

10th DGRA Annual Congress Heading for a New Decade *Transatlantic Simplification of Administrative Procedures in the Area of Pharmaceuticals*

Bonn 17 and 18 June 2008 Arielle North



Bilateral arrangements

- Currently 3 arrangements
 - EU/US FDA
 - EU/Japan MHLW-PMDA
 - EU/Health Canada
- EU represented by European Commission and EMEA











EU/US FDA arrangement

- Signed in September 2003 for 2 years
- Implementation plan and pilot programme for parallel scientific advice signed in September 2004
- Extension of the arrangement for 5 years signed in September 2005
- Implementation plan updated in June 2007











- Scope central applications/authorisations and referrals
- Specific topics
 - Guiding principles for joint FDA/EMEA voluntary genomic data submission briefing meetings in May 2006
 - Principles of interaction between EMEA and FDA on paediatric therapeutic in June 2007
 - The EU and FDA have created a common application form for orphan designation in November 2007





- Some outcomes
 - Quarterly reports on on-going procedures
 - Safety information
 - Systematic in relation with CHMP meetings
 - Case-by-case
 - Inspections
 - Case-by-case
 - Database access
 - EMEA access to COMSTAT
 - EudraGMP access for FDA on going
 - Includes module for sharing inspections plans





- Already: oncology, vaccines, orphans, paediatrics, pharmacogenomics
- On going: central nervous system, diabetes
- Common orphan designation forms
- Exchange of staff
- General information











EU/Japan MHLW-PMDA arrangement

- Signed in February 2007
- Implementation plan still under preparation
- Exchanges already in place
- Mainly focused on product specific issues
- Language represents a challenge





EU/Health Canada arrangement









- Implementation plan still on going
- Will be probably very similar to the FDA
- Exchanges already in place















Transatlantic Administrative Simplification

- Built on successful bilateral cooperation EU/FDA
- Transatlantic Economic Council (TEC) as political support
- Workshop November 2007
- Deliverables
- Action Plan















Workshop November 2007

- Under the auspices of the TEC
- Hosted by the Commission
- Organised in collaboration with EMEA and Heads of Agencies
- Co-chaired by Commission/FDA
- EU Industry organisations (EFPIA, EGA, AESGP, EuropaBio)
- US Industry organisations (BIO, CHPA, PhRMA)











Objectives

- Harmonisation
- Reduction administrative burden
- Saving resources
- For administrative practices/guidelines
- Rules
 - No change in the EU/US legislation
 - Transatlantic dimension
 - Not reduce public health















- Identification opportunities for administrative simplification
- Deliverables
 - Bilateral work (confidentiality arrangements)
 - Multilateral work (e.g. ICH)
 - Careful selection on unnecessary burden on administrative practices
 - Legal/practical considerations
- Action Plan











Milestones

- First trimester 2007 project agreed EU/US
- Second-third trimester 2007 consultation
 EU/US pharmaceutical industry
- 28 November 2007 workshop examination of proposals
- June 2008 publication of the Action Plan by the EU and FDA











- Large range of proposals
- Organised in four thematic panels
 - Quality and inspections
 - Pharmacovigilance
 - Scientific collaboration
 - Guidelines, formats, electronic submission
- List of agreed actions













- Original long list shortened
- ICH topics to be pursued under ICH umbrella
- 20 projects
 - Specified deliverables
 - Realistic deadlines
 - EU/FDA lead persons
- Concrete deliverables for TEC meetings











Transatlantic Economic Council

- Meeting 13 May 2008
- TEC noted for pharmaceuticals
 - Commission/EMEA and FDA
 - Pilot joint inspections in the EU and US and inspections of active substance manufacturers in third countries
 - Pilot exchange inspection schedules and results active substances in third countries
 - Dedicated production facilities for certain medicines on risk-based approach, revision EU guideline











- EMEA and FDA

- Biomarkers development and validation
- Cooperation in the field of veterinary medicinal products













- Industry has been cautious on sharing information with regulators on genomics
- Workshops at the EMEA
- EMEA introduced concept "safe harbour" to facilitate exchanges
- Done through Pharmacogenomics Working Party
- Involving also experts from Academia













- Pooled data from different companies
- Critical mass of scientific information
- Submission to both agencies
- Strong collaboration with FDA
- Joint evaluation
- At ICH level
 - Terminology
 - Format submission data











- Pilot experience
- EMEA/FDA conclusion
 - Renal biomarkers submitted are acceptable in the context of non-clinical development for detection acute drug-induced renal toxicity
 - Added value to currently available standards
 - Use of renal biomarkers in clinical trials caseby-case basis to gather further data











- Final report public consultation until June 2008
- Introducing new routine scientific advice, methodology and qualification procedure April 2008
- Publication on EMEA website of a Guidance to Applicants for procedure on Biomarkers Qualification for consultation until 30 June 2008





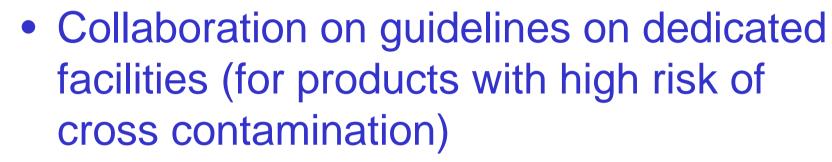
- EU-US Bilateral Technical Working Group on Human and Veterinary (Medicines Quality and Manufacturing)
 - Meeting EU/FDA October 2007
 - Terms of reference adopted
 - Quarterly meetings (video/teleconferences)





- Pilot joint inspections in US and EU for finished products
- Pilot joint inspections outside EU/US for active substances (APIs)
- Pilot exchange of inspection schedules and results
 - Risk based approach/high risk products
 - Sites of interest
 - No duplication and more effective use of resources
 - Higher safety level for products coming from third countries





- Revision of the EU GMP guidance
- FDA guidance for penicillins/cephalosporins
- Risk based approach













- Within the framework of administrative simplification
- No duplication
- Risk based approach
- Equivalent GMP standards/mutual confidence
- Coordination inspection planning
- Based on EMEA yearly planning centralised
- Templates to be prepared





- Pilot programme for APIs
 - Agreement to share inspection plans
 - Coordination/collaboration on sites of inetrest
 - Possible joint inspections
 - Greater transparency from manufacturers
 - Risk based approach
- EMEA access to COMSTAT
- EudraGMP
 - Access for FDA on going
 - Includes module for sharing inspection plans





- Other projects
 - Already on going (parallel scientific advice, paediatrics)
 - To be further developed (risk management plans, biologicals/biosimilars, counterfeits)
 - To start (advanced therapies, herbal medicinal products)
- Publication of the action plan





- The transatlantic administrative simplification project has been built on
 - Confidence
 - Experience due to daily exchanges
 - Commitment from both parties
- Results to be regularly published within the TEC umbrella