Annex 1

COMMON TECHNICAL DOCUMENT

Module 1: Administrative information

1.0 Cover Letter

1.1 Comprehensive Table of Contents

1.2 Application Form (Annex 1-1)

1.3 Product Information

1.3.1 SmPC, Labelling and Package Leaflet (also electronic versions in Microsoft Word format)

1.3.2 Mock-up (also electronic version in PDF)

1.3.3 Specimen

1.3.4 Consultation with Target Patient Groups /if available/

1.3.5 Product Information already approved in other countries

1.3.6 Braille /if available/

1.4 Information about the Experts

1.4.1 Quality

1.4.2 Non-Clinical

1.4.3 Clinical

1.5 Specific Requirements for Different Types of Applications

1.5.1 Information for Bibliographical Applications

1.5.2 Information for Generic, ‘Hybrid’ or Bio-similar Applications

1.5.3 (Extended) Data / Market Exclusivity /if available/

1.5.4 Exceptional Circumstances

1.5.5 Conditional Marketing Authorisation

1.6 Environmental Risk Assessment

1.6.1 Non-GMO

1.6.2 GMO

1.7 Information relating to Orphan Market Exclusivity

1.7.1 Similarity

1.7.2 Market Exclusivity /if available/

1.8 Information relating to Pharmacovigilance

1.8.1 Pharmacovigilance System

1.8.2 Risk-management System

1.9 Information relating to Clinical Trials

1.10 Information relating to Paediatrics

Additional Data

1.11 Manufacturing Authorisation(s) for all manufacturing sites involved in the manufacturing process of the medicinal product and the active substance issued by the competent authority of country of origin (original or verified copy).

1.12 GMP certificate(s) or other GMP statement(s) for all manufacturing sites involved in the manufacturing process of the medicinal product and the active substance issued by the competent authority of country of origin (original or verified copy).

1.13 Letters of access to Active Master File(s) or copy of Ph. Eur. Certificate(s) of suitability. Ph. Eur. Certificates of suitability for TSE.

1.14 Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications.

1.15 Written consent(s) of the competent authorities regarding GMO release in the environment.

1.16 Marketing Authorisation or Certificate of Pharmaceutical Product (CPP) or Registration certificate issued by the competent authority either of country of origin or the country of Marketing authorization holder (original or verified copy).

1.17 Worldwide registration status: Copies of Marketing Authorisations or tabular listing (marketing authorization number, date of authorization, country, trade name and etc.).

1.18 Information on patent protection (including Armenia).

1.19 Information on trade mark protection (including Armenia).

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2.5 Clinical Overview

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2.6.5 Pharmacokinetics Tabulated Summary

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2.6.7 Toxicology Tabulated Summary

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3.2.1.2.5 Process Validation and/or Evaluation

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