

LÆGEMIDDEL
STYRELSEN

DANISH MEDICINES AGENCY



Role of the National Competent Authorities in the European Medicines Network

Denmark – The Danish Medicines Agency

Dr. Per Helboe, Senior Director, Licensing Division





Role of the National Competent Authorities in the European Medicines Network

Denmark – The Danish Medicines Agency

- Introduction
- DKMA – A self financing agency since 1997
- The role as a national agency in the European network
- A national agency as an active player in the EU procedures
- How to organise the work on licensing medicinal products
- The challenges of changing workloads in the licensing procedure
- Conclusions





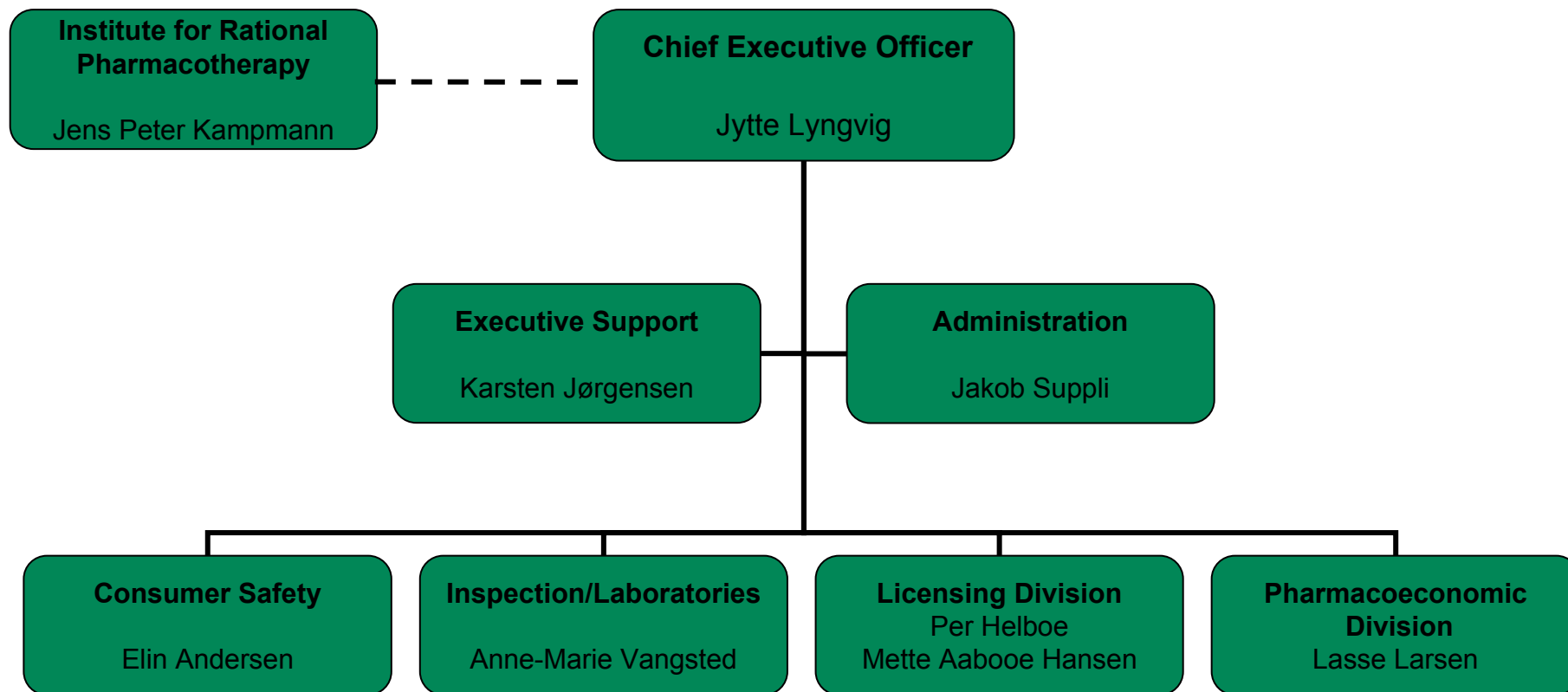
Danish Medicines Agency

- Independent Agency 1997
 - Total staff 200
 - Traditional organisation
- Reorganisation 2001
 - Self supporting divisions
 - All licensing processes in one division
- Status 2006 –organisational adjustments
 - Increased focus on consumer safety
 - Inspection and laboratory control combined in one division
 - Total staff 350





Danish Medicines Agency





The European Medicines Network

Key Players since 1995

- European Medicines Agency – EMEA
 - Coordinating the centralised procedure
 - Coordinating work on general guidelines for requirements to all licensing procedures
- 42 National agencies in Member States (human and veterinary)
 - Responsible for all nationally licensed products
 - Participate in the European procedures – activity of choice





Network of NCA's – Why?

- EMEA – Roadmap
 - Collaboration on centralised procedure, and general matters, in particular pharmacovigilance
- NCA network
 - Collaboration on matters of mutual interest
 - Cooperative partner to the EMEA
 - Activities in relation to pharmacovigilance and information to health care professionals and citizens
 - A huge portfolio of nationally licensed products





Network of NCA's

- Traditionally a loose, informal network
- HoA – Heads of medicines agencies – Human
- HEVRA – Heads of medicines agencies – Veterinary
- Quarterly meetings, lead by the MS holding the EU presidency
- Continuity in the work was not easy
- Firm decisions and dedicated efforts were not the rule





The New and Improved Network - HMA

- Collaboration improved and well structured
- Quarterly meetings lead by the presidency of the day
- The network assisted by
 - HMA-PS - a permanent, virtual secretariat, assisting the Presidency and HMA-MG
 - HMA-MG – a management group, 4 member states + Presidency
- HMA is now a well functioning network
 - Better continuity
 - Strategy paper developed and published. Recommendations under implementation.
 - Improved web site is being planned





The Roles of a National Agency in

- Centralised procedure
 - Decentralised procedure
 - Mutual recognition procedure
 - National procedure
-
- The individual agency has a choice – on level of activity
 - Broad participation is important





DKMA Vision Statements and Values

extract from our vision statements:

- we will influence the European development of medicinal products, medical devices and new therapies

extract from our values

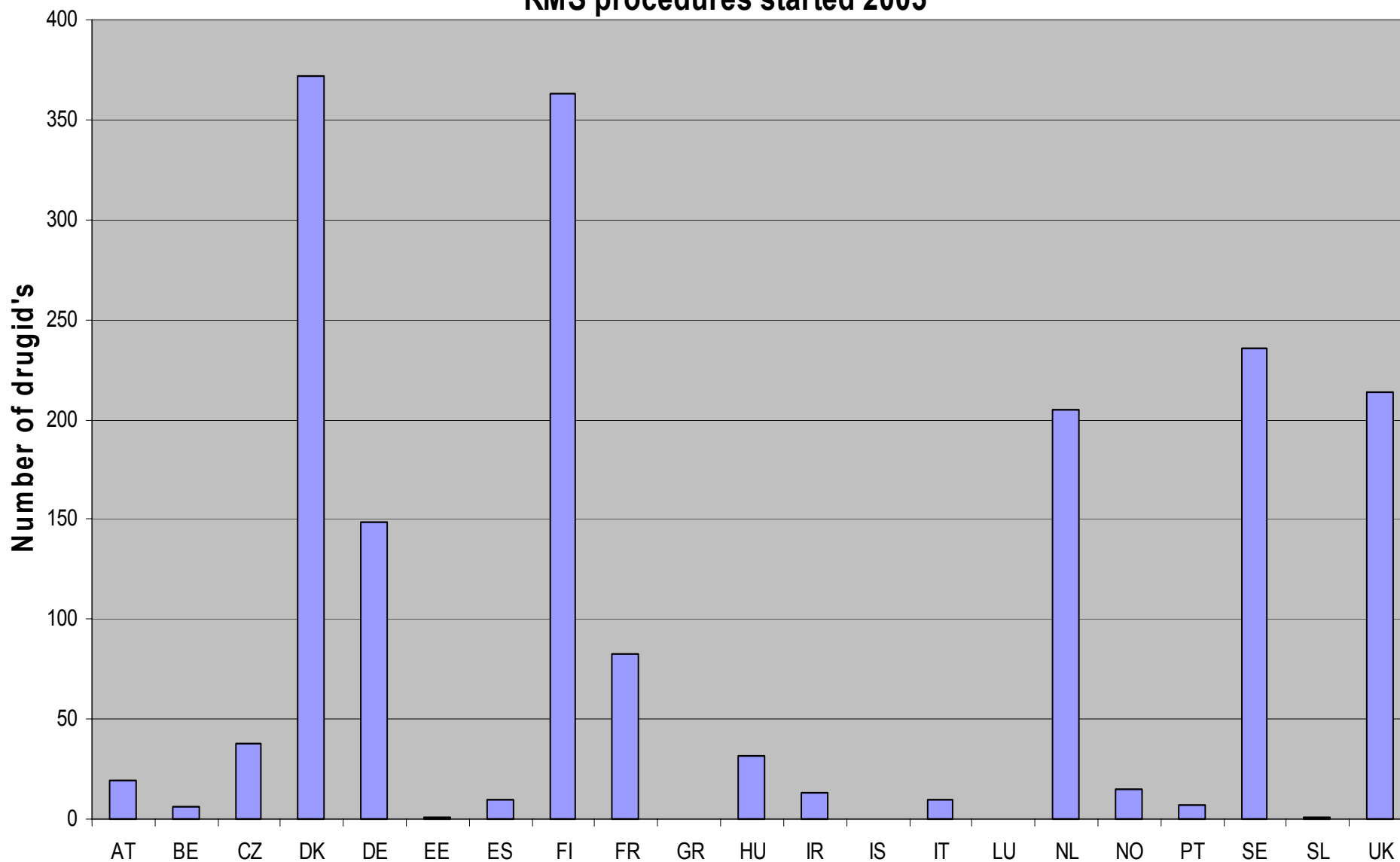
- **We are European**
We participate actively in the European arena by giving the correct priority to individual cases, in formulating general requirements and in setting a common European course for the better regulation of health care products.

- results from the European efforts 2005 ...



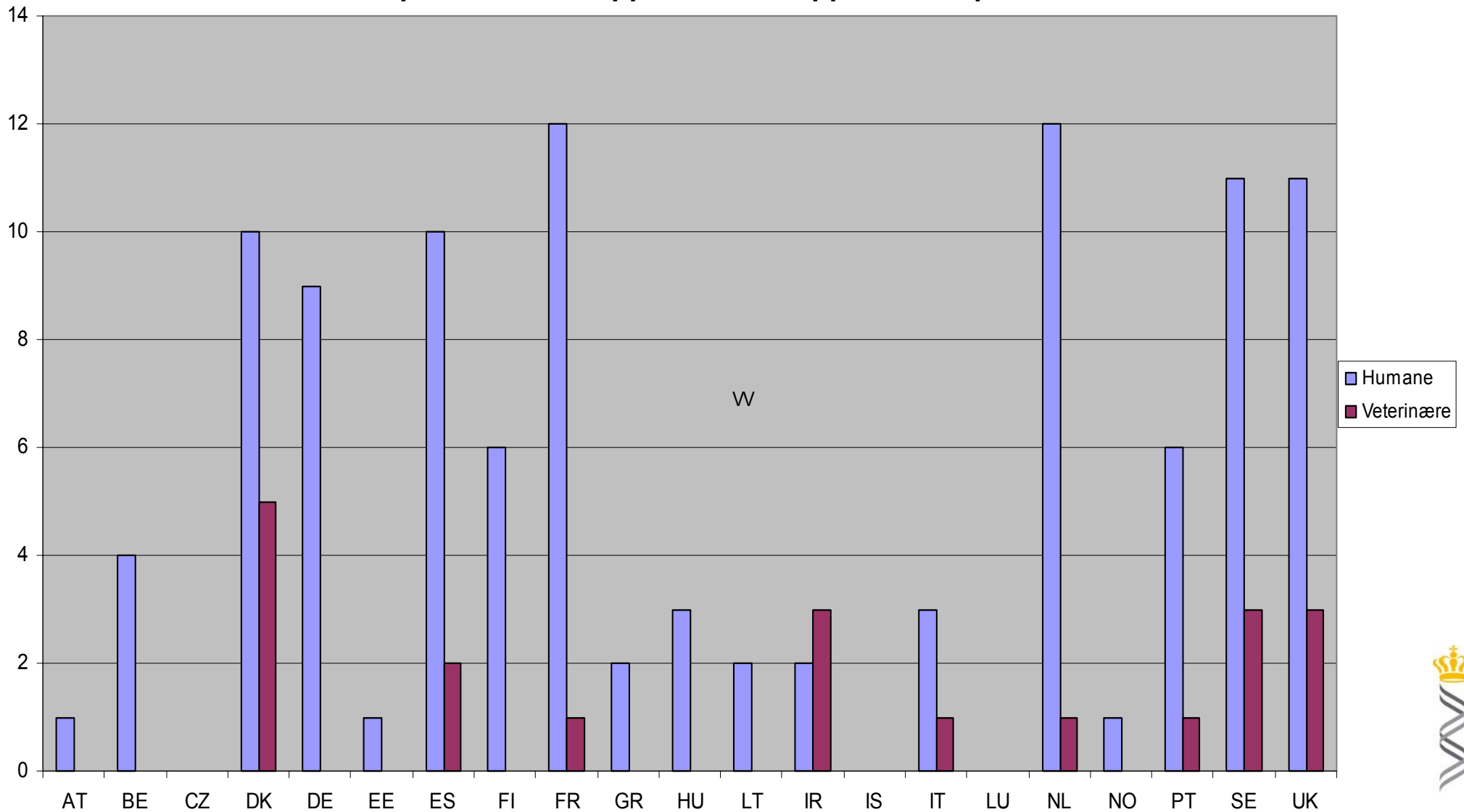


RMS procedures started 2005





Centralised procedures. Rapporteur/co-rapporteurships 2005 total





Applications via the National Procedure

Number of applications handled in 2005: 802

- The challenge of all times
- Centralised, decentralised, and MRP procedures run according to fixed and well controlled dead lines
- If resources are insufficient?
- The handling of national procedures will suffer
- The handling of the challenges of national applications in the Danish Medicines Agency





After 3 years experience with the Licensing Division

- Backlogs are a never-ending story?
- Increased number of applications
- Resource adjustments (new staff) is possible – but cumbersome
- Backlog management project 2003
 - Successfully accomplished
 - All pending cases brought forward
 - New problems arose
 - Increasing number of applications
 - Backlog in recruitment
 - Bottleneck problems





Status Licensing Division 2004

- New backlogs have built up
- Production cannot match number of applications
- Complaints from industry
- Staff feel frustrated and under pressure
- Insufficient overview on the situation – for both management and staff





Reorganising the Licensing Division

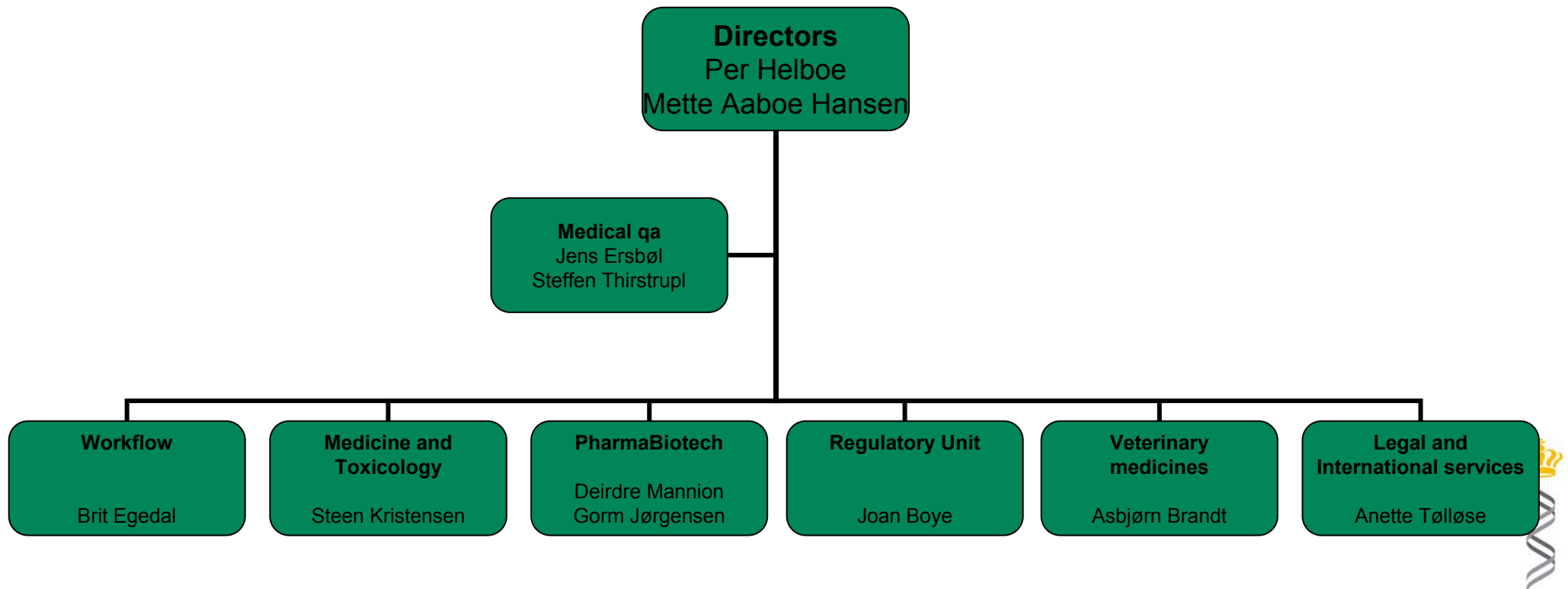
For the following reasons

- A need for more efficient handling of applications
- Improved planning tools
- Strengthening the professional skills
- Better defined lines of authority
- Implementation 1 January 2005





Licensing Division 2006



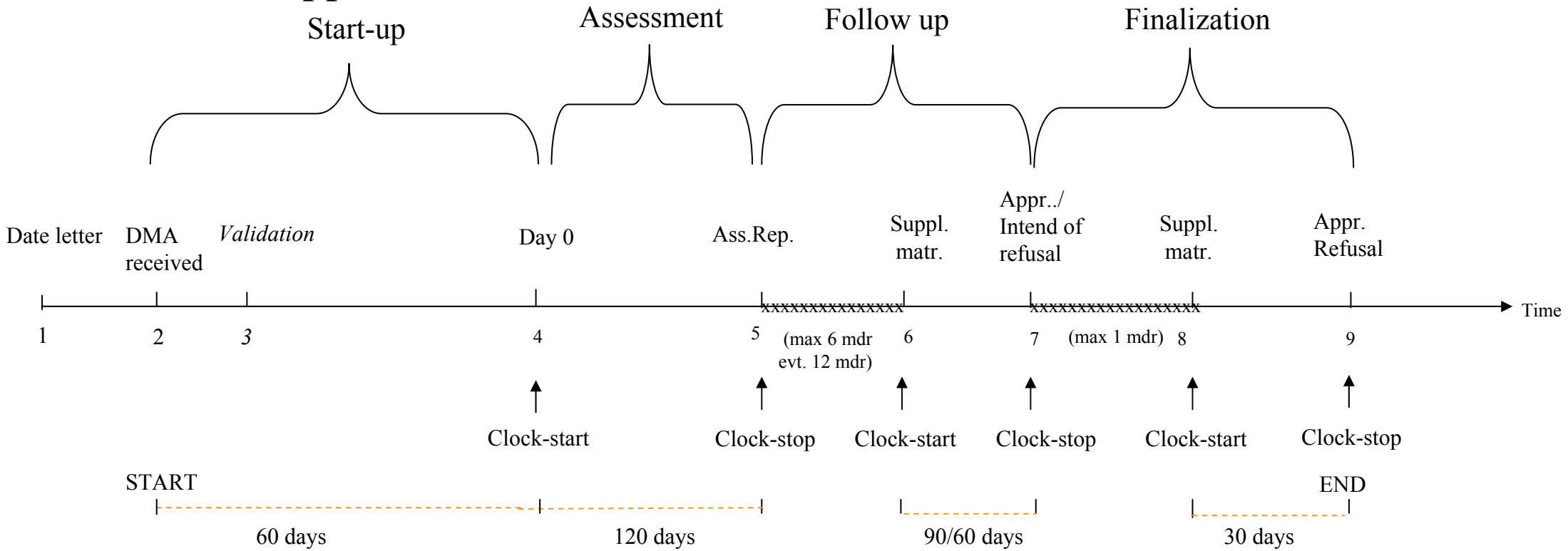


Results from the Efforts

- Meeting in June 2005 with ministry and industry
- Preliminary results and prognosis for handling new national applications and applications for parallel import
- Structure of handling national applications



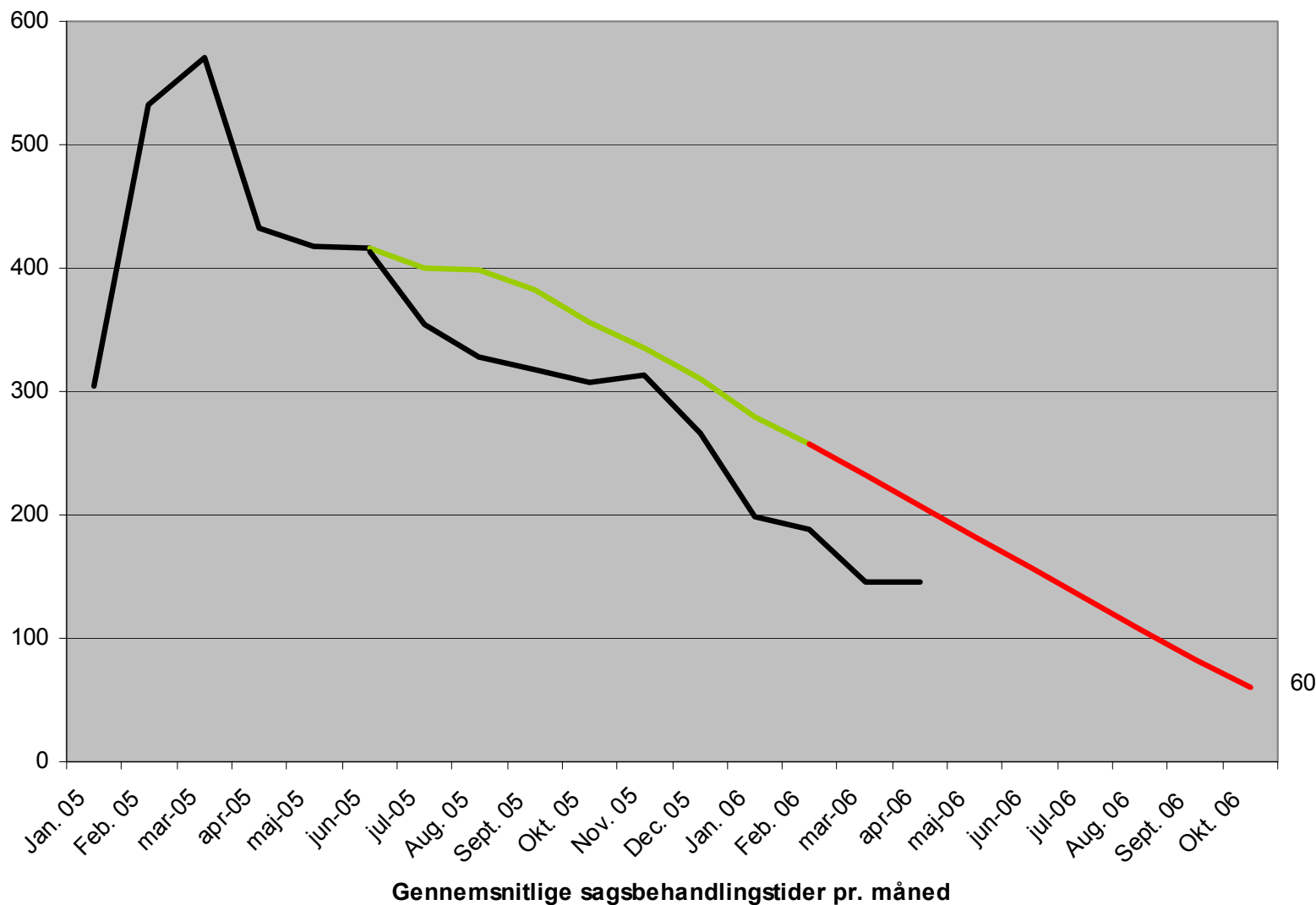
New national applications





Prognosis for delay before start-up - order book (24. June 2005)

Calendar days



Sort = faktiske sagstider

Grøn = Prognose for modtagne sager i ordrebog t.o.m. juni 2005

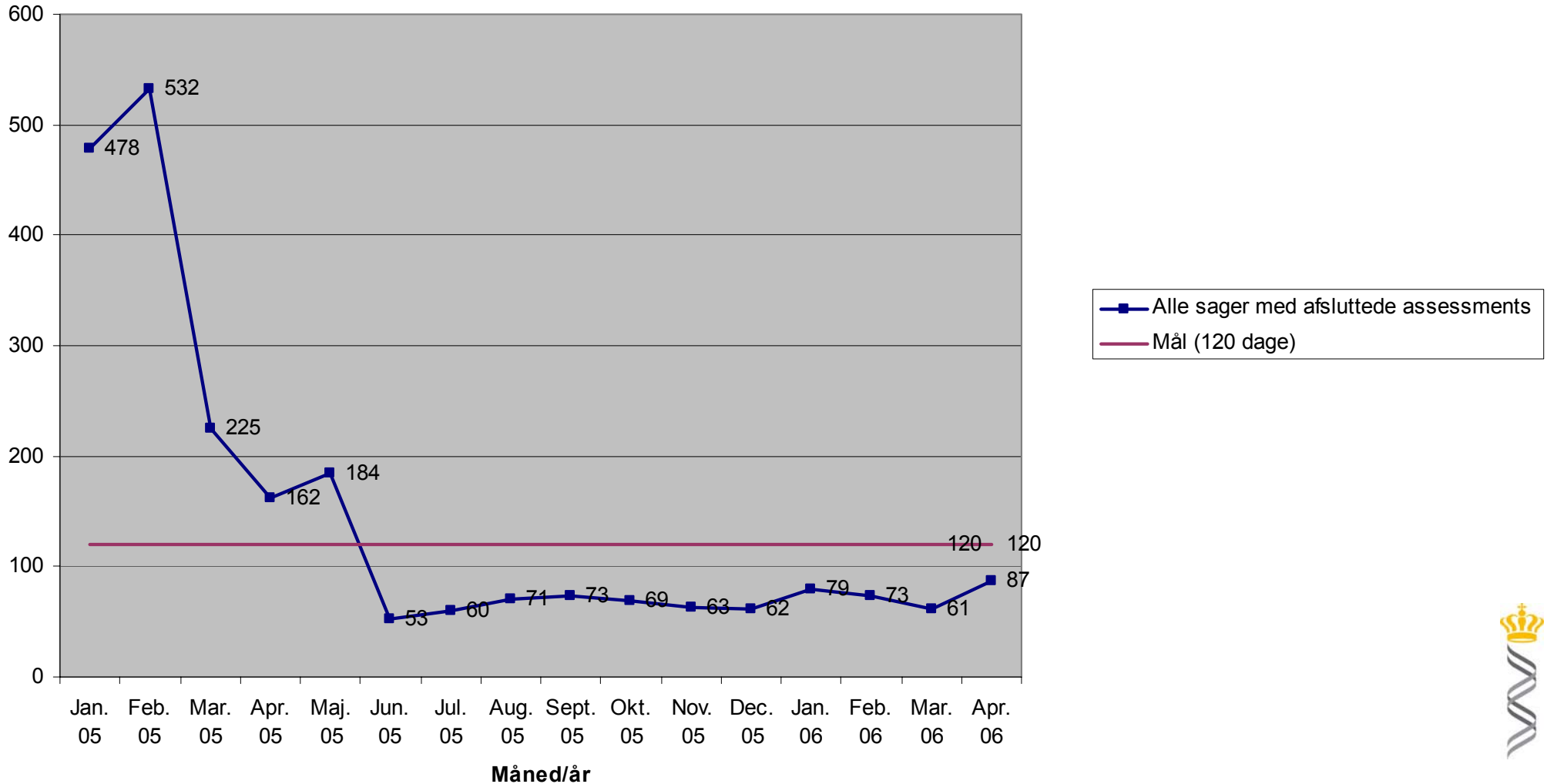
Rød = Prognose ved fremtidig modtagelse af 10 ansøgninger pr. måned





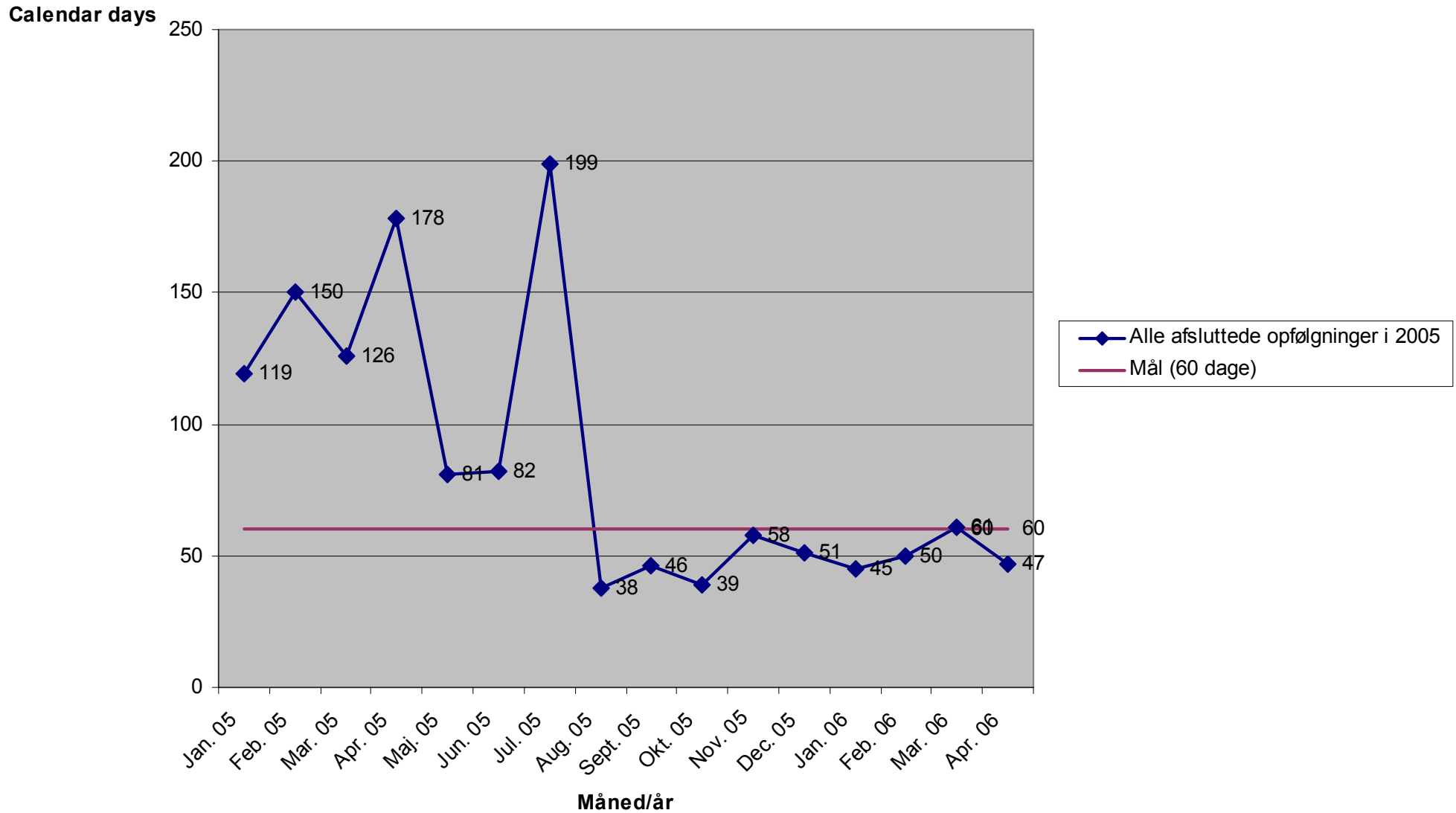
Mean handling time during the assessment phase

Calendar days



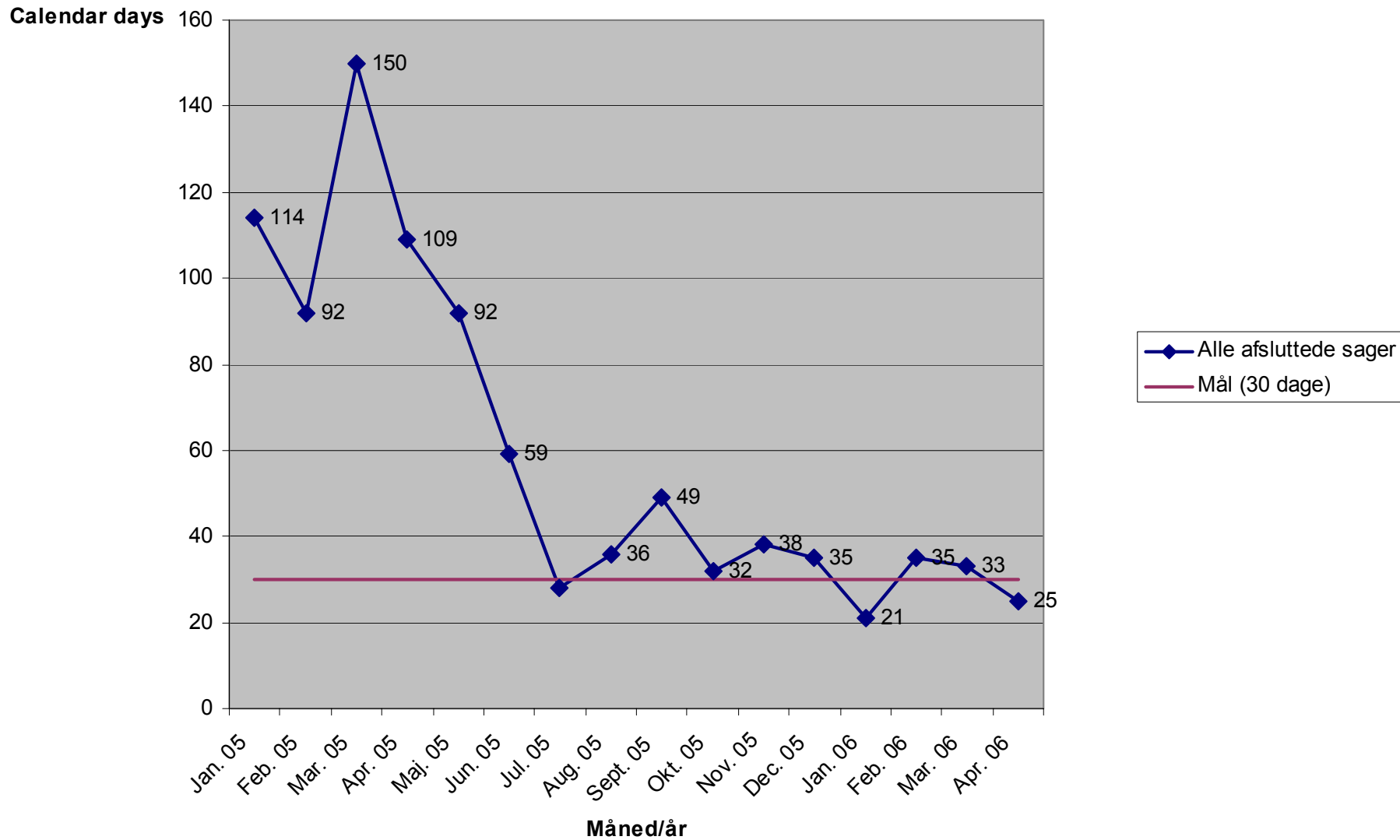


Mean handling time during follow-up phase



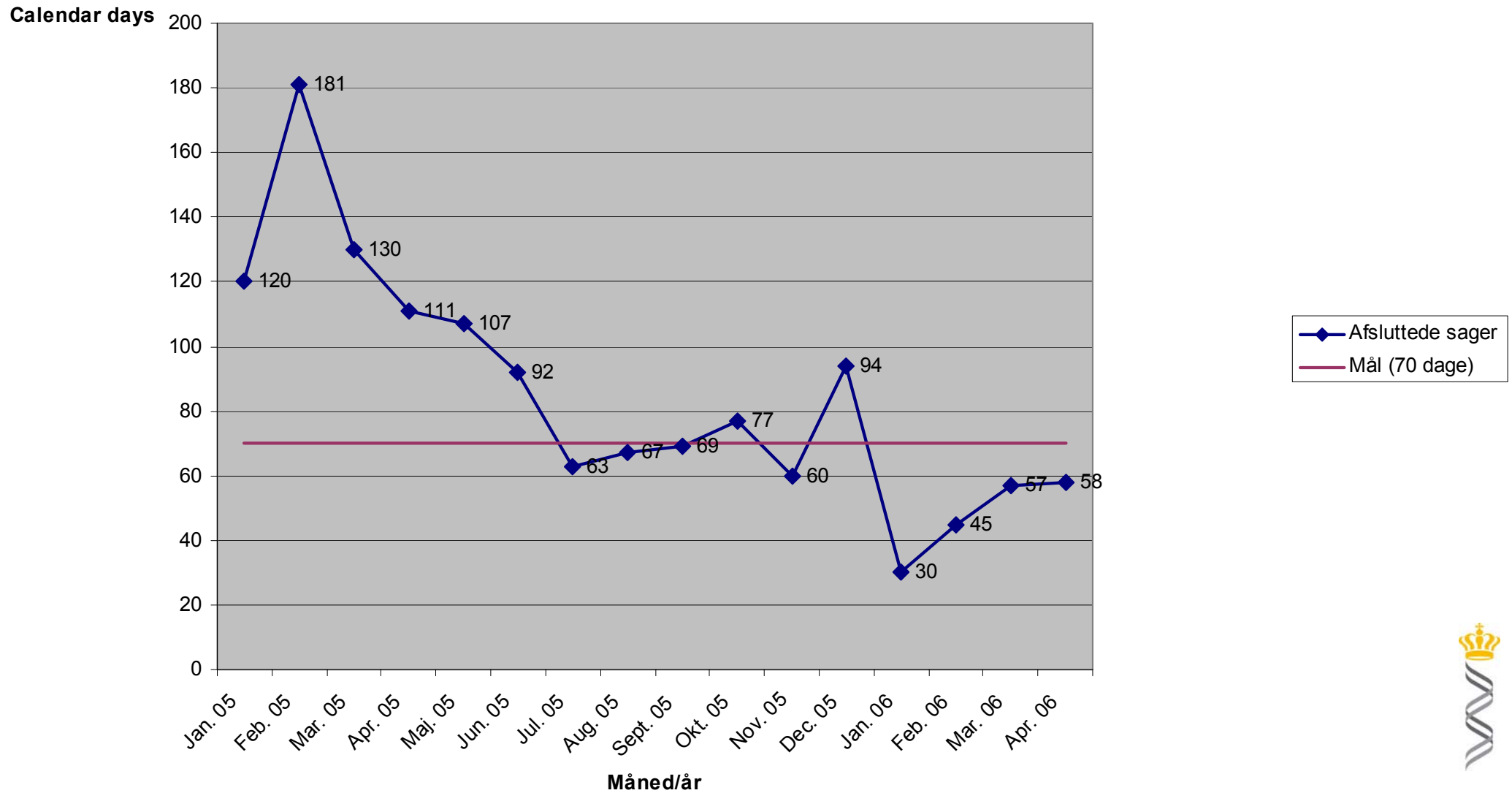


Mean handling time during finalization phase





Mean net handling time for parallel import





The New Challenge for NCA's

The decentralised procedure

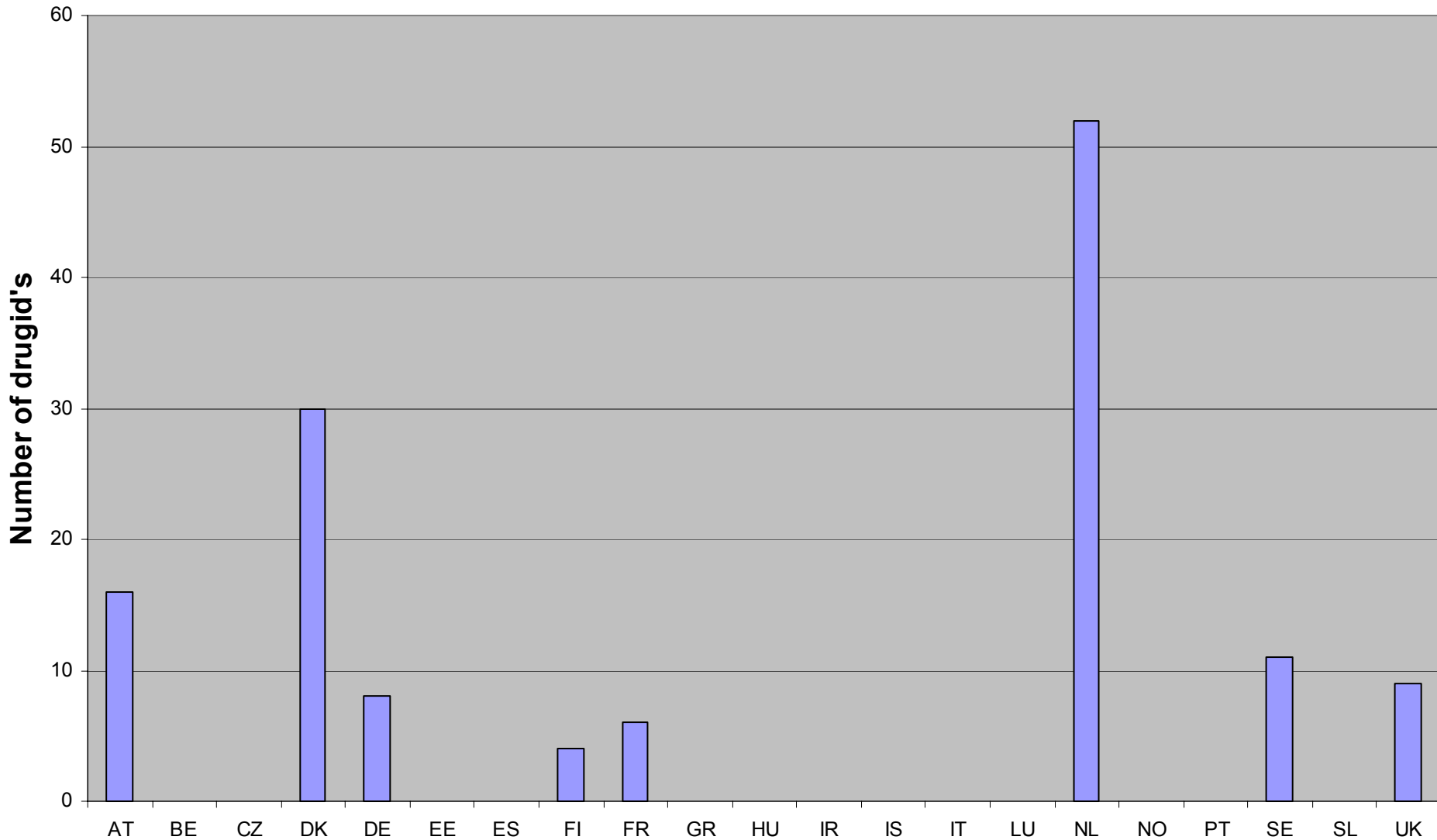
- The procedure will start with immediate effect, i.e. prior to national applications.

DKMA has chosen the role as an active participant





Number of decentralised procedures started. Status for 2006





Conclusions

- The Network of NCA's is well functioning and complimentary to the EMEA
- The Danish Agency has taken the choice to be an active player in the network and in the EU procedures
- The challenges of handling also national applications are better met

