

CMDh Meeting with Interested Parties

21 June 2010

Decentralised Procedure:

Clock-stop

Objective

Provide Metrics Through an Evidence-based Survey

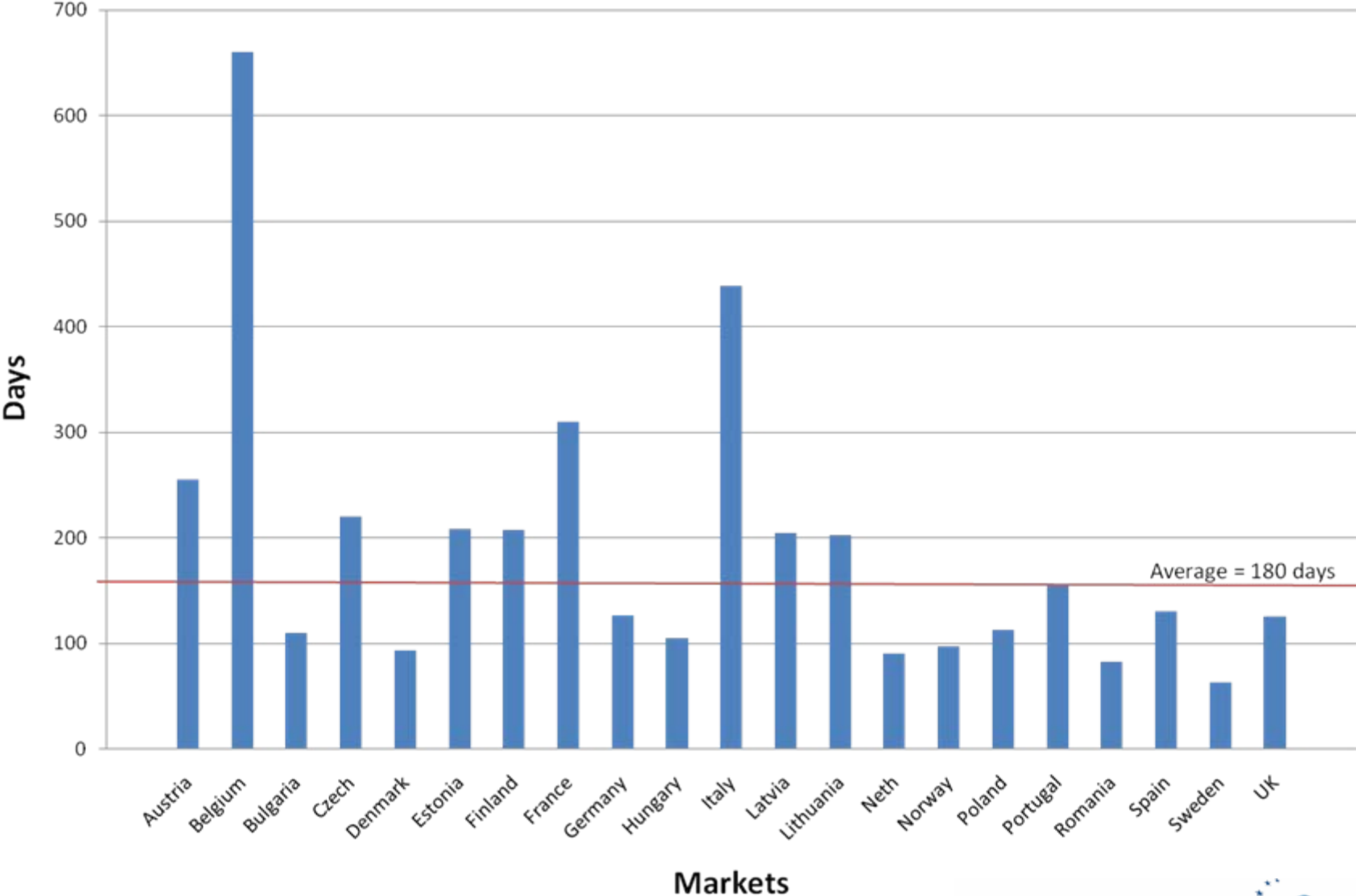
Data based on the exercise discussed earlier.

Scope of the Pooled Database

Completed and incomplete Procedures in 2009 for New Applications

Total database for 21 EU markets = 81 EU Procedures

Clock Stop



Observations

The analysis yielded some interesting results:

- Experience shows that clock stops lasting 6 months (#180 days) can be expected (data shows range from 80-660 days)
- Frequently procedures are delayed by subjects that should be simple to resolve, e.g.
 - Risks to public health should not be raised here, especially since these are predominantly well-established products with a proven safety profile
 - Naming issues that could be discussed in the National Phase of the assessment, rather than delaying the procedure overall
 - Assessors changing during the procedure raising new questions
 - Revisiting the validity/legal status of the application during procedure

The end-result is a delay in market access