Challenges and opportunities for Croatia

13-14 November 2008

Transatlantic simplification of administrative procedures

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Bilateral arrangements

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

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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

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- 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

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- Some outcomes
  - Quarterly reports on on-going procedures
  - Safety information
    - Systematic safety warnings before each CHMP meeting
    - 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**

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  - Clusters
    - Already: oncology, vaccines, orphans, paediatrics, pharmacogenomics
    - On going: advanced therapies, central nervous system, diabetes
  - Common orphan designation forms
  - Exchange of staff
  - General information
  - Face to face meetings once a year

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

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EU/Health Canada arrangement

- Signed in December 2007
- Implementation plan still on going
- Will be probably very similar to the FDA
- Exchanges already in place

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Transatlantic Administrative Simplification

- Built on successful bilateral cooperation EU/FDA
- Political support of the Transatlantic Economic Council (TEC)
- Workshop November 2007
- List of possible deliverables
- Action Plan to be prepared

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- 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

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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)

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

- Methodology
  - Identification opportunities for administrative simplification
  - Proposals for possible deliverables
    - Bilateral work (confidentiality arrangements)
    - Multilateral work (e.g. ICH)
    - Careful selection on unnecessary burden on administrative practices
    - Legal/practical considerations
  - Publication of an action Plan

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

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Action Plan

- Original long list shortened
- ICH topics to be pursued under ICH umbrella (4 projects mainly related to CTD)
- 14 projects
  - Specified deliverables
  - Realistic deadlines
  - EU/FDA lead persons
- Published 18 June 2008

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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

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

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Biomarkers

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

- Industry collecting important amount data
- 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

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- First common EMEA-FDA acceptance to qualify the use of 7 biomarkers
- 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 case-by-case basis to gather further data

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- 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
- Comments will be taken into account

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Quality and Inspection

- 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)

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- Specific targets agreed
  - 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

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- Collaboration on guidelines on dedicated facilities (for products with high risk of cross contamination)
  - Revision of the EU GMP guidance
  - FDA guidance for penicillins/cephalosporins
  - Risk based approach
- EMEA access to COMSTAT
- EudraGMP
  - Access for FDA on going
  - Includes module for sharing inspection plans

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Other Projects

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

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Pilot programme for APIs

- Within this framework but including more participants (Canada, Australia)
- Agreement to share inspection plans
- Coordination/collaboration on sites of inetrest
- Possible joint inspections
- Greater transparency from manufacturers
- Risk based approach

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Conclusion

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