Strengthening of expert capacity in implementation of EU legislation on medicines in the Croatian Agency for Medicinal Products and Medical Devices

The European Union's IPA 2007 programme

MANUAL

for BC

assessors

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MANUAL FOR BC ASSESSORS

The *Manual for BC assessors* is prepared as a result of Twinning light project: "Strengthening of expert capacity in implementation of EU legislation on medicines in the Croatian Agency for Medicinal Products and Medical Devices", funded by The European Union and implemented by Spanish Agency of Medicines and Medical Devices (AEMPS). The goal of this project was to strengthen the evaluation and quality control of medicinal products for human use in line with European standards. As BC (Beneficiary Country) is Croatia, it is obvious that the intention of the manual is to be used by Croatian experts, who are in charge of assessing medicinal products in pre- and post-registration phases.

The structure of the Manual was agreed between twinning partners (HALMED and AEMPS). It contains (in Part I) Introduction, Twinning light project fiche, List of contact persons and List of abbreviations used in presentations; (in Part II) Materials of seminars and Workshop materials: Marketing authorisations [The European System for Medicinal products, Centralised Procedures: Organisational matters and Biosimilar MP, Medicinal Product Development: Scientific Advice, Working Parties and Related Groups, Quality Review of Documents: SmPC guideline, European Pharmaceutical Guidelines], Inspection and enforcement [Inspection and Enforcement Directorate, Quality System for Pharmaceutical Inspectorate, Training and Qualification of Inspectors, GMP Inspections Planning, a Risk Based Approach, Type of Inspections and Inspection Indicators, Inspection Procedure, International Organizations and coordination, Manufacturing / Importation Authorisations, Market Surveillance: Post-approval Market Surveillance, Post-Approval Market Surveillance: Sampling programmes, Market Surveillance, Basic Requirements for Medicinal Products: GMP and Quality Assurance, APIs – GMP Inspections, Good Laboratory Practice, Good Distribution Practices], Regulatory affairs [Regulatory Affairs Sector AEMPS: Internal Organization, European Regulatory Principles, Notice to applicants working group and regulatory guidelines medicinal products for human use, The Co-ordination Group for Mutual Recognition and Decentralised Procedures, Name Review Group, Common Technical Document (CTD), Legal Basis of Procedures, EU Procedures: MRP&DCP Pre-referrals & Repeat Use, Flow of Information, National Procedure, Parallel Import Applications, Validation EU Procedures: MRP&DCP, Key points during the validation phase, New Application - National Procedure, EU Tracking System for the coordination of the MR/DC procedures: CTS database, Spanish Data Base RAEFAR, Technical Requirements for New Applications, Fast track, Final documents of MA, Renewal of the MA, Sunset clause, CIMA (Webpage Database) Medicinal products online information center, MAH transfer, REGULATION (EC) No 1901/2006 on medicinal products for paediatric use, Worksharing according to Article 45/46, Article 29: use of the Referral Procedures of Regulation (EC) 1901/2006, Community Referrals in Human Medicines, COMMISSION REGULATION (EC) No 1234/2008, National Variations, Structure of the Guideline on the Details of the Various Categories, CTS Database Management: Post-authorisation procedures, RAEFAR variations regulation], Well-established use [Drug Advertising, Classification of Medicinal Products, Herbal Medicinal Products, (Traditional) Herbal Medicinal Products: Quality, Herbal Medicinal Products: WEU & Traditional Use, SmPc–Package leaflet –Labelling, Clinical Assessment of medicines with a "WEU", Spanish Pharmacovigilance System, Switching from Prescriptional MP to Non-prescriptional MP], Assessment on generics [European Pharmacopoeia, Active Substance Master File, CEP Procedure. Drug Substance, Validation of Analytical Procedures, Brief

Summary, Legislative framework, Scientific guidelines, European Pharmacopoeia, Manufacture of medicinal products, Process validation, Pharmaceutical development of medicinal products: Points for consideration, Quality assessment, Setting specifications for medicinal products. Points to consider in generic medicinal products, Stability testing of drug substances and medicinal products, New quality paradigm: Q8-9-10], Biological products: vaccines and sera [Clinical evaluation - Quality connection, Marketing Authorization Application: Module 3, Intradermal Influenza Vaccine (IDFlu/Intanza), Influenza vaccines, Guidelines, Thiomersal in vaccines, Vaccines: different aspects for discussion, The influenza vaccines, seasonal, pandemic and prepandemicon], Blood products [CJD and Blood products, Evaluation and Control of Blood Plasma Derived Medicinal Products, European legal documents on Blood Plasma Derived Medicinal Products (II), Plasma Master File (Legislative aspects), Practical assessment of a Plasma-derived product, Adventitious Agents Safety, Evaluation Viral Safety], Clinical and non-clinical [Seminar on clinical and non-clinical data of biologicals. Case studies on non-clinical and clinical documentation, Seminar on clinical and non-clinical data of biologicals. Case studies on non-clinical and clinical documentation, Seminar on clinical and non-clinical data of biologicals. Case studies on non-clinical and clinical documentation, Seminar on clinical and non-clinical data of biologicals. Case studies on non-clinical and clinical documentation, Scientific guidelines: Antineoplastic and immunomodulating agents, Respiratory System Guidelines (EMA)], Bioequivalence [EU legislation on generics, Principles of Interchangeability Testing, Design of Bioequivalence Studies, Regulatory requirements for BE and Existing Guidelines, Analytical Considerations, Statistical Considerations, Biowaivers, Biosimilars, Biosimilars quality issue, Biotech products: quality aspects]; and (in Part III) Annex: Twinning project final report [Twinning Contract number: HR/2007/IB/SO/01TL].

All incorporated materials of seminars and workshops were prepared by Spanish experts. A List of abbreviations (needed to understand the text with usual and some unusual abbreviations) was prepared in HALMED. The Manual has only one paper copy, stored in HALMED. Electronic version of all materials of seminars and workshops (near to five thousand pages), as prepared by Spanish experts, is on HALMED extranet. The users of Manual will benefit by finding in it all current procedures and practice for medicine authorisation. But, using the Manual, it is to bear in mind that it reflects regulations effective in the period of project implementation (December 2010 till June 2011).

A confidentiality declaration was applied during the project implementation dealing with medicinal products documentation, as usual. Consequently, Manual for BC assessors will be used by those Croatian experts who have signed statement of confidentiality as HALMED employees or contracted experts.