



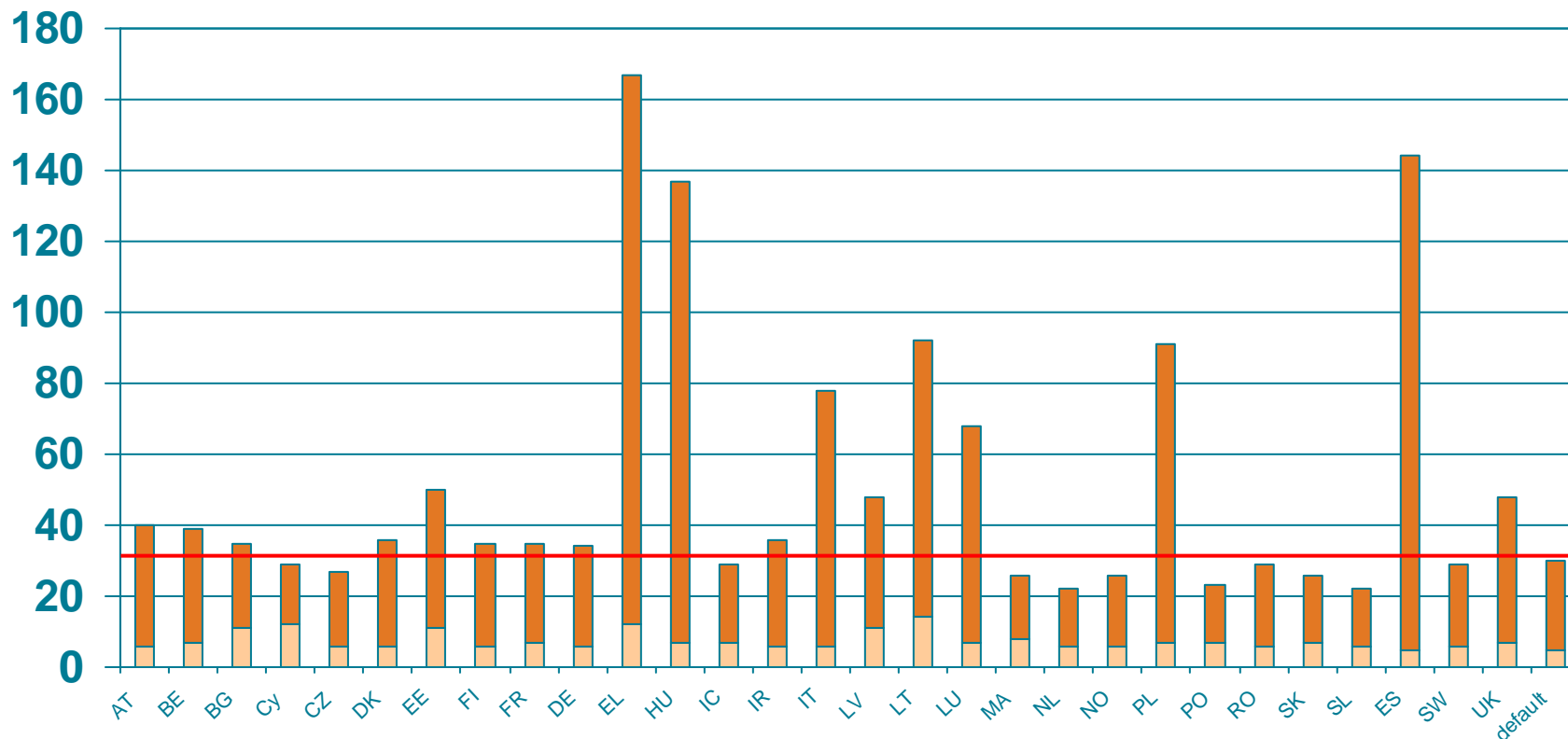
European Federation of Pharmaceutical
Industries and Associations

CMDh Meeting with Interested Parties – EFPIA contributions

20 September 2010

- Efpia welcomes the clarifications in the updated CMD guidance
 - Appointment of RMS is helpful to act a facilitator amongst agencies
- Include always a compliance statement in the Marketing authorisation
- Issue national marketing authorisations within 30 days after Commission Decision
 - Actual licence issue, after (verbal) notification of approval, in some instances can take quite some time

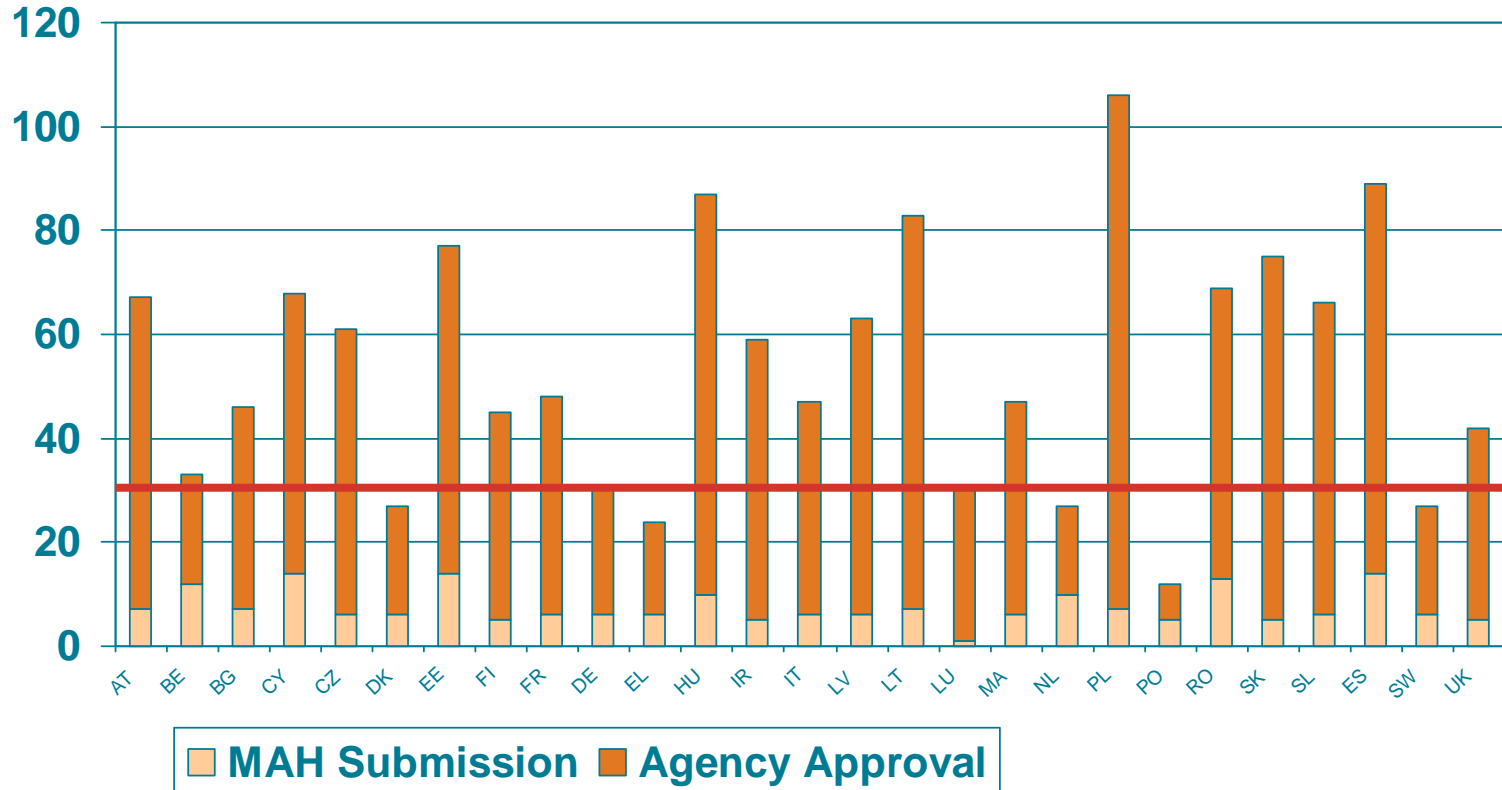
days



MAH submission
 Agency approval

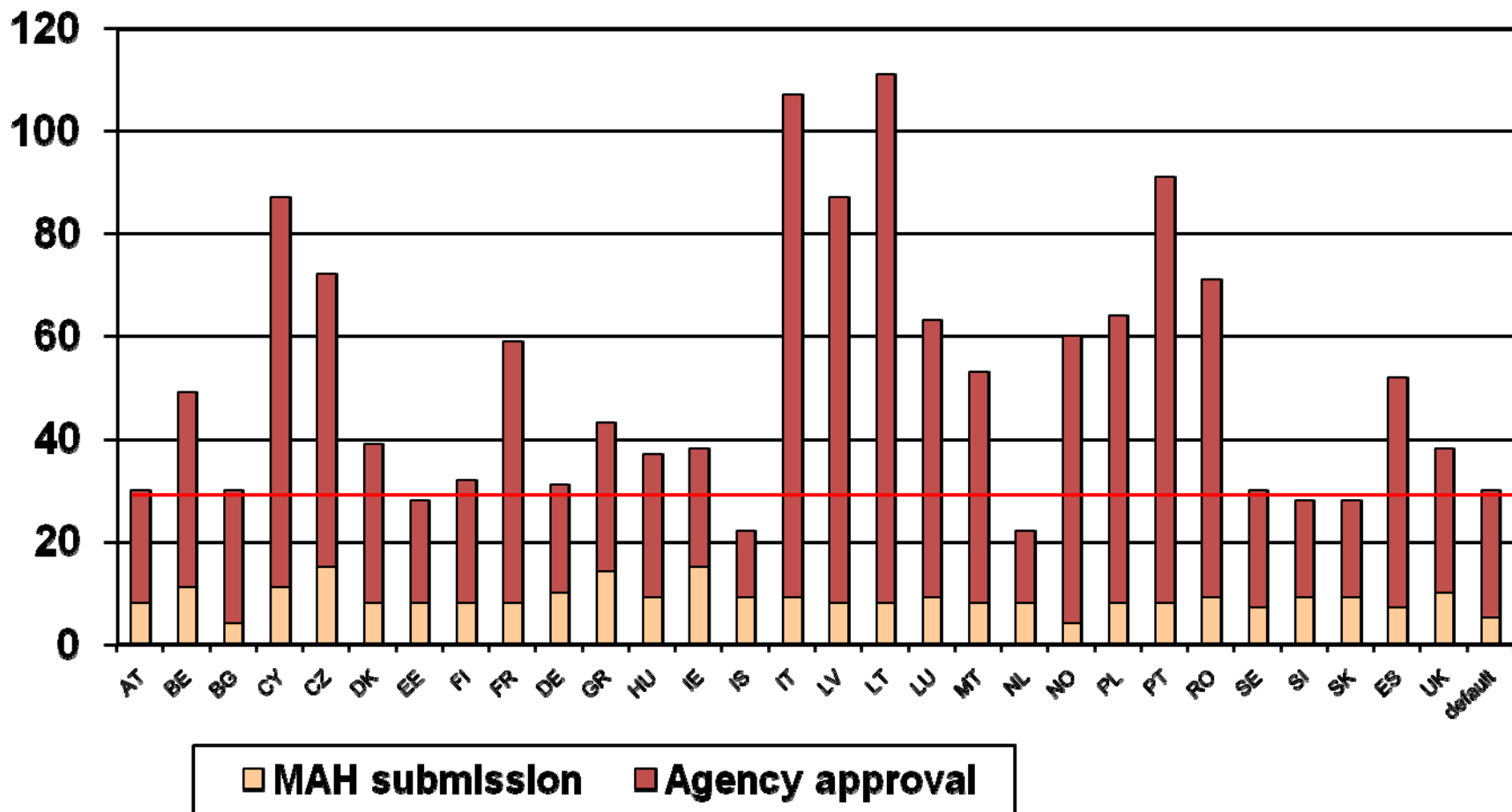
Note: EC time (4 days) to post Decision and delivery to local agencies included in MAH submission time

days



Note: EC time (5 days) to post Decision and delivery to local agencies included in MAH submission time

days



days

