



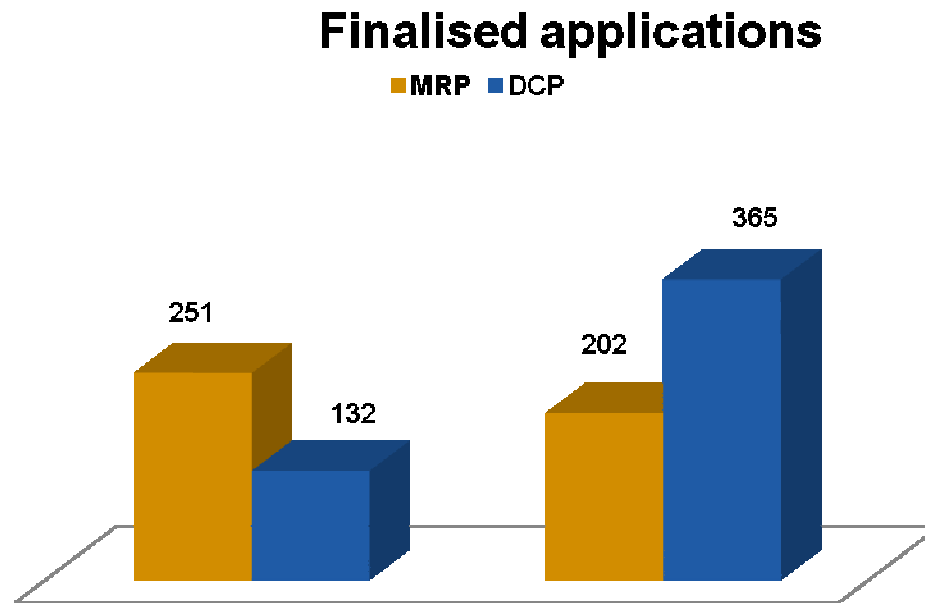
Resources in MRP/DCP

Meeting with interested parties
November 2009

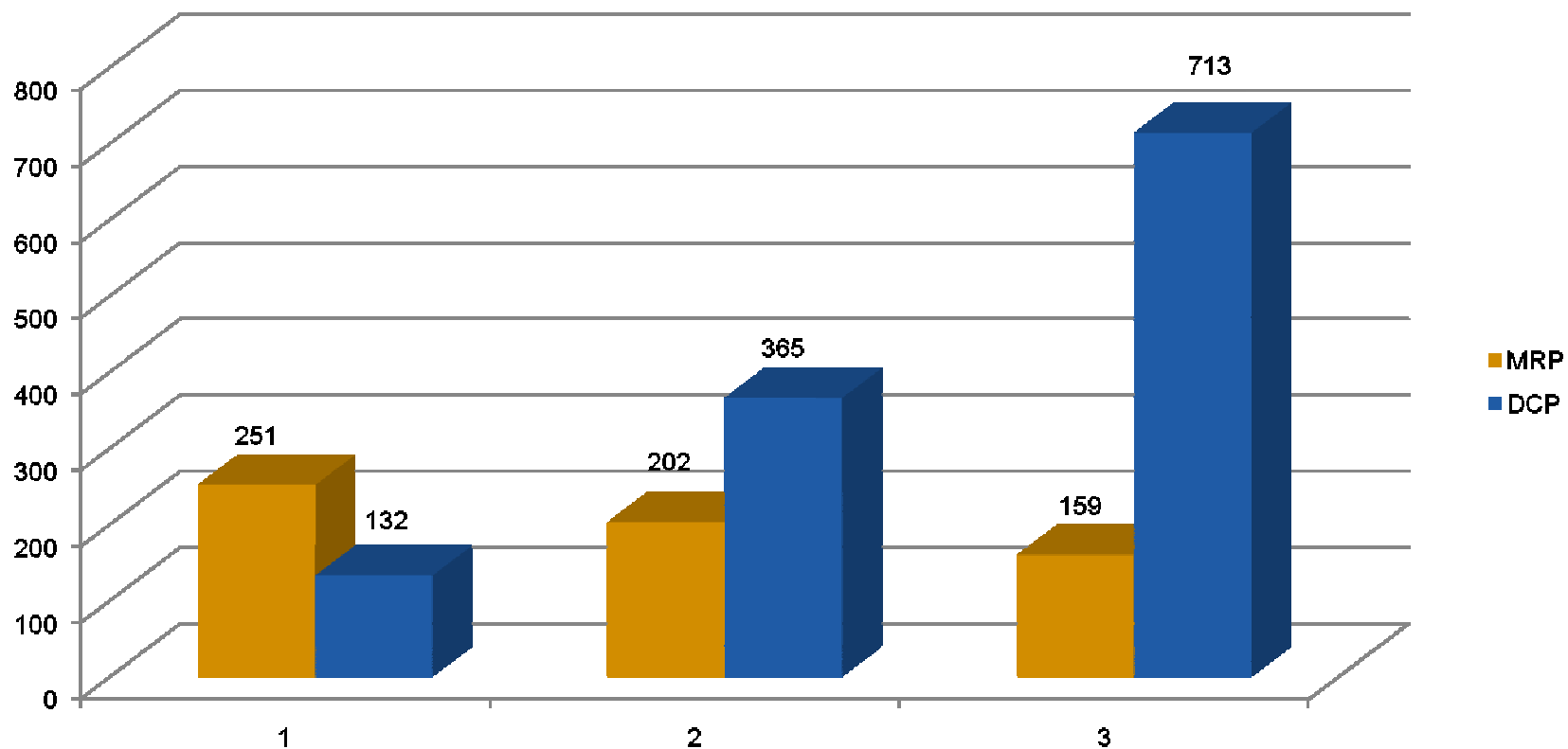
Christer Backman

Increase of DCP

- **Jan-June 2007 vs 2008**



January-June 2007 - 2009



Heads of Medicines Agencies



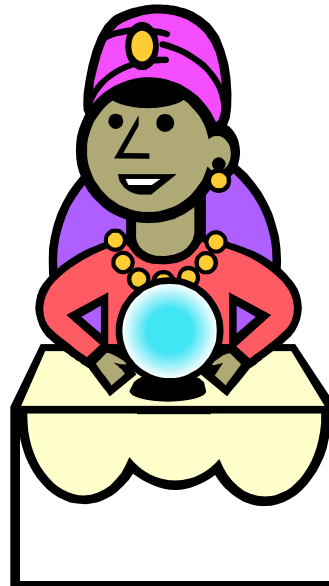
Task Force on Availability of Resources at NCAs for MRP and DCP

What has been done/tried

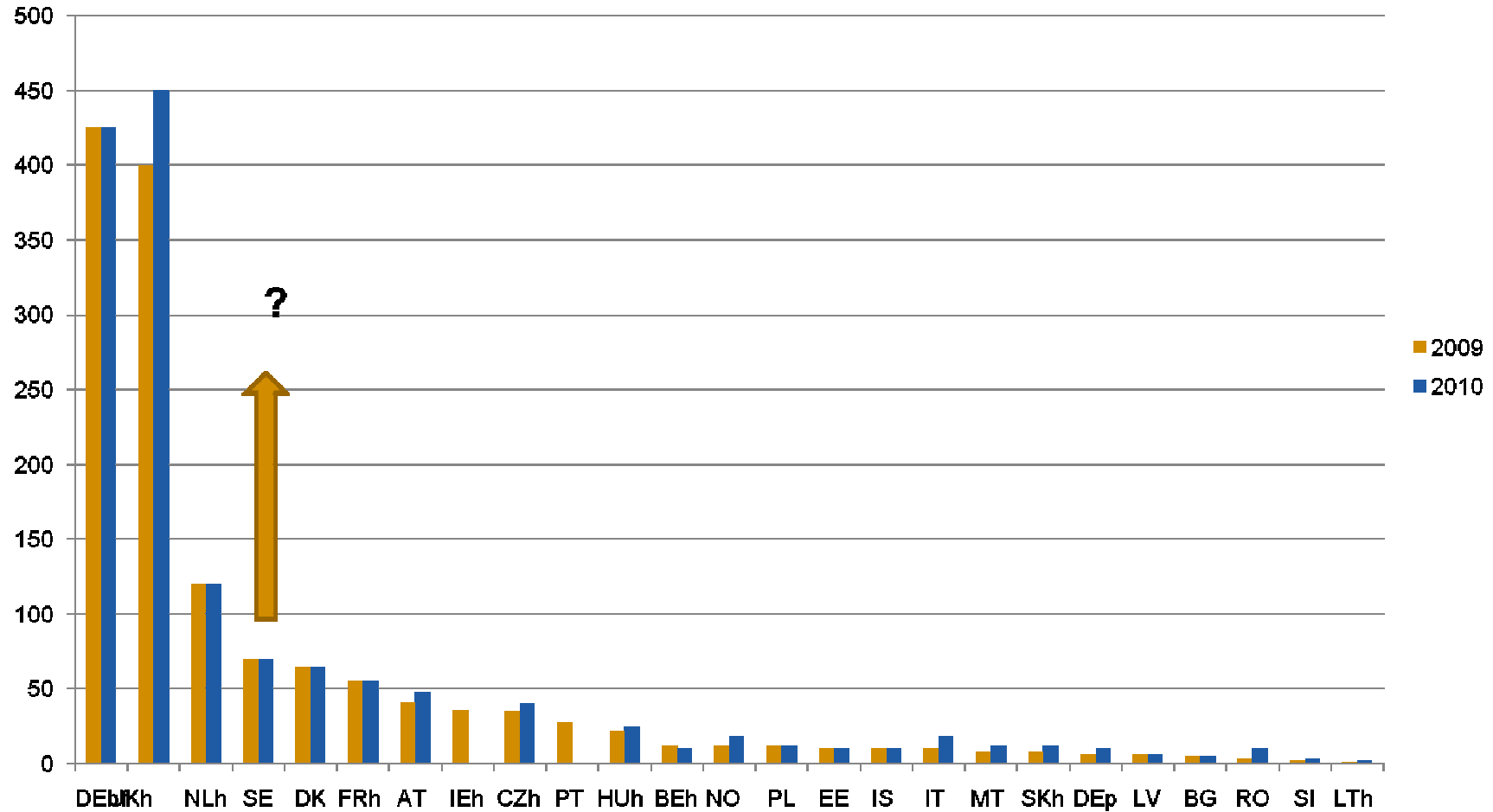
- 1. Examination of authority policies**
- 2. Estimation of applications**
- 3. Identifying problem areas**
- 4. Actions in order to improve**
- 5. Awareness for HMA**
- 6. New approaches**

Second questionnaire

What is current and future capacity?



Estimated capacity, human

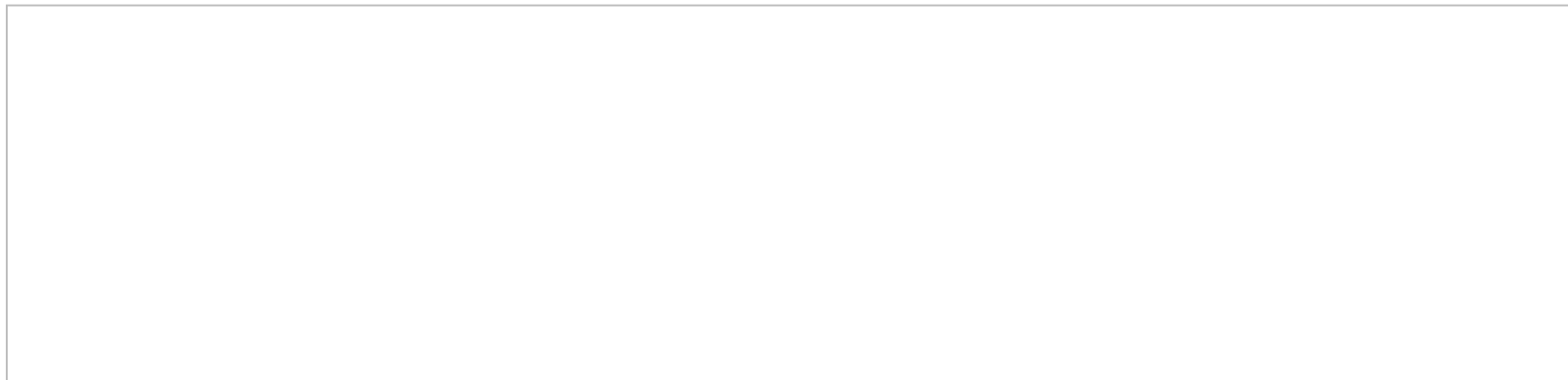
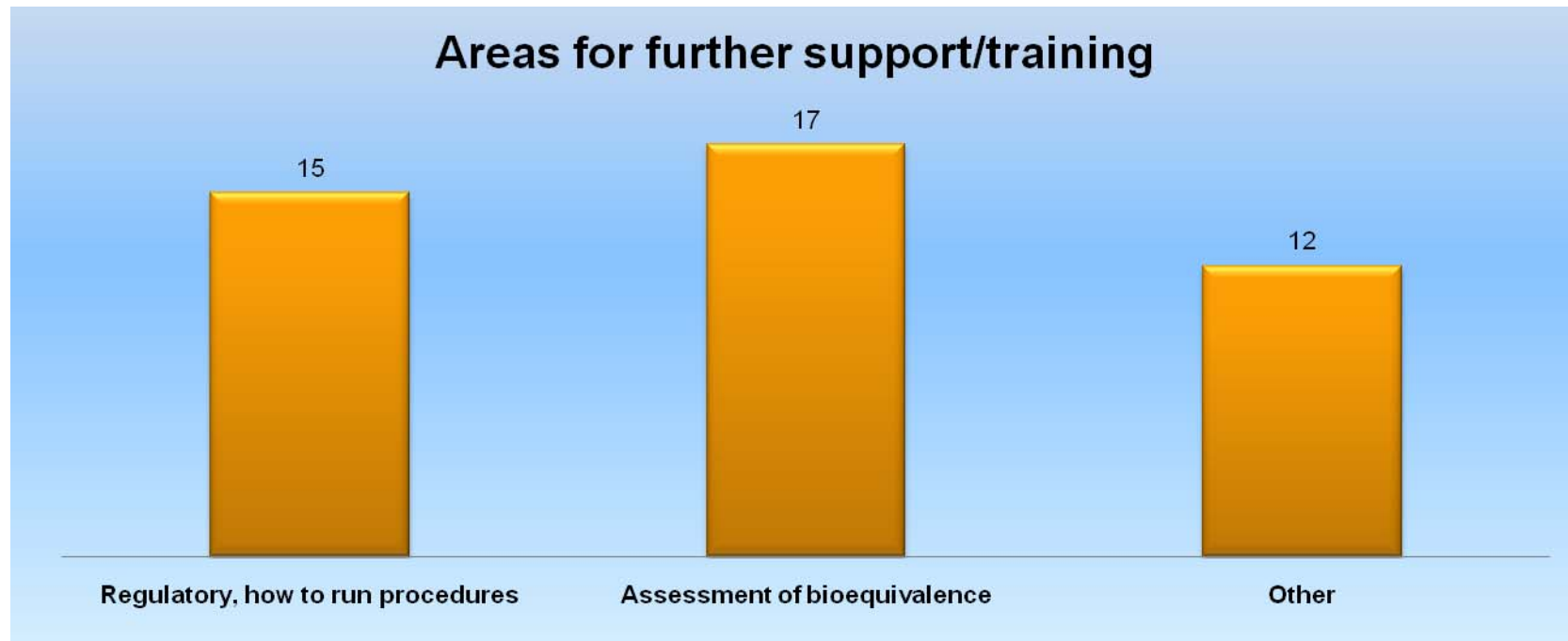


Second questionnaire

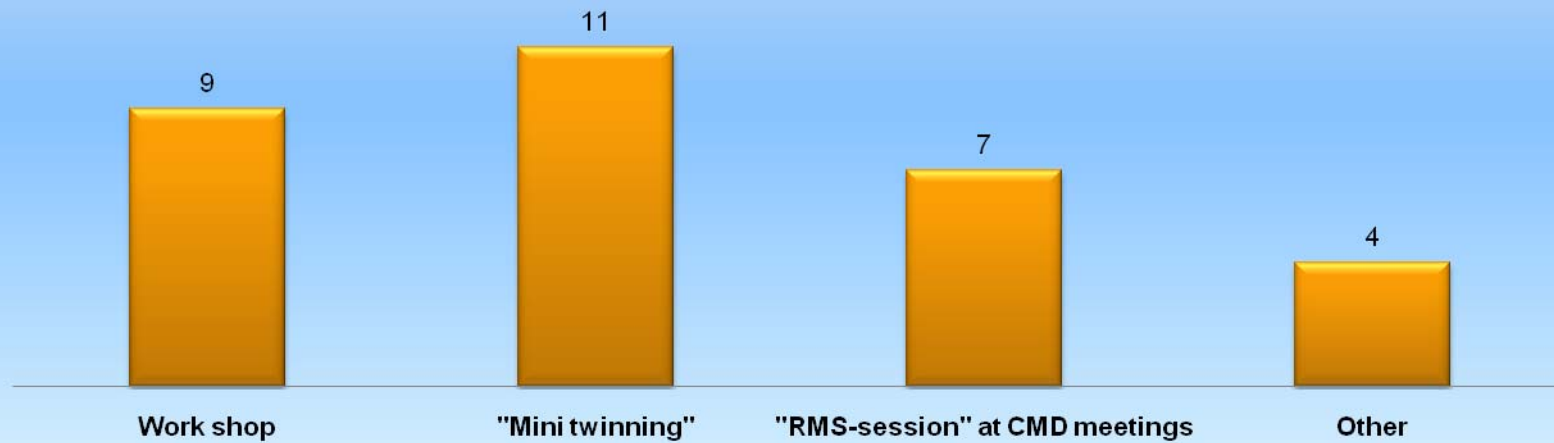
Is there a need for training?



Areas for further support/training



What type of support/training would you prefer?



Structured training for new assessors and regulatory coordinators

Second questionnaire

How is the assessment as CMS performed ?

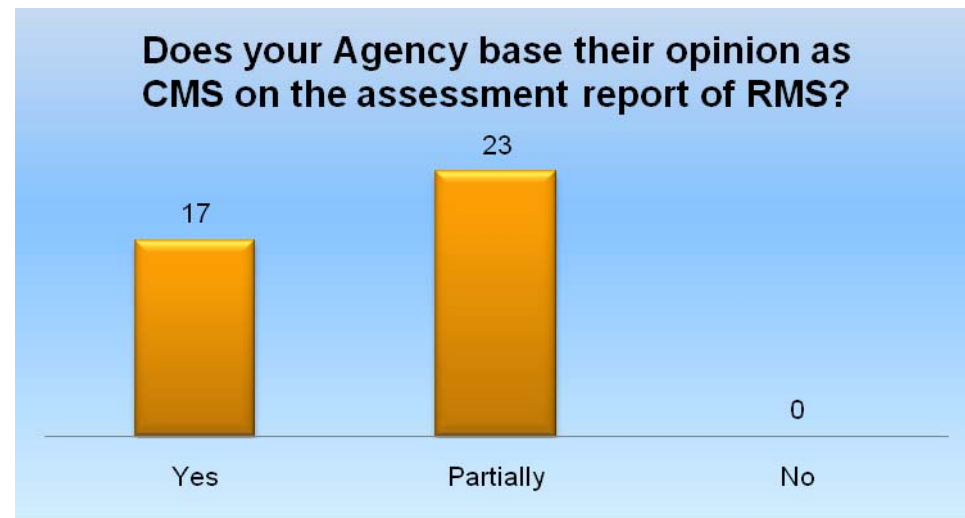


Assessment as CMS

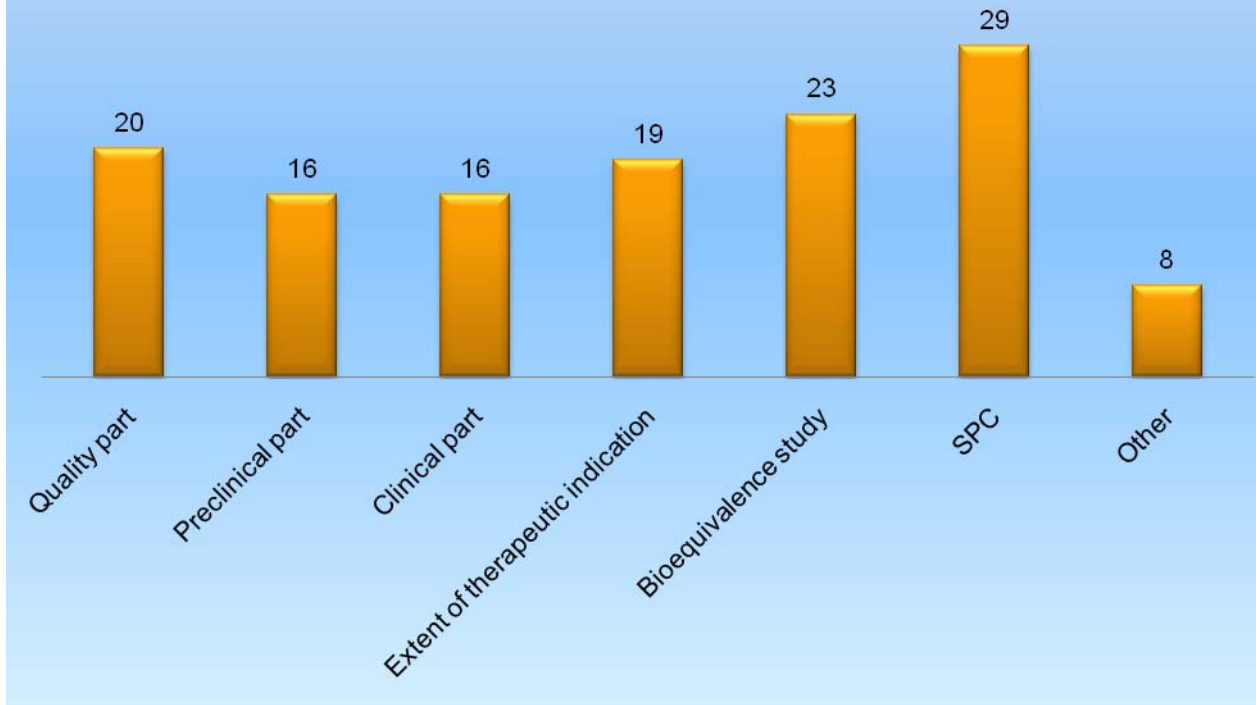
1. All NCAs base their opinion on the AR (totally or partially)



2. Most NCAs assess parts of the dossier



Which part of the dossier is assessed?



What has been done so far ?

Estimation of number of applications

- **Letters to industry**
- **Poor result**
- **A fact that generics increase in CP**

Expiry of exclusivity

- **Centrally authorised**
- **Nationally authorised**

Conclusion – no reduction in DCP to 2011

National requirements



CMD(h) validation subgroup

- **Reduction of national requirements**
- **Validation issues**

Chapter 7, 2007

- 6 MSs without additional national requirements

Task Force, July 2008

- 12 MSs without additional national requirements

Task Force, September 2009

- 15 MSs without additional national requirements

Common booking form



Request for RMS in a decentralised procedure, medicinal products for human use

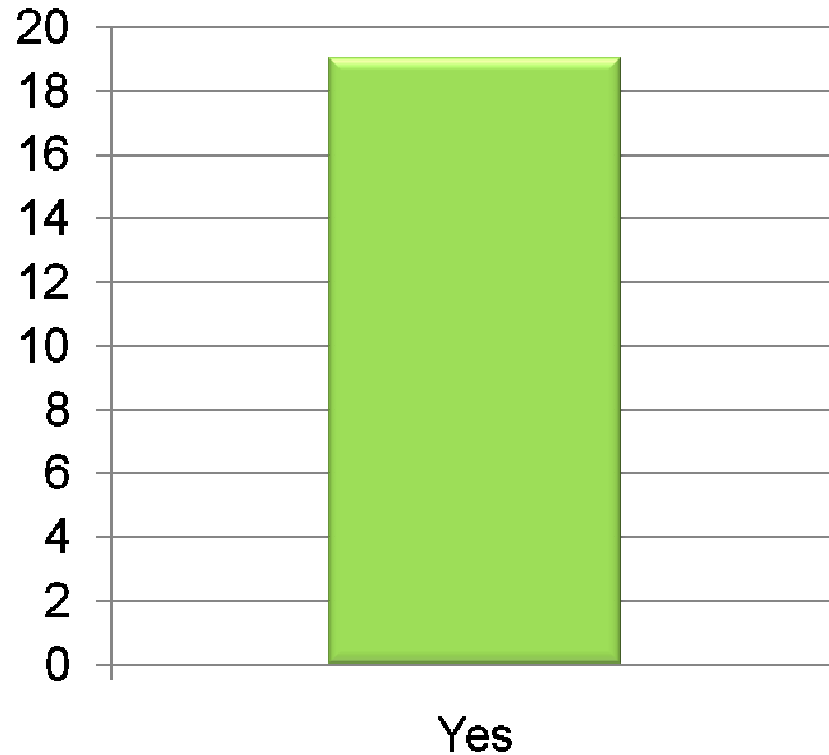
Requested MS to act as RMS:			
Intended number of CMSs (if known):			
Active Substance(s):			
ATC Code:			
Proposed Product Name	Pharmaceutical Form(s)	Strength(s)	
Legal basis of application:			
<input type="checkbox"/> Art. 8(3)	<input type="checkbox"/> Art. 10(1)	<input type="checkbox"/> Art. 10(3)	<input type="checkbox"/> Art. 10(4)
<input type="checkbox"/> Art. 10b	<input type="checkbox"/> Art. 10c	<input type="checkbox"/> Art. 16a	<input type="checkbox"/> Extension
This is a duplicate of an ongoing or finalised procedure: <input type="checkbox"/>			
Indicate the procedure number of the original dossier:			
Indicate the number of duplicates:			
For generics only			
Reference medicinal product authorised for not less than 6/10 years in the EEA			
Product name, strength, pharmaceutical form:			
Marketing authorisation holder:			
First authorisation date (yyyy-mm-dd):			
Member State (EEA)/Community:			
Reference medicinal product in the proposed RMS			
Product name, strength, pharmaceutical form:			
Marketing authorisation holder:			
Reference medicinal product is/has been authorised in all proposed CMSs <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A			
For bioequivalence study, name and address of the site:			
The new product will be marketed in the proposed RMS: <input type="checkbox"/> Yes <input type="checkbox"/> No			
Name(s) and address(es) of the manufacturer(s) of active substance:			
Has a Ph. Eur. Certificate of suitability (CEP) been issued for the active substance and/or will an Active Substance Master File (ASMF) be used? <input type="checkbox"/> CEP <input type="checkbox"/> ASMF <input type="checkbox"/> N/A			
Applicant's preferred submission date:			
Other information:			
I herewith declare that no other Member State has agreed to act as Reference Member State for a Decentralised Procedure for the above mentioned product.			
Applicant:			
Authorised contact person:			
Address:			
Phone:			
Fax:			
E-mail address:			

Request for RMS DCP, medicinal products for human use

CMDh/03/6/2009, February 20 09

Page 1/1

Do applicants use the form?



Parallel assessment

- **Encourage a risk based approach**
- **Promoted at CMD and HMA level**
- **Synthon case and lack of resources forces MSs into more trust**

Assessment reports

- **Feed back form assessment reports**
- **Pilot from 1 November 2009**

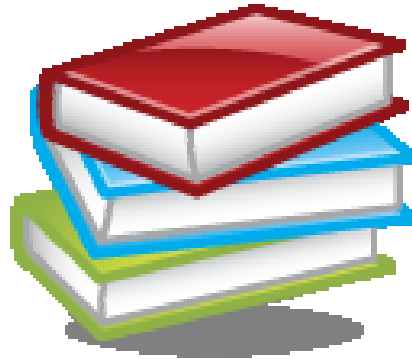
Duration of clock stops

- **Examined by CMD(h)**
- **Proposals to come**



Training of assessors

- **HMA Task Force on training**



Storing of documents

- **Central repository to be examined**



HMA Strategic Paper II

- **Task Force on resources in DCP/MRP in parallel to the strategic planning**

Common portal for applications

- **Is it possible?**



Conclusions

- **Save resources in many ways**
- **Work more efficient**
- **Easier validation**
- **Less parallel assessment**
- **Enhance quality in dossiers and evaluation**
- **Work more harmonised**
- **Key point – more resources from NCAs**

Thank you for your attention

