RENEWALS IN THE MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES (MRP/DCP) – DOCUMENTS REQUIRED

Module 1:		
1.0	☐	Cover letter (**original signature required***)
1.1	☐	Comprehensive table of contents
1.2	☐	Renewal Application form (**original signature required***) with the following annexes:
	☐	List of all authorised product presentations for which renewal is sought, in tabular format
	☐	Details of contact persons: • Qualified person in the EEA for pharmacovigilance • Contact person in the EEA with the overall responsibility for product defects and recalls • Contact person for scientific service in the EEA in charge of information about the medicinal product
	☐	List of EU Member States/Norway/Iceland where the product is on the market and indicating for each country which presentations are marketed and the launch date
	☐	Chronological list of all post-authorisation submissions since granting of the MA or last renewal: a list of all approved or pending Type IA & Type IAIN, Type IB and Type II variations, Extensions, Art 61(3) Notifications, and PSURs giving the procedure number (where applicable), date of submission, date of approval (if approved) and brief description of the change
	☐	Chronological list of conditions/post-authorisation commitments submitted since granting of the MA or last renewal indicating scope, status, date of submission and date when issue resolved (where applicable)
	☐	A revised list of all remaining conditions (where applicable)
	☐	A certificate of GMP compliance, not more than three years old, for the manufacturer(s) of the medicinal product listed in the application issued by an EEA competent authority or MRA partner authority. A reference to the Community EudraGMDP database, if available, will suffice
	☐	For manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out indicating the date, inspection team and outcome
		In accordance with Article 46(f) of Directive 2001/83/EC manufacturing authorisation holders (i.e. located in the EEA) are required to use as starting materials only active substances which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials as adopted by the Union. The following declarations are required:
	☐	• A declaration by the Qualified Person (QP) of each of the manufacturing authorisation holders listed in the application form where the active substance is used as a starting material.

	☐	• A declaration by the Qualified Person (QP) of the manufacturing authorisation holder(s) listed in the application as responsible for batch release.
		These declarations should state that all the active substance manufacturer(s) referred to in the application form operate in compliance with the detailed guidelines on good manufacturing practice for starting material.
1.3	☐	Current Summary of Product Characteristics (English version)
	☐	Current Labelling (English version)
	☐	Current Package Leaflet (English version)
	☐	Proposed Summary of Product Characteristics (English version) clean and highlighted version *(applicable only for expanded renewals)*
	☐	Proposed Labelling (English version) clean and highlighted version *(applicable only for expanded renewals)*
	☐	Proposed Package Leaflet (English version) clean and highlighted version *(applicable only for expanded renewals)*
1.4		Information about experts:
	☐	• Information about the Expert – Quality (incl. Signature + CV)
	☐	• Information about the Expert – Non-Clinical (incl. signature + CV) – if applicable
	☐	• Information about the Expert – Clinical (incl. Signature + CV)
1.8.2	☐	Updated Risk Management Plan (if requested by the RMS) *(applicable only for expanded renewals)*

Module 2		
2.3	☐	Addendum to the Quality Overall Summary with: • declaration of compliance with Directive 2001/83/EC which obliges the MAH to take account of technical and scientific progress and introduce any changes that may be required to enable the medicinal product to be manufactured and checked by means of generally accepted scientific methods • confirmation that all changes relating to the quality of the product have been made following applications for variations and that the product conforms to current CHMP Quality guidelines • confirmation of currently authorised specifications for the active substance and the finished product (with date of latest approval and procedure number) • qualitative and quantitative composition in terms of the active substance(s) and the excipient(s) (with date of latest approval and procedure number)
2.4	☐	Addendum to the Non-Clinical Overview (if applicable)

2.5	☐	Addendum to the Clinical Overview with: • confirmation that no new clinical (or pre-clinical data in the absence of a non-clinical overview) are available which changes or results in a new benefit/risk evaluation. Where there are new pre-clinical data, the MAH should submit a non-clinical expert report as appropriate • confirmation that the product can be safely renewed at the end of a 5-year period for an unlimited period, or any action recommended or initiated should be specified and justified • confirmation that the authorities have been kept informed of any additional data significant for the assessment of the benefit/risk balance of the product concerned • confirmation that the product information is up to date with current scientific knowledge including the conclusions of assessments and recommendations made publicly available on the European medicines web-portal In cases where the benefit/risk balance of the medicinal product is questioned by the member states, additional clinical documentation can be required.

ADDITIONAL DOCUMENTS REQUIRED		
1.	☐	Proof of payment
2.	☐	Proof of establishment – an extract from the relevant register of entrepreneurs identifying the person authorised to represent the Marketing Authorisation Holder.
3.	☐	Power of attorney – a letter of authorization for contact person to act on behalf of the Marketing Authorisation Holder (**original signature required***). The power of attorney or commercial power of attorney shall be accompanied by a proof of payment of stamp duty.
4.	☐	Commitment to update the product information by the appropriate variation within 3 months of the finalisation of the renewal, if product information is not up to date (**original signature required***). *(applicable only for standard renewals).*

DOCUMENTS THAT WILL IMPROVE PROCESSING OF THE RENEWAL APPLICATION – NOT REQUIRED DOCUMENTS		
1.	☐	Copy of marketing authorisation and all decisions concerning variations in marketing authorization granted in Poland.
2.	☐	Copy of manufacturing authorisations for all manufacturers listed in renewal application or reference to the Community EudraGMP database.
3.	☐	Flow-chart

*** Original signature required** – it means that the document should be signed with an electronic qualified signature (as defined in regulation EU No 910/2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC) or

trusted signature (signature related to the Polish platform of public administration services ePUAP), or handwritten signature. If a document in eCTD is a copy of the document signed with a handwritten signature, the MAH should additionally submit the paper document signed with an original handwritten signature.

All documents should be prepared in English or translated into English.
All documents should be submitted via CESP in eCTD format.
Submitting documentation in any other way (e.g. via Eudralink, email) is unacceptable.

Proof of payment (**PoP**) for renewal application should include in the description:
152 PL/DZL/ZLR *MA number, EU procedure number*

Bank account number for renewal application fees:
Domestic transfer:
NBP O/O Warszawa: 30 1010 1010 0094 1022 3100 0000

International transfer:
Narodowy Bank Polski
00-950 Warszawa, Plac Powstańców Warszawy 4
PL30 1010 1010 0094 1022 3100 0000
BIC code: NBPLPLPW

Stamp duty shall be paid for submission of a power of attorney or commercial power of attorney. Stamp duty should be paid to the bank account of the competent tax authority (Warsaw City Hall).

Bank account number for **domestic transfers for stamp duty**:
Urząd Miasta Stołecznego Warszawy
Centrum Obsługi Podatnika
21 1030 1508 0000 0005 5000 0070

Bank account number for **international transfers for stamp duty**:
Urząd Miasta Stołecznego Warszawy
Centrum Obsługi Podatnika
PL21 1030 1508 0000 0005 5000 0070
SWIFT code: CITIPLPX