

CMDh Meeting with Interested Parties

21 June 2010

**Member States' resources in the Mutual
Recognition and Decentralised Procedures:
CMDh contribution to Task force on resources**

Objective

Provide Metrics Through an Evidence-based Survey

A detailed survey of experiences from multi-company (10 multi-Nationals)
(anonymized by AESGP)

Timeline:

- New Product Applications - September 2008 (and before, where relevant) to December 2009

Criteria defined for predominantly objective measurements, where possible

All captured data needed to be capable of being “metricized” to permit graphical representation (where possible)

- 25 market submissions for New Applications
- Focus on EEA for this session

Raw data “cleaned”, data-based and analysed by J&J

Criteria for Analysis

- Market
- Route of application: National/EU
- RMS if EU
- Type of application
 - Line extension etc
- Notice required for DCP timeslot and transparency of the process
- Date of submission
- Date of acknowledgment
- Total number days for pick-up
- Date of approval
- Total number days for procedure (minus clock-stops, where relevant)
- Key strengths of the review process
 - Willingness to meet, enter negotiation, clarify issues and overall flexibility
 - Appropriate level of data requirements (for OTCs)
 - Speed of review and approval process

Scope of the Pooled Database

Completed and incomplete Procedures in 2009 for New Applications

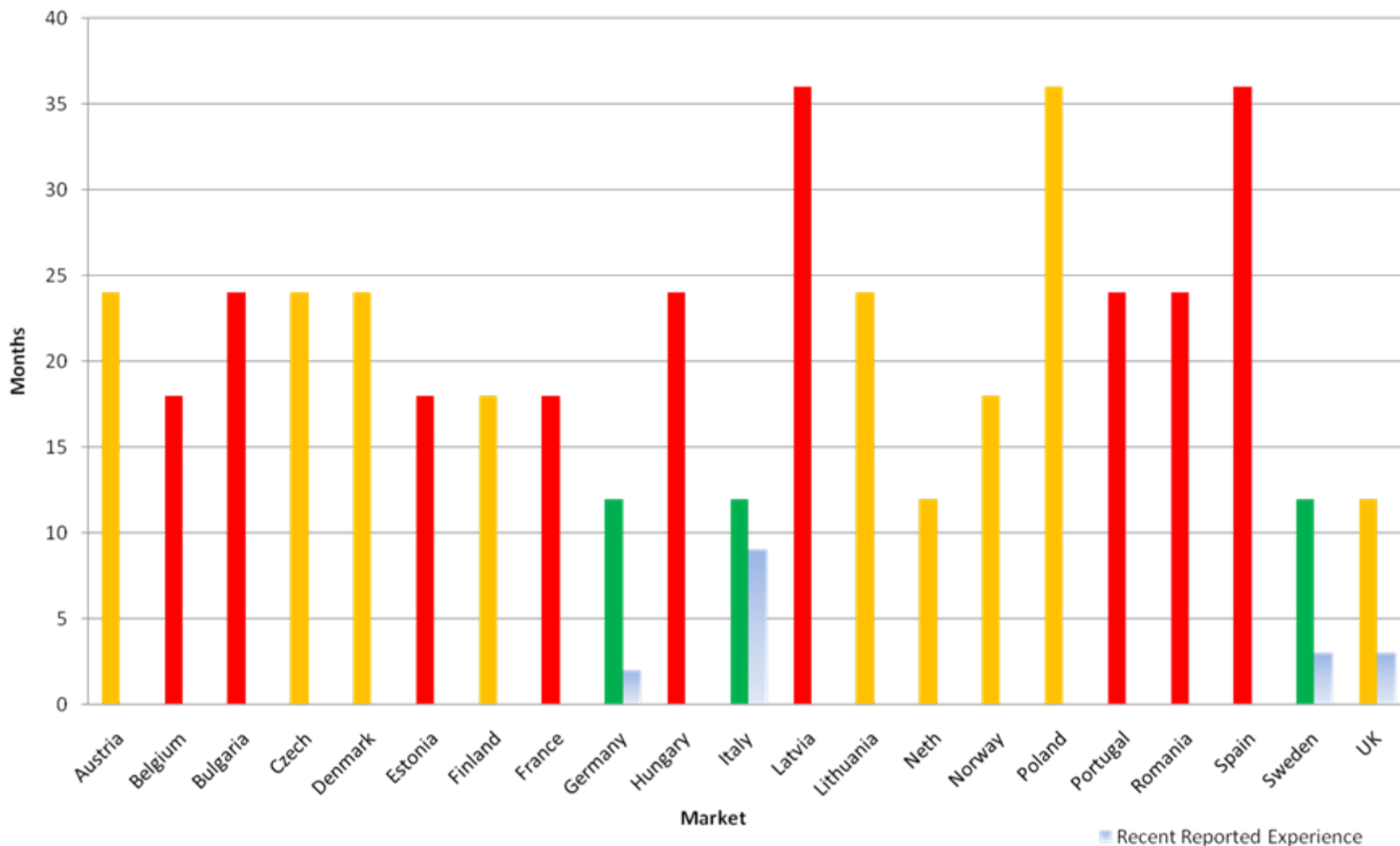
Total database for EEA markets = 195 procedures, of which

- National = 114
- EU = 81

Supports message that non-prescription industry *is* using the EU procedures for New Product Applications in spite of ongoing challenges with DCP queue times

For this discussion data from National Procedures will be used for comparative purposes, only

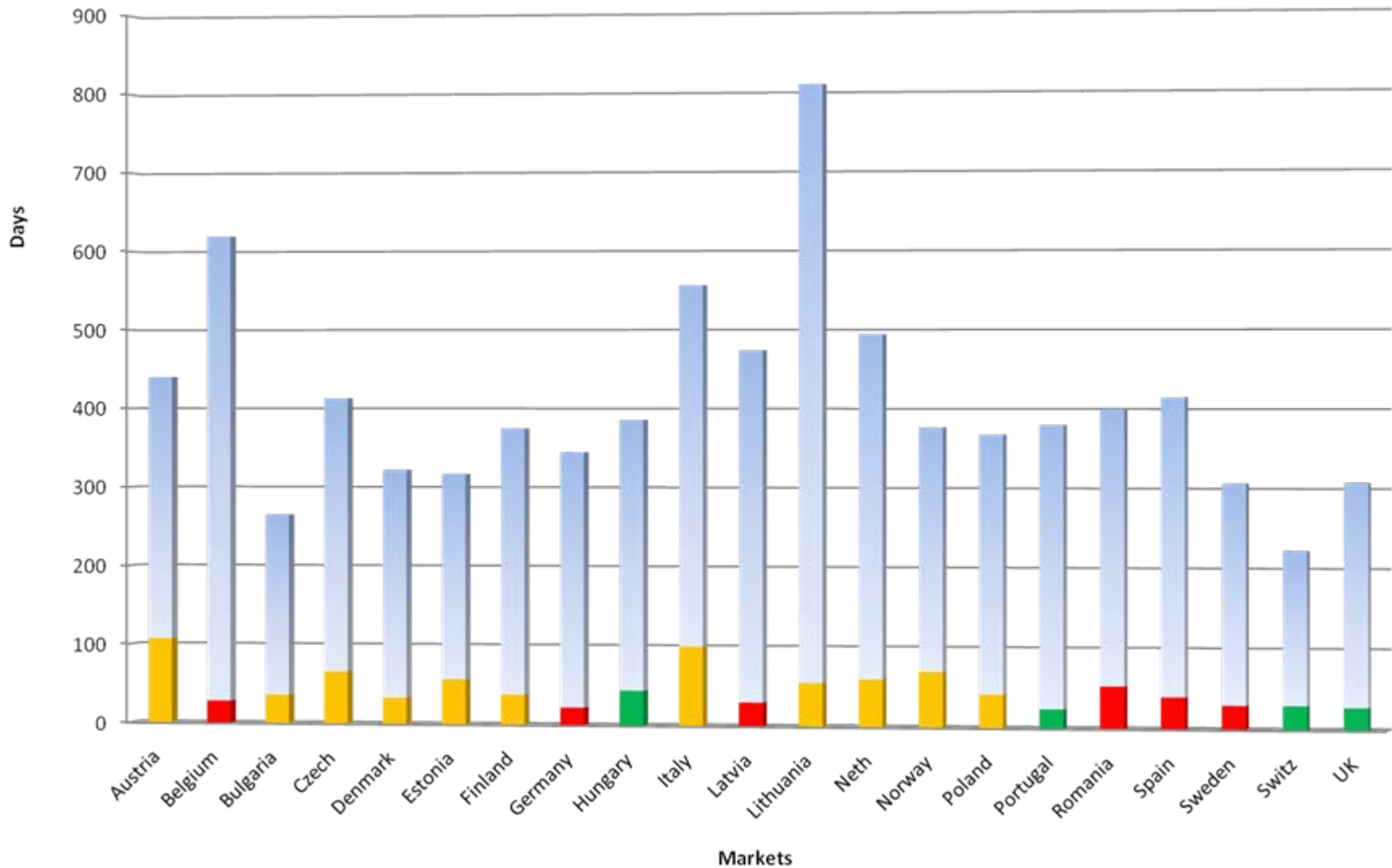
DCP Queue Times & Receptiveness to OTCs/Transparency of the Process



Colour-Coding = “receptiveness to OTCs and transparency of the process

- Green = 1 (good)
- Yellow = 2 (average)
- Red = 3 (poor)

National - Pick-Up Times & Approachability + Overall Assessment time



Colour-Coding = “receptiveness to OTCs and transparency of the overall process” Lower bar = pick-up time

- Green = 1 (good)
- Yellow = 2 (average)
- Red = 3 (poor)

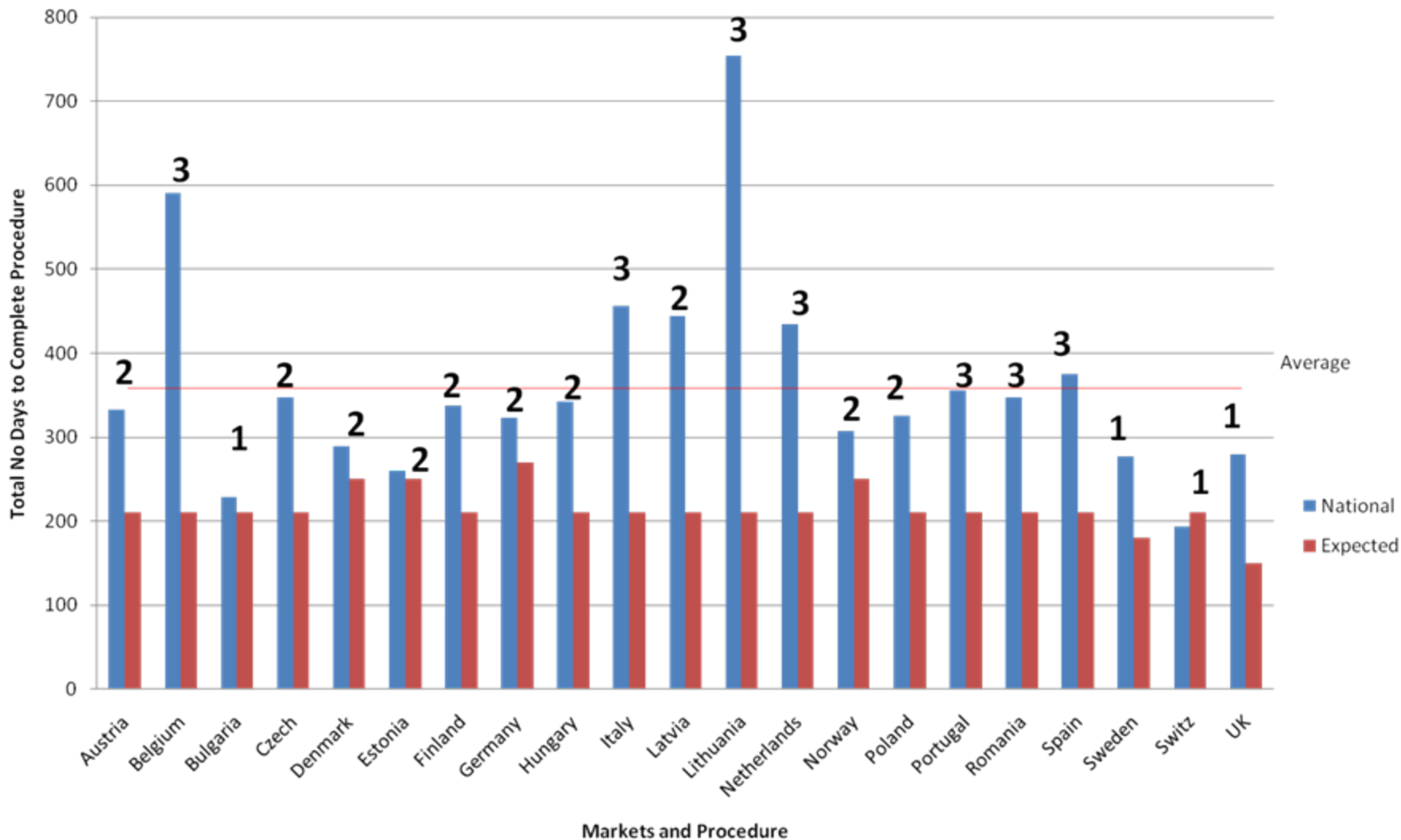
Observations: DCP Timeslots vs. National Pick-Up Times – As a measure of pre-assessment delay

- Experience with DCP slot times is typically 2-3 years
- **National Procedure** : Slot Times not required, however Pick-Up times very variable (range 10-100 days)
- **DCP**: Recent experience with shorter /improved Slot Times: e.g. Germany, Italy, Sweden and UK
- **National and DCP**: Receptiveness to OTC application/transparency of the process (colour-coded/graded 1-3)
- Reasons given by Authorities for *not* accepting position of RMS:
 - No resource (long waiting times)
 - Lack of experience as RMS
 - Lack of experience with presentation (e.g. focus on actives/presentations)
 - Only accepting generic applications
 - Only accepting products in specific disease areas

Where resource is an issue, suggested that Industry approach other Competent Authorities, however if others are not prepared to accept RMS, what is our next option?

This would suggest that National is the better route for OTCs?

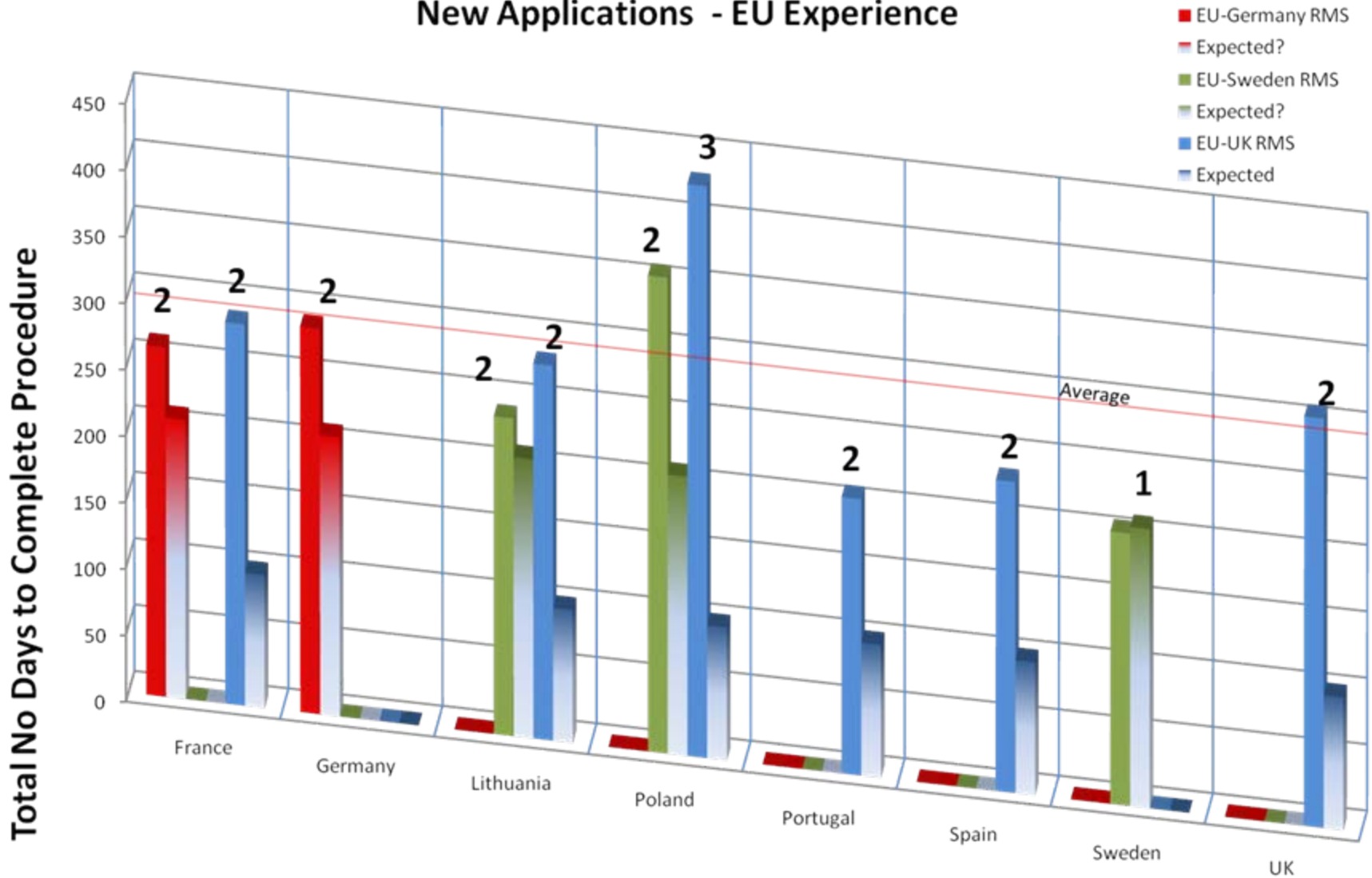
New Applications: Assessment Times (actual versus published) National Experience



Numerical Coding = “receptiveness to OTCs

- 1 = good
- 2 = average
- 3 = poor

New Applications - EU Experience



Numerical Coding = “receptiveness to OTCs

- 1 = good
- 2 = average
- 3 = poor

Markets and Procedure



Observations: National versus EU

Review Times (submission to approval in days, minus clock stop)

The analysis yielded some interesting results:

- Considerable variability in review times across MSs (irrespective of procedure)
- Variable difference between review times & published data/norms (where available)
- Data suggest that the National approval process is still causing delays in the CMS, even though RMS has approved
- **National** average ~360 days versus **EU**~310 days (includes pick-up time)
- Adding DCP slot increases the overall timelines for DCP: ~ average 310 days + 2-3 years!
- Adding National Pick-Up times increases the overall timelines for National: ~ average 360 days + 10-100 days!
- Review timelines closer to published data for EU compared to National
- Receptiveness to OTC applications (1-3) in terms of meetings, flexibility on data needs etc (again with OTCs) is very variable

How does Non-prescription industry improve its opportunities?

Discussion (1)

Setting the Context

- These are observations based on recent, actual OTC experience
- All data was “cleaned” before submission to J&J: no references to products or source-company
- These findings should not be seen as either “good or bad” – the intention has been to simply present the experiences of the companies involved
- Accepted there are many variables e.g. numbers of applications collated per market, complexity of applications included
- This review enables the comparison of OTC timings for National versus EU procedures (e.g. national pick up times versus DCP queue times versus overall procedure timings).

Discussion (2)

Why are the needs of the Non-Prescription Industry different to Prescription Medicines (Pharma)

- Innovative OTC operate on a different timeline to Pharma – less up-front development/discussion (as in formal pharma NPD)
- Less opportunity to seek ‘buy-in’ by Agencies?
- Need to react fast to changes in non-prescription seasonal needs (e.g. Allergy/hay fever; strong cold/flu seasons etc)
- Need to be proactive and meet changing market needs without the ability to plan for the longer term
- Need for competitive flexibility and transparency

Review criteria

- Review of OTCs should (in the main) be simpler since we are dealing with well-established active ingredients with known treatments regimes
- Accepted that Manufacturing data similar to NCEs
- Preclinical/Clinical data packages should allow for shorter review times

Discussion (3)

From our data we appear to have review timings longer than expected

- Do Rx/Generics more closely fit with published norms & averages?
- We accept our “n” is limited; does this mean that we typically lie at the extremes of the normal curve?
- Do we offer a lesser scientific challenge?

What can we do to help?

- We published our estimated submissions 12 months to February 2010
- We are prepared to repeat this which should facilitate resource-planning in the Competent Authorities
- We are willing to make more use of MRP/DCP but need more transparency on Slot Times (a major concern for us)

In conclusion

- We look forward to sharing these collated observations with Competent Authorities and to work together to ensure that timelines meet the needs of the Industry, including OTC.