REG-89 version 3 Documents Attached to Marketing Authorisation Renewal Applications

This Guideline supersedes guideline REG-89 version 2 with the effect from April 5 2016.

INTRODUCTION

This instruction aims to define the scope of information and documents submitted to the State Institute for Drug Control ("Institute") along with applications for the renewal of the marketing authorisations for medicinal products authorised via national procedure.

LEGISLATIVE FRAMEWORK

Under Section 32(2) of Act No. 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Associated Acts (Act on Pharmaceuticals), as amended ("Act on Pharmaceuticals"), the marketing authorisation is valid for five years of its effective date. Section 34(1) of the Act on Pharmaceuticals stipulates that the Institute may renew the marketing authorisation after the five years on a review of the benefit/risk ratio. The application for the renewal of the marketing authorisation should be filed **no later than 9 months prior to the expiry of the marketing authorisation**; therefore, the Institute shall suspend any marketing authorisation renewal applications submitted after that date. The validity of a medicinal product's marketing authorisation will thus cease to exist upon the expiry of the marketing authorisation unless an application for the renewal of its validity is submitted within the statutory period of time.

The marketing authorisation holder shall provide, along with the application, a consolidated version of the file in respect of **quality, safety and efficacy** including an evaluation of data contained in suspected adverse reaction reports, Periodic Safety Update Report (PSUR) data (if applicable) and any relevant new information affecting the benefit/risk of the product together with a list of all variations introduced since the marketing authorisation was granted. Section 11 of Regulation No. 228/2008 Coll., on Marketing Authorisation of Medicinal Products, as amended ("Marketing Authorisation Regulation"), sets out the **scope of information and documentation attached to the marketing authorisation renewal application with the reference to the guideline of the Institute**, which means this document. For renewal applications submitted after September 1, 2013 has to be attached the documentation that complies with the requirements, set out herein.

Once the marketing authorisation is renewed one time under the Act on Pharmaceuticals, the marketing authorisation is valid for an unlimited period unless the Institute decides, on justified grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product, to proceed with one additional five-year renewal.

DOCUMENTATION REQUIREMENTS

The marketing authorisation holder shall ensure that the documentation for each authorised medicinal product be **kept up to date throughout the life cycle of the medicinal product by way of the variation procedures** when new information is found out, and that Summary of Product Characteristics, Package Leaflet and Labelling ("product information") are kept up to date with current scientific knowledge including the conclusions of assessments and recommendations made publicly available by means of the European medicines web-portal. Along with the marketing authorisation renewal application, the marketing authorisation holder shall provide a consolidated version of the file relating to the given medicinal product, containing at least the documents listed below. Further documentation should be made available from the marketing authorisation holder on request, if considered necessary to complete the benefit/risk assessment.

The requirements for the documents that are to be attached to the marketing authorisation renewal application are set out in the document CMDh BEST PRACTICE GUIDE ON THE PROCESSING OF RENEWALS IN THE MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES available online at http://www.hma.eu/95.html.

REQUIREMENTS FOR SUBMISSION OF DOCUMENTATION

1) The aforementioned documentation should be submitted **in electronic form, namely in the eCTD or NeeS format according to the requirements set out in the Guideline REG-84 in version valid at the date of submission of the application**.
2) If the documents are submitted on a CD/DVD carrier, the files may not zipped in line with the TIGes Harmonised Guidance for eCTD Submissions in the EU document.
3) **Original power of attorney or proxy**, unless submitted to the Institute previously, shall be submitted with the electronic documents.