



**MUTUAL RECOGNITION PROCEDURE**  
**(RMS: Hungary)**



**MRP CHECKLIST : Declaration on submitted documents**

This application form is to be used for an application for a marketing authorisation of a medicinal product for human use submitted to the National Institute of Pharmacy (NIP) under mutual recognition or decentralised procedure in which Hungary is the reference member state.

This form lists those documents and their format, which have to be submitted for the above application besides the requirements stated in the Notice to Applicants.

**A combined application form is acceptable for the different strengths of the medicinal product.**

**DECLARATION and SIGNATURE**

**Product (invented) name:**

**Applicant:**

**The following documents\* have been submitted to the NIP:**

- Letter of intent on the MRP(RMS) procedure (product, proposed timetable)
- Request for the MRP(RMS) procedure
- Request for the preparation of the Assessment Report
- SmPC<sup>1</sup>
  - Product with MA: The loan translation of the valid Hungarian SmPC (according to the SmPC guideline\*\*).
  - Product without MA: The loan translation of the proposed Hungarian SmPC (according to the SmPC guideline\*\*).
- Nonclinical Overview<sup>1\*\*</sup>
- Clinical Overview<sup>1\*\*</sup>
- Nonclinical Summaries<sup>1\*\*</sup>
- Clinical Summaries<sup>1\*\*</sup>
- PSUR (product with MA)<sup>1</sup>
- Modul 4<sup>1</sup>
- Modul 5<sup>1</sup>
- Quality Overall Summary<sup>1</sup>
- Composition<sup>1</sup>
- Specifications: active substance, product<sup>1</sup>
- Flow chart of the manufacturing process<sup>1</sup>
- Readability testing<sup>1</sup>
- PIL<sup>1</sup>
- Labelling<sup>1</sup>
- EudraLink Access<sup>2</sup>

Please check the attachments for details.

It is hereby confirmed that all documentations checked in the list above have been submitted to the NIP.

It is hereby confirmed that fees\*\*\* for the MRP(RMS) will be paid according to the national rules\*\*.

On behalf of the applicant

\_\_\_\_\_  
Signature(s)

\_\_\_\_\_  
NAME

\_\_\_\_\_  
Function

\_\_\_\_\_  
Place

\_\_\_\_\_  
date (yyyy-mm-dd)

<sup>1</sup> (English; electronic format; text can be selected, copied and pasted)

<sup>2</sup> not mandatory; access can be ordered from EMEA: [Eudralink@emea.eu.int](mailto:Eudralink@emea.eu.int)

\* Without the documents (excluding the letter of intent) listed the NIP cannot prepare the Assessment Report.

\*\* Note: Requirements, guidelines can be found on the Notice to Applicants' website:

<http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm>

A short guidance document about writing bioequivalence expert reports to generic application is available upon request.

\*\*\* Note: if fees have been paid, attach proof of payment - see information on fee payments in the Notice to Applicants, Volume 2A, chapter 7 and [Decree No. 32/2005. \(VIII.11.\)](#) EüM. of the Minister of Health on fees to be paid