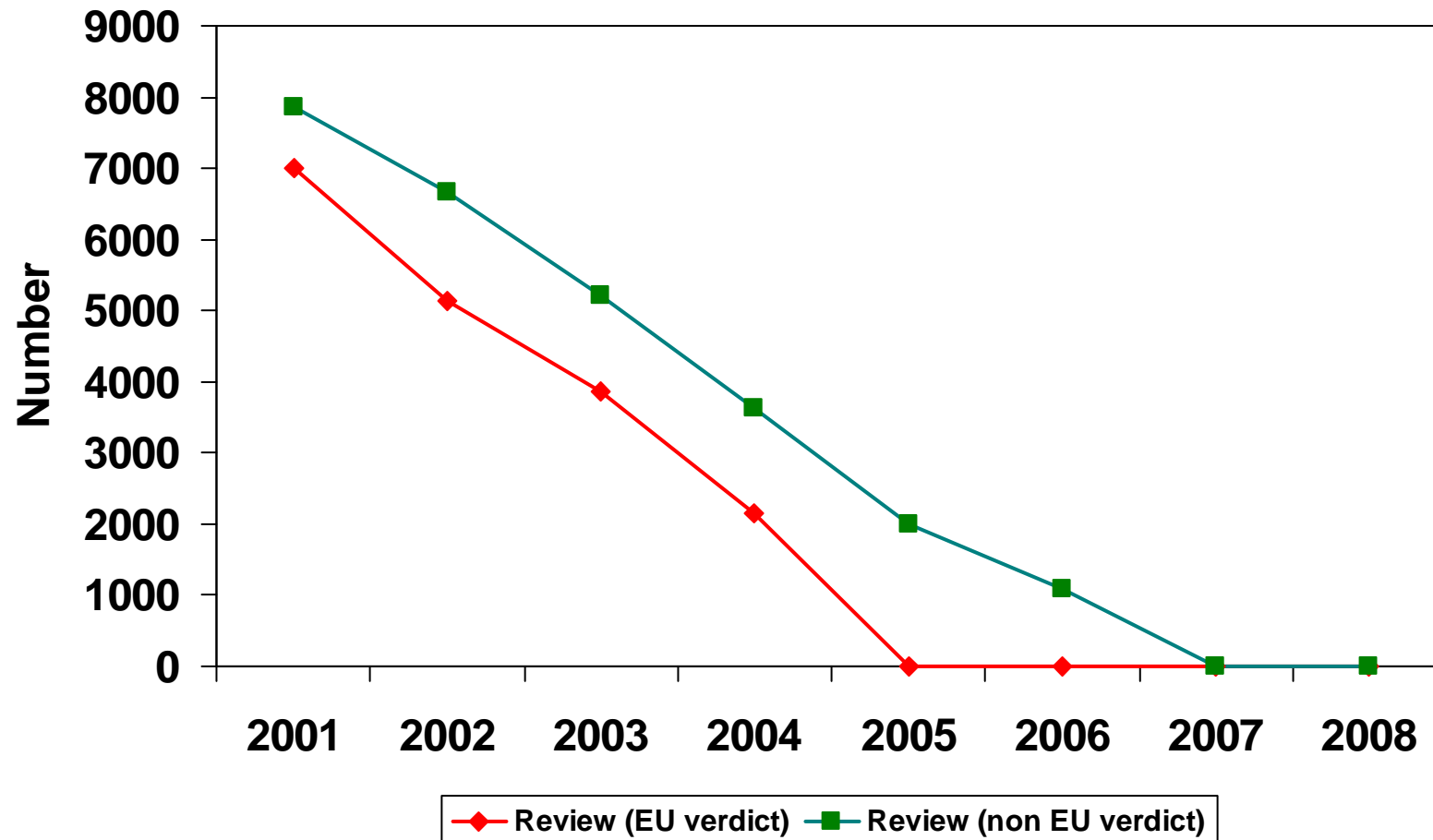


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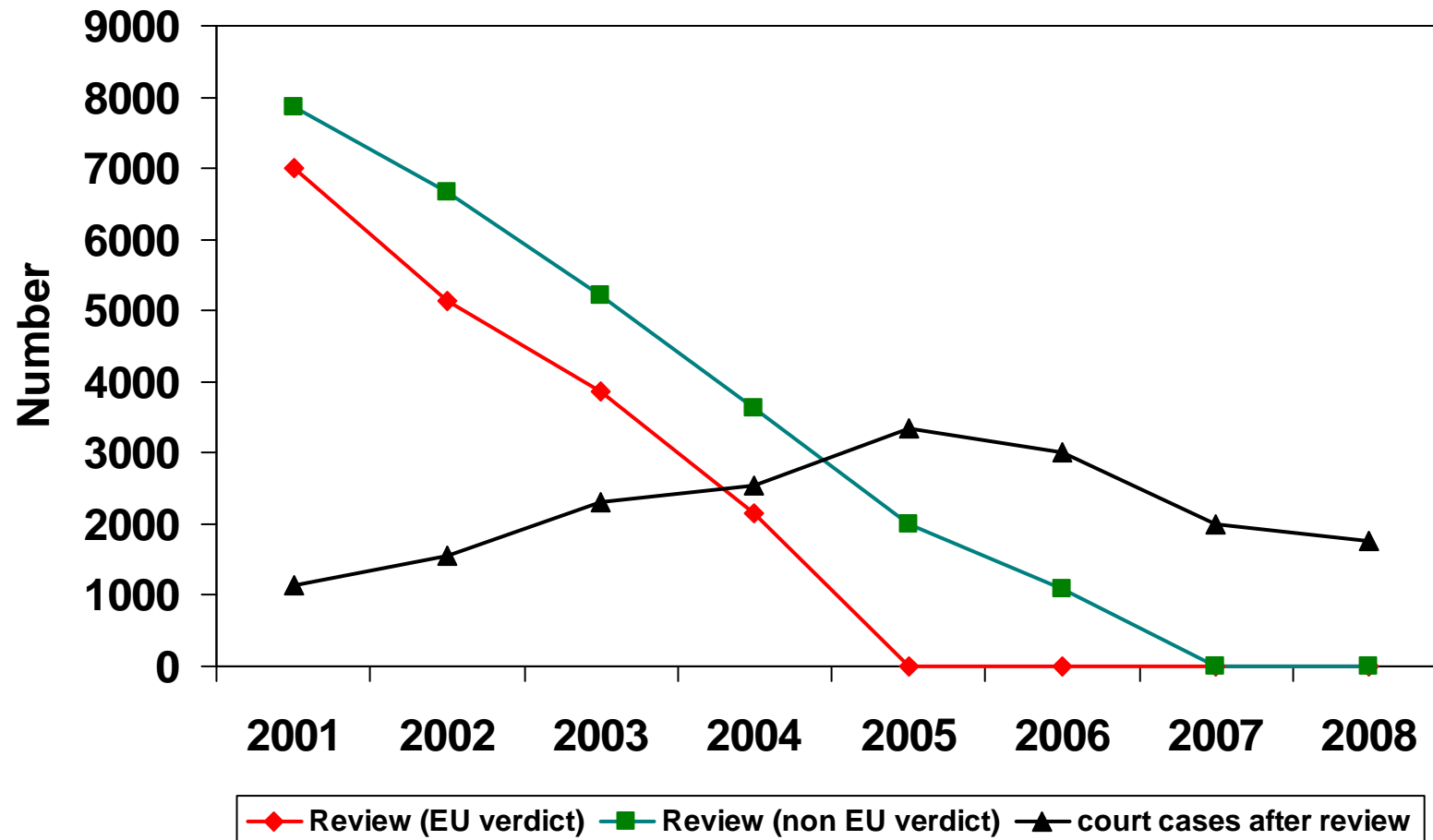
Changes around year 2005

- End of review of pre-1978 medicines
- Introduction of de-centralized procedure
- New organization of BfArM

Review of pre-1978 Medicinal Products



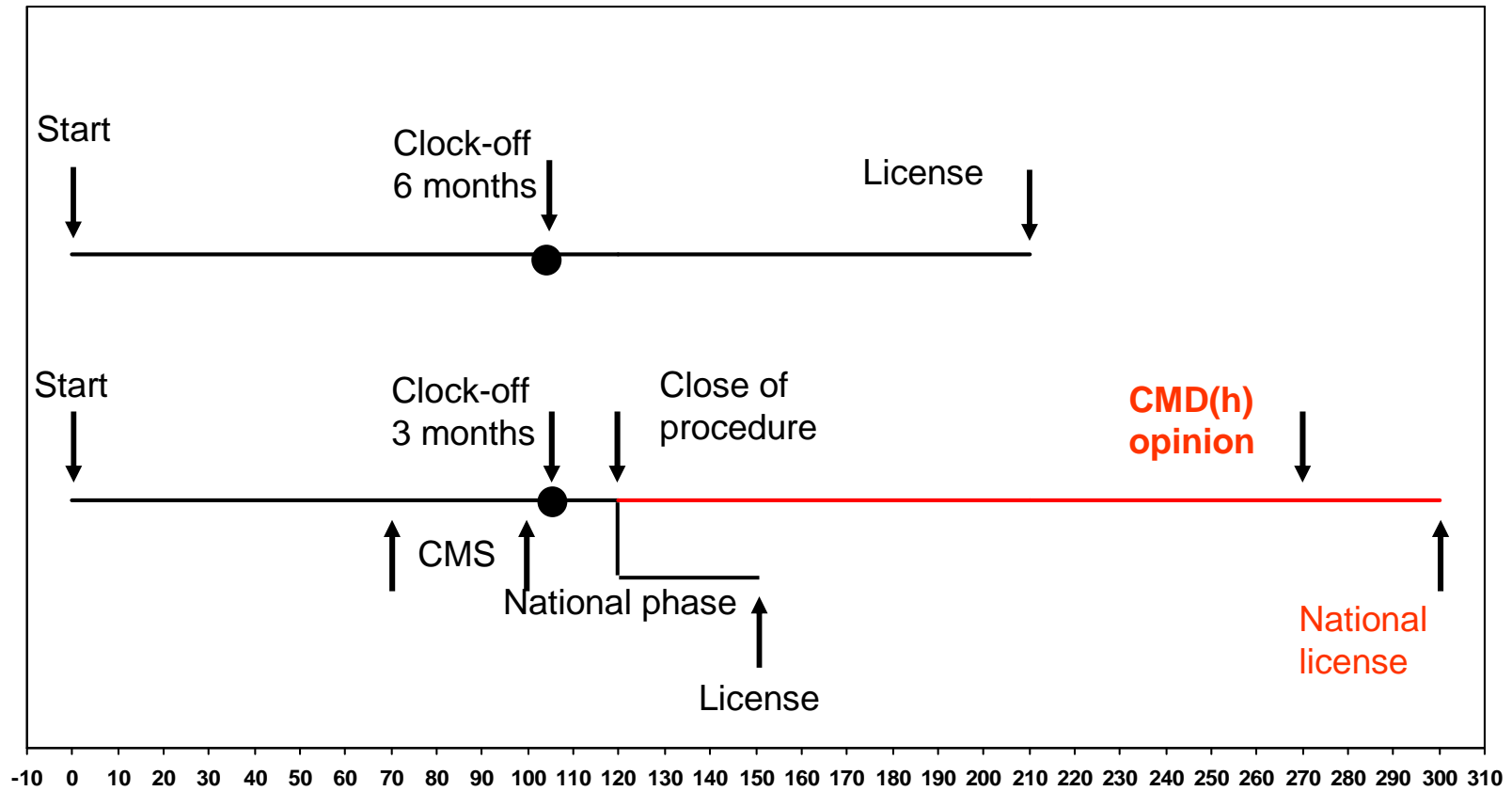
Review of pre-1978 Medicinal Products



Changes around year 2005

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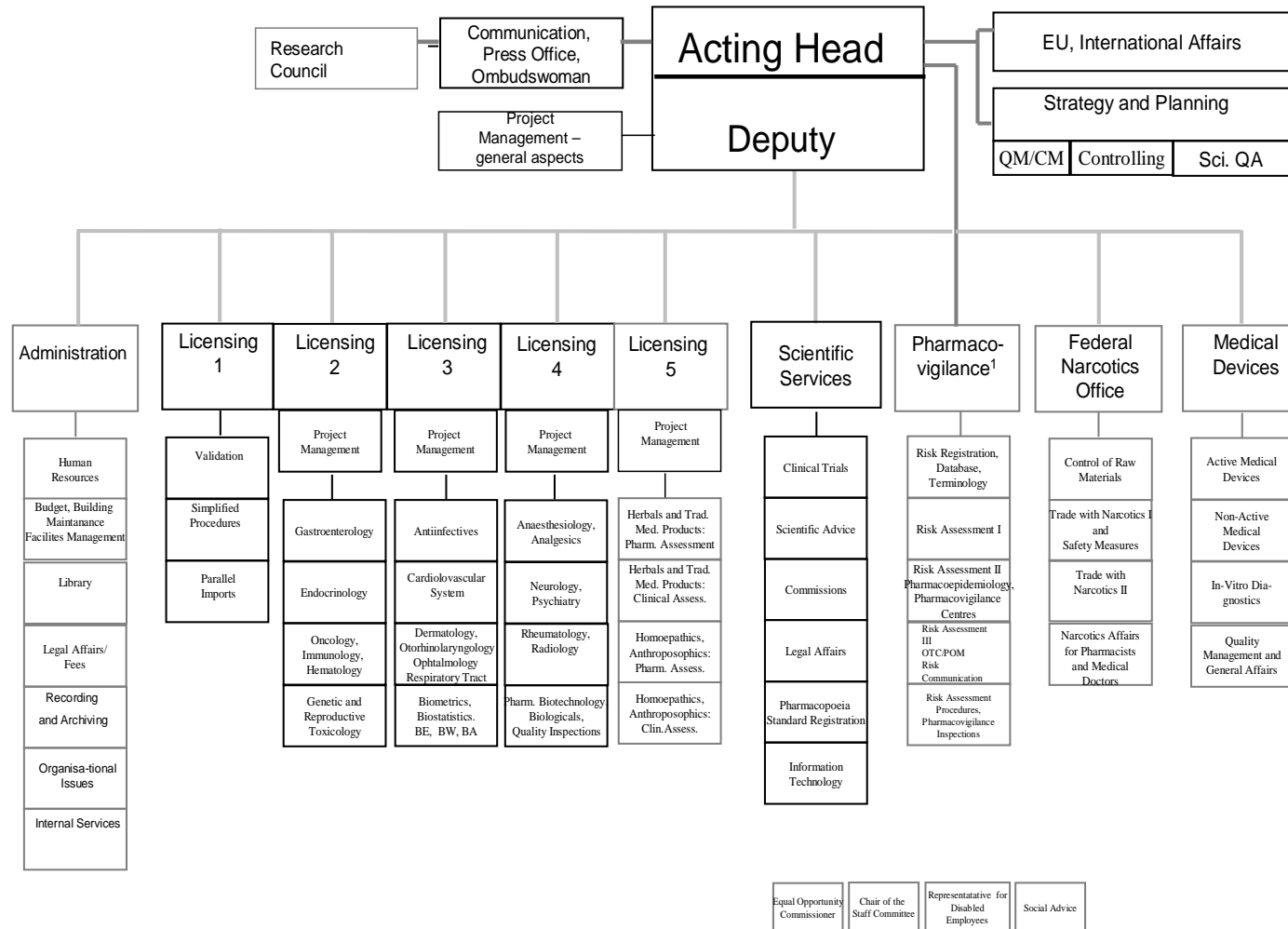
Comparison MRP and DCP



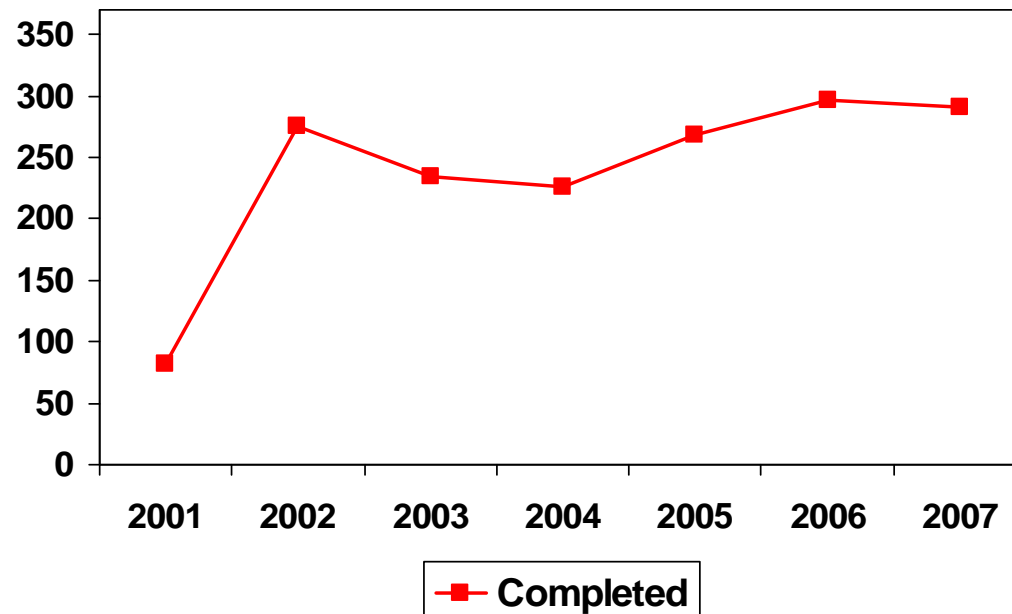
Changes around year 2005

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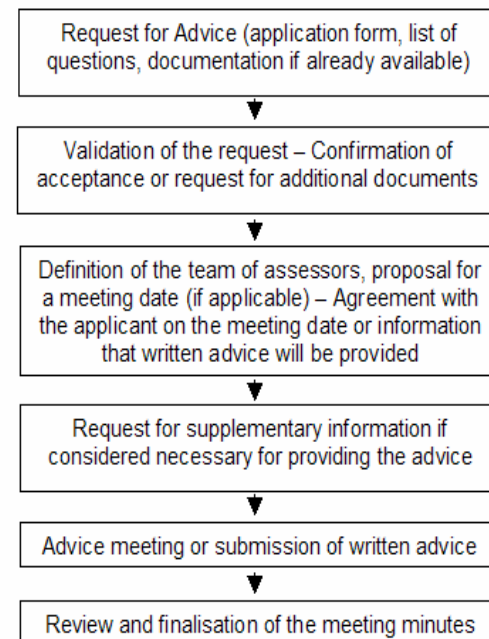
National Scientific Advice procedures



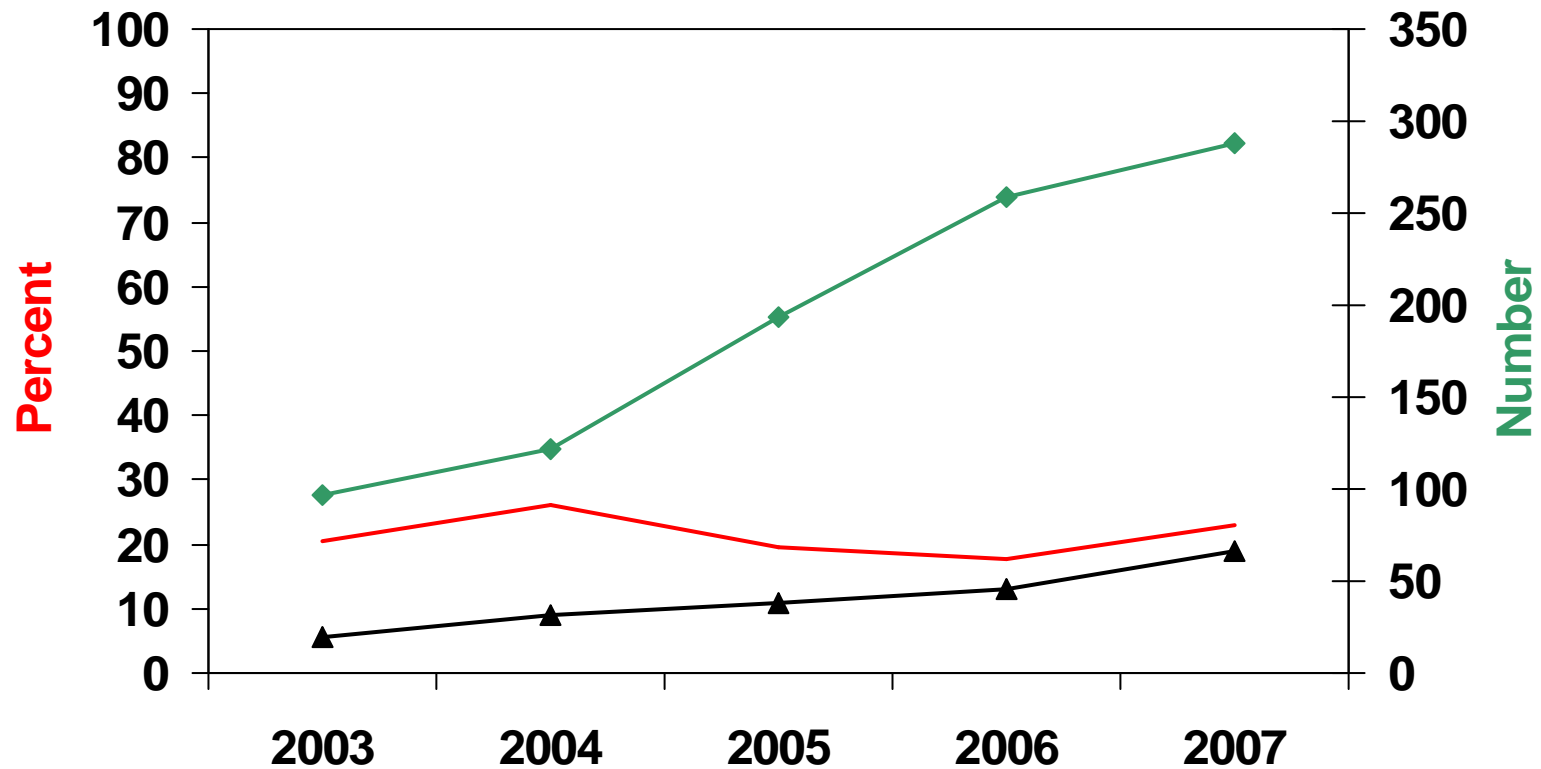
The general process:

Start of the procedure

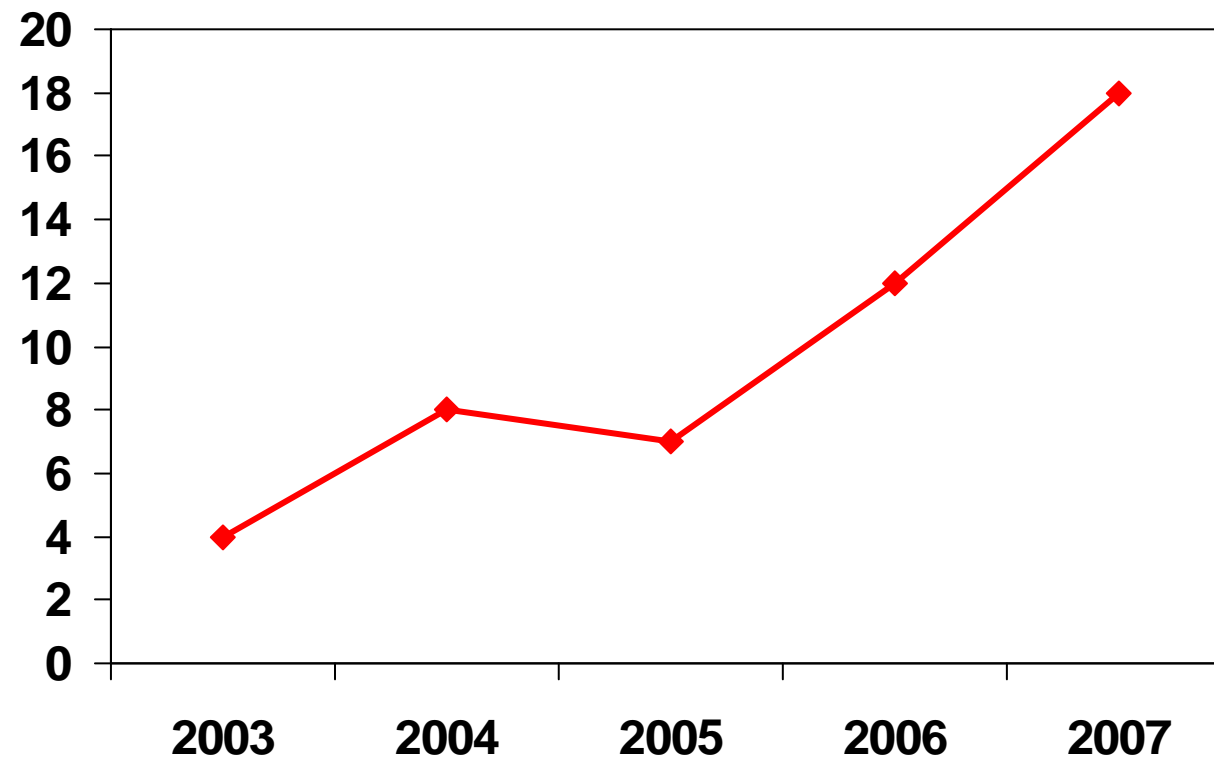
approx.
6 weeks



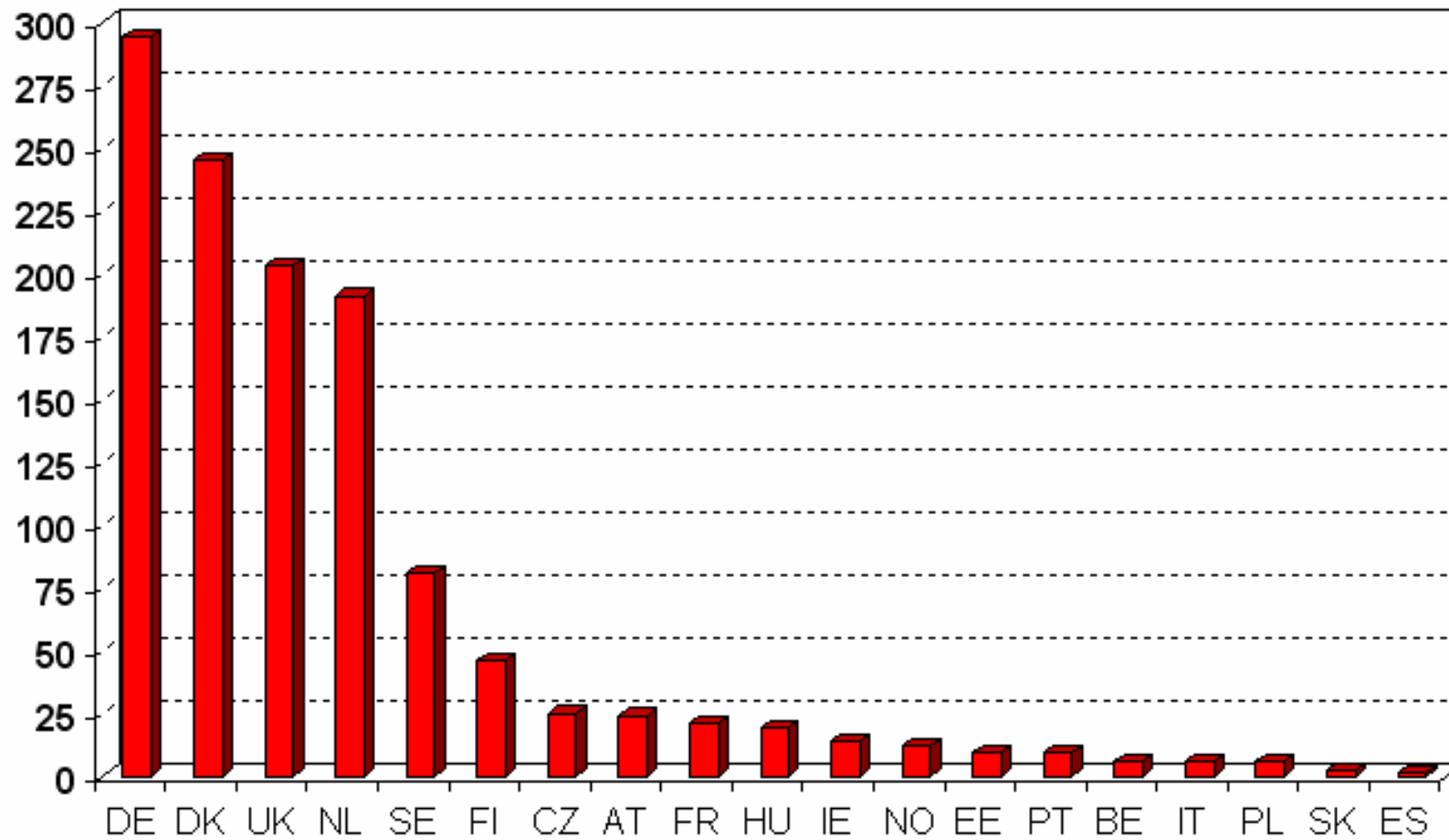
Scientific Advice Co-ordination by BfArM



CHMP (Co-) rapporteurships

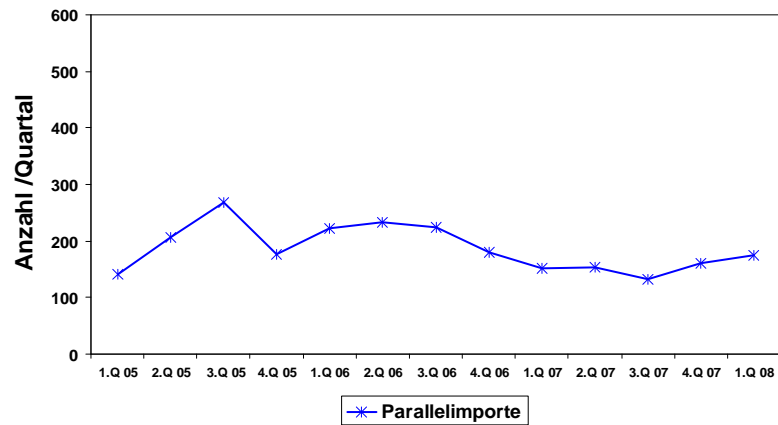


RMS for MA-Applications (MRP/DCP) in 2007

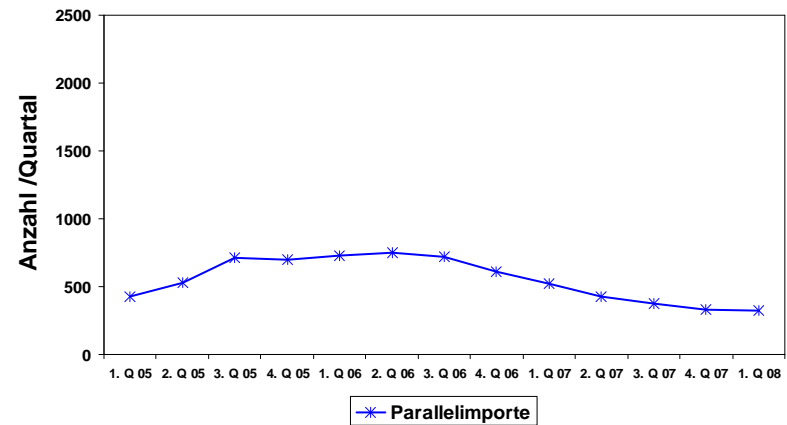


Parallel imports

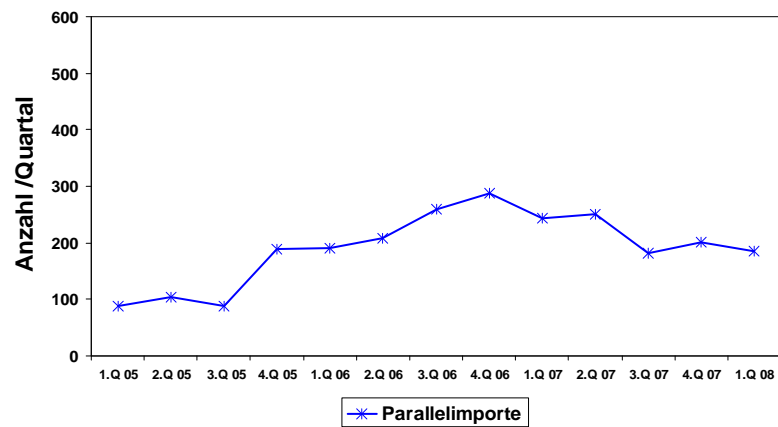
New applications



Open Procedures

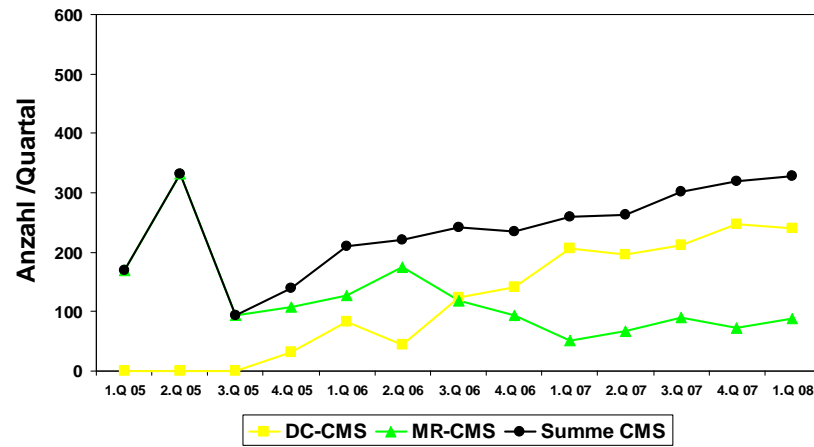


Finalized procedures

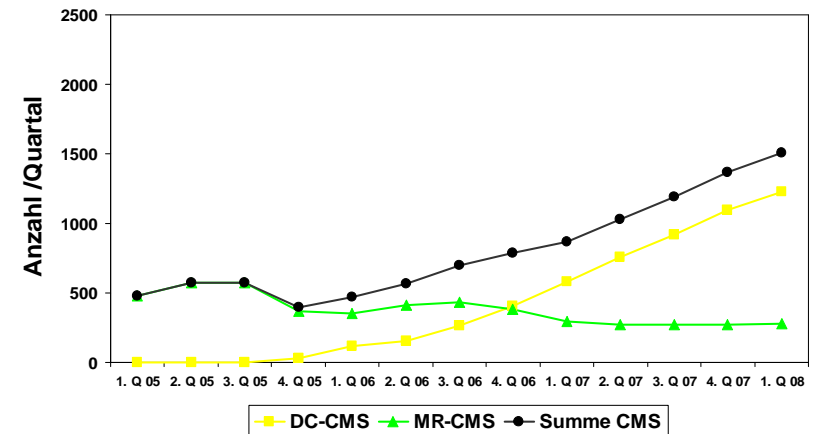


CMS Procedures

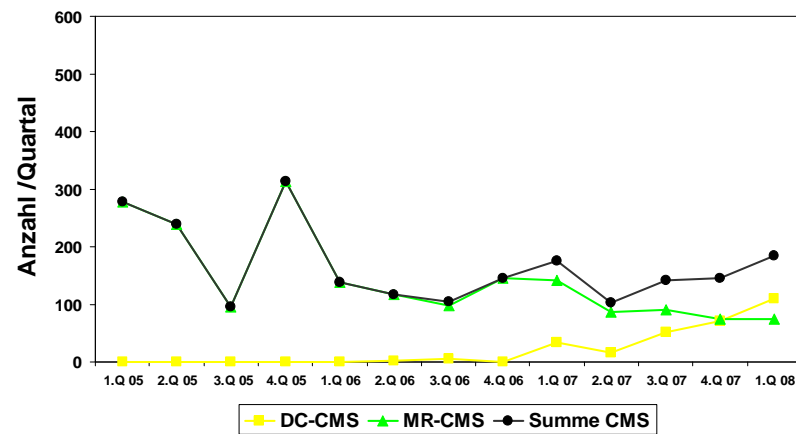
New applications




Open Procedures



Finalized procedures



SOP: Allocation of Resources to Core Tasks in Centralized and Decentralized Procedures

 BfArM	VAW-Nr. P-044	Seite 1 von 5
Festlegungen zur Konzentration der Ressourcen der Zulassungsbereiche auf die Kernaufgaben bei zentralen und dezentralen Europäischen Verfahren (Ausgestaltung der Verfahrensinhalte bei DE=OMS und DE=CMS)		Version: 01 Gültig ab:

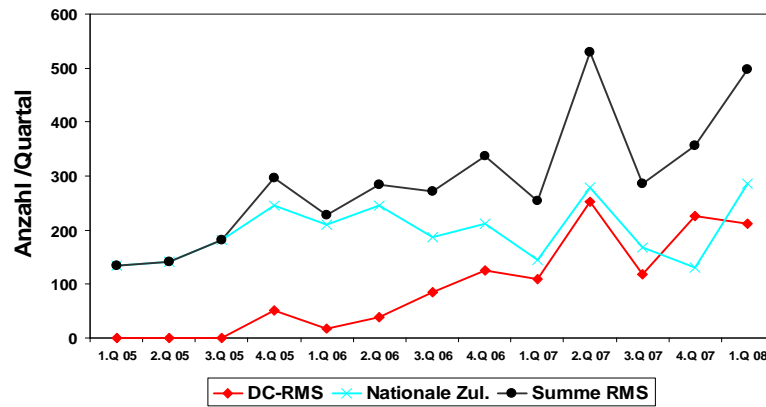
Geltungsbereich	ZAK (Zulassungsabteilungen 1 bis 5)
Zweck	Bearbeitung von zentralen und dezentralen Verfahren als „Other Member State“ (OMS) oder „Concerned Member State“ (CMS)
Zuständigkeiten	ZAK (Abteilungsleitungen 1 bis 5)
Mitgeltende Unterlagen	GVP, VAW-Nr. ZAK-005 (Festlegung der Prioritäten der Bearbeitung in den Zulassungsabteilungen)
Anlagen	
Begriffe, Abkürzungen, Erklärungen	Siehe elektronisches QM-Glossar des BfArM
Verteiler	P, P2, ZAK (1-5)
Kurzbeschreibung	
- Nur intern zu verwenden -	

Exceptions from Evaluation via AR

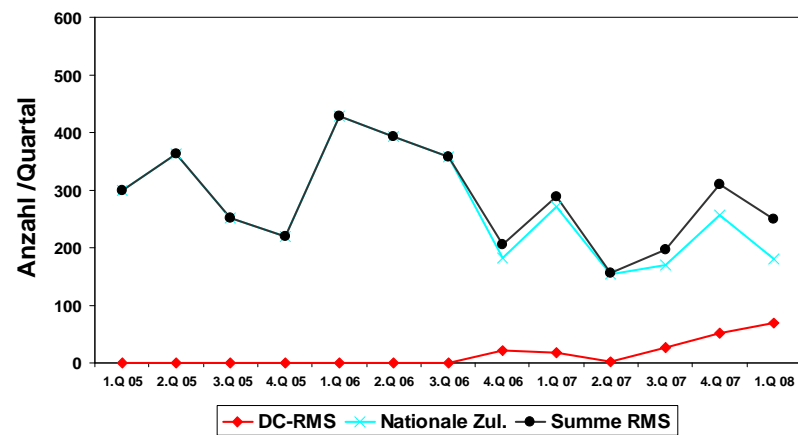
- Implausibility in the RMS-AR
- Conflicting recommendations for MA between RMS and BfArM
- Particular importance for public health
- Contribution to the scientific focus of the unit

RMS Procedures

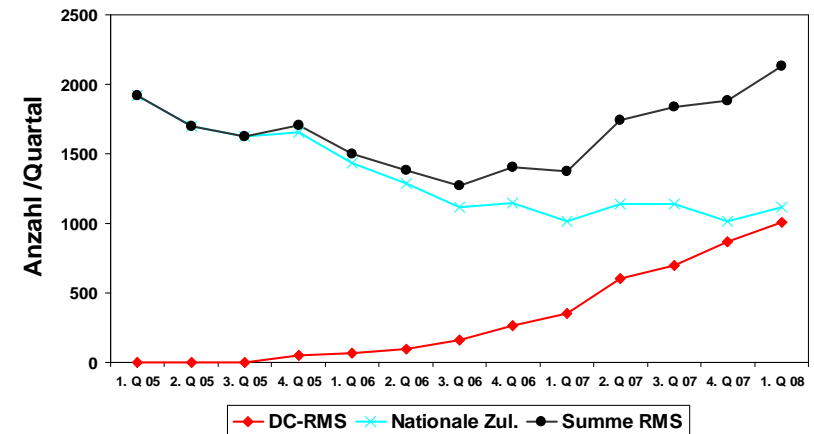
New applications



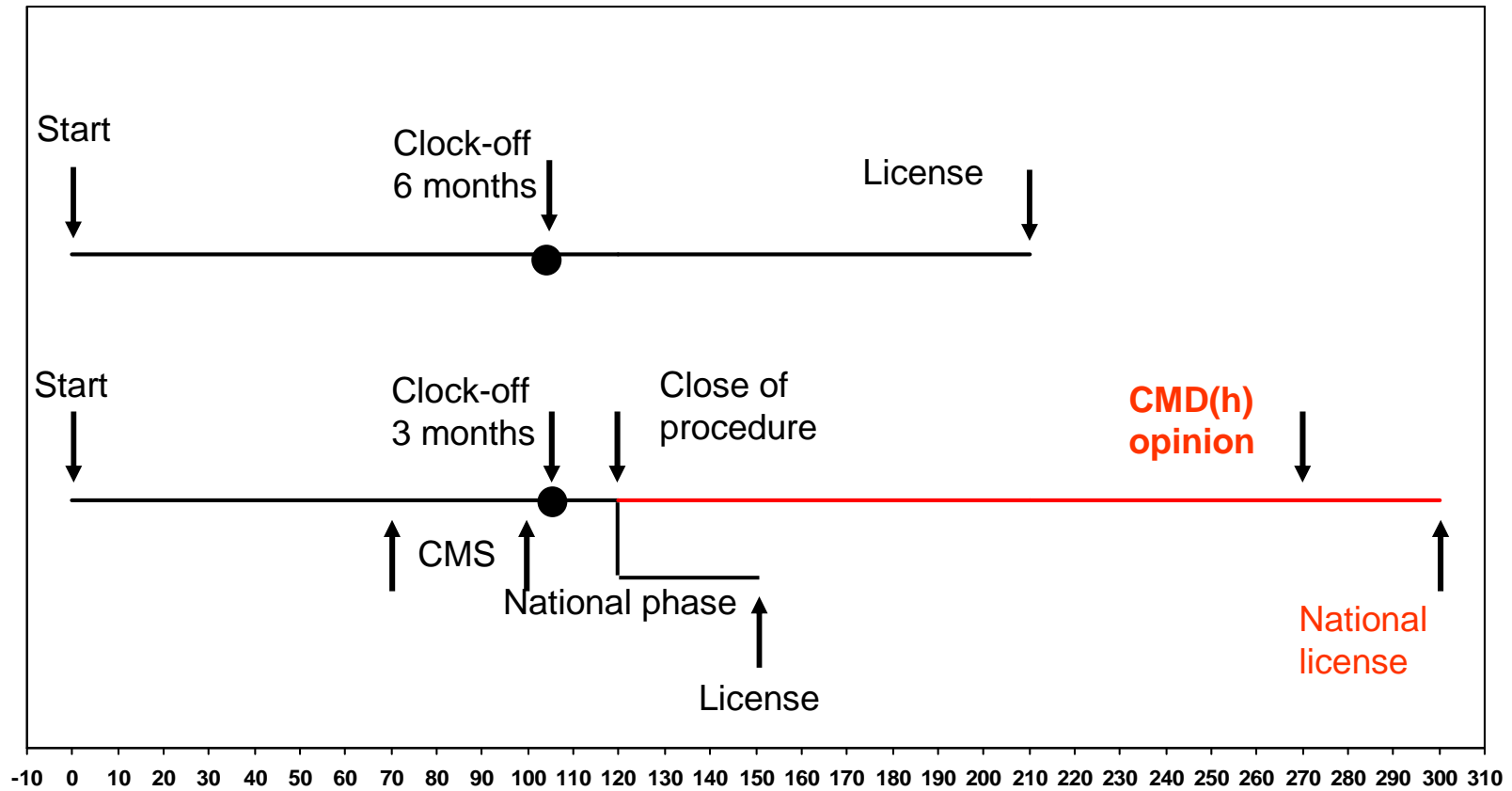
Finalized procedures



Open Procedures



Comparison MRP and DCP



“Flying” Teams

At the end of the data protection period:

- Open slot for generic applications for a given active substance
- Evaluate all applications in parallel by a “flying” team
- After evaluation, re-focus the team on the next active substance

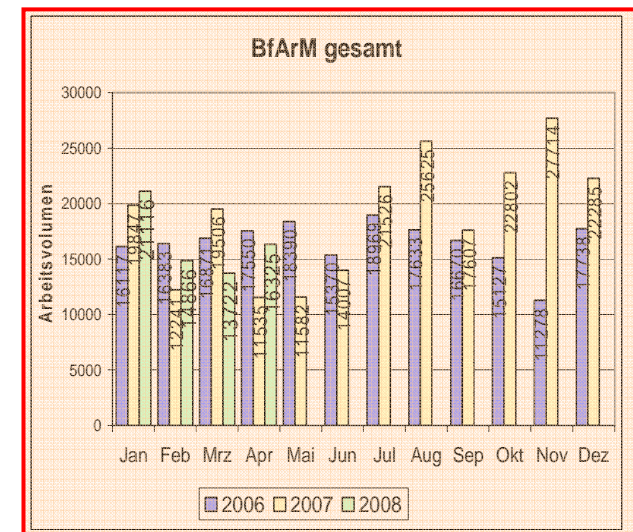
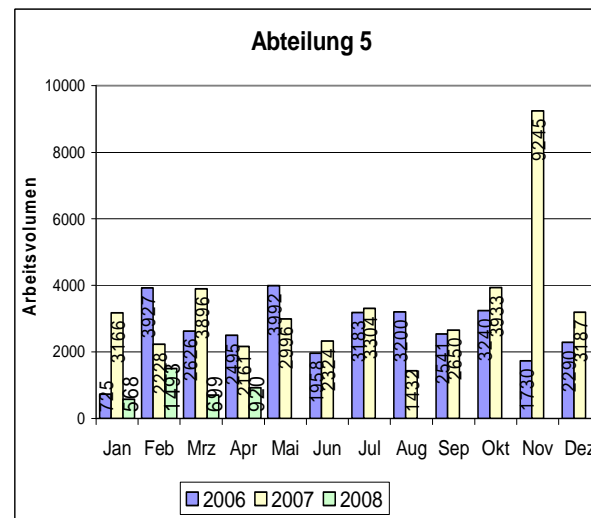
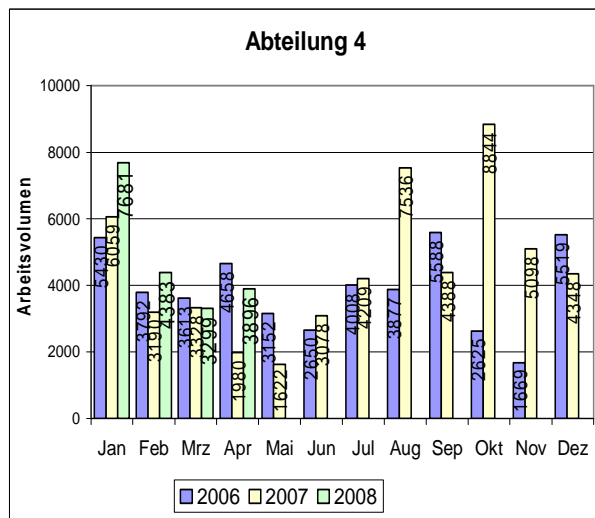
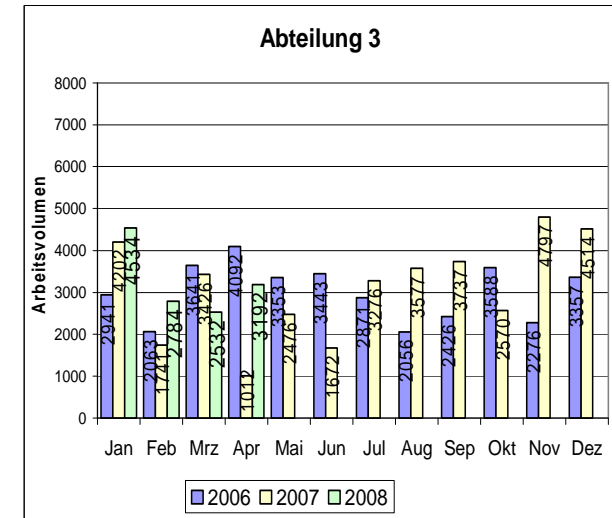
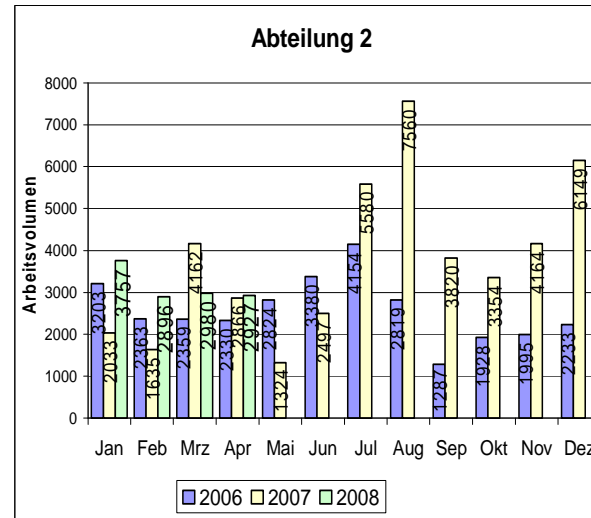
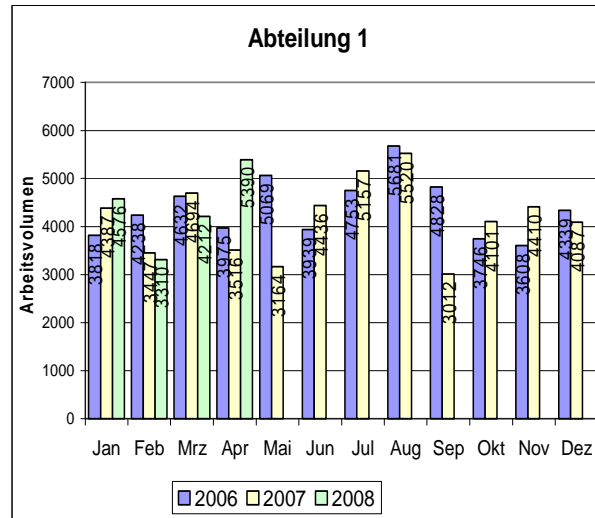
Time Needed for Different Procedures Measured by an Accounting System

(Angaben in Stunden)

	neue St. Einzel ohne Bezug	neue St. Einzel mit Bezug	neue St. Serien/ Flöten	bek. St. Einzel ohne Bezug	bek. St. Einzel mit Bezug	bek. St. Serien/ Flöten	Generika	Dubletten		
Nationale Zulassung	415,4	219,6	26,7	156,1	119,1	20,9	11,8	10,5		
MRP-RMS Zulassung	326,2	245,8	61,7	182,5	143,5	46,3				
MRP-CMS Zulassung	18,0	14,3	5,5	12,0	8,8	5,4				
DCP-RMS Zulassung	735,8	458,8	87,8	334,8	258,8	66,8				
DCP-CMS Zulassung	34,1	23,0	8,5	24,2	21,6	7,8				
	DE=Rapp. neue St.	DE=CoRapp .neue St.	OMS-neue St.	DE=Rapp.- bek. St.	DE=CoRapp -Bek. St.	OMS-bek. St.				
Zentrale EU-Verfahren	919,8	735,8	69,0	418,8	334,8	31,5				
	mit Muster ohne Serie	mit Muster mit Serie	mit Textvor- lagen ohne Serie	mit Textvor- lagen mit Serie	ohne Muster ohne Serie	ohne Muster mit Serie				
Verlängerungen	7,7	6,8	7,7	6,8	17,5	8,8				
	RMS	CMS	Zentrale EU- Verfahren							
Renewals	24,2	11,8	25,7							
	nicht zustpfl.	Sunset- Clause	zustpfl. (FG12 nur Pack.gr.)	zustpfl. (außer Packung+In d.erw.)	zustpfl. Ind.erweiter ung					
Änderungen	1,2	0,3	1,4	7,6	19,7					
	IA - DE=RMS	IA - DE=RMS Serie	IA - DE=CMS	IA - DE=CMS Serie	IB - DE=CMS	IB - DE=CMS Serie	IB - DE=RMS Bezeichn.+P ack.	IB - DE=RMS Bezeichn.+P ack. - Serie	IB - DE=RMS (außer Bezänd+Pac k.)	IB - DE=RMS (außer Bezänd+Pac k.) - Serie
Variations Typ I und II	1,8	1,5	0,9	0,3	1,1	0,3	1,8	1,5	7,1	4,5
	Typ II - DE=RMS	Typ II - DE=RMS - komplex	Typ II - DE=CMS	Typ II - DE=CMS - komplex	Typ II - DE=RMS - Serie	Typ II - DE=RMS - komplex - Serie	Typ II - DE=CMS - Serie	Typ II - DE=CMS - komplex - Serie	Zentrale EU- Variations	Variations, PI / zentrale EU
Variations Typ II	28,3	47,7	7,6	15,3	6,2	8,2	2,1	3,7	40	1,7

**Diese normativen Zeit-
aufwände wurden im
KLR-Projekt in 2006
repräsentativ ermittelt und
werden fortgeschrieben**

Workload of Finalized Procedures per Division (January 2006 – April 2008)



Workload

To cope with the increasing workload:

- Make processes more efficient (e.g. “flying” teams)
- Introduce electronic workflow system
- Hire more personnel

BfArM: Possible Goals

- Improve position in regulation
 - Improve processes with focus on the decentralized procedure
 - Focus on neurodegenerative diseases
- Improve position in research
 - Focus on neurodegenerative diseases
 - Cooperate with academic environment

Cooperation with Academics

- Pharma Zentrum Bonn
- Helmholtz Centre for Neurodegenerative Diseases
- NRW International Graduate School BIOTECH-PHARMA
- c a e s a r

- Cooperation agreement Bonn University
- Bilateral research projects with universities
- Participation in 7th EU framework program

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 - Cooperate with academic environment
- Think European

Good luck, BfArM!