

CMDh Meeting with Interested Parties – EFPIA contributions

15 November 2010

- With reference to the draft HMA strategy II paper, we would like to make some concrete proposals for the streamlining of renewal procedures following referral, repeat MRP or informed consent authorisations, in order to achieve a risk-based management of resources, reducing administrative burden and improving regulatory efficiency:
 - Any national Marketing Authorisation (MA) coming under the MRP umbrella through a referral or repeat MRP procedure should follow the MRP renewal requirements as determined by the RMS. In addition, any duplicate MA obtained later during the life cycle of a product should be automatically following the renewal requirements of the original MA.
 - The benefit/risk of a specific product is being evaluated during the MRP renewal process and additional renewal requirements based on justified public health grounds will be determined during that process.
 - During any Article 30 referral process a re-assessment of the current data is being made for the EU wide harmonisation based on a benefit/risk evaluation of the product. The assessment of duplicate informed consent applications should be based on the same data set as the original product and does not need to be re-assessed for its own benefit/risk balance.
 - Hence, considerable resource savings on authority and company side can be achieved, if a harmonised approach and the acceptance of the common EU renewal date for those cases can be supported by all Agencies.