DOCUMENTI DA ALLEGARE ALLA DOMANDA DI RINNOVO

(ANNEX 2 - Cmdh Best Practice Guide on the processing of Renewals in the Mutual Recognition and Decentralised Procedures - *CMDh/004/2005/Rev.13 November 2015* - applicabile anche alle Procedure Nazionali come previsto dalla Circolare esplicativa del 20/05/2013)

MODULO 1			
1.0	Cover letter	La domanda: - deve essere firmata in originale - sulla stessa deve essere apposta e annullata la marca da bollo - deve essere allegata la ricevuta del POL relativa al versamento della tariffa.	Avviso alle Aziende farmaceutiche del 26/06/2013 - Rideterminazione valore marche da bollo Avviso alle Aziende Farmaceutiche del 27/06/2013 - Nuova piattaforma Sistema di versamento tariffe e Nuovi conti correnti per AIFA e Ministero della Salute Avviso alle Aziende Farmaceutiche del 28/03/2013 - Aggiornamento degli importi delle tariffe e dei diritti per le prestazioni rese a richiesta ed a utilità dei soggetti interessati a seguito entrata in vigore Decreto del Ministero della Salute 21 dicembre 2012 (GU 15/03/2013)
1.1	Comprehensive table of content		
1.2	Renewal Application Form with the following annexes:	Per le procedure Nazionali e Mutuo Riconoscimento IT RMS Renewal Application Form deve essere firmata in originale	Modulo Renewal Application Form : NOTICE TO APPLICANTS – VOLUME 2 C - Application form for renewal of a marketing authorisation (June 2015)

	A list of all authorised product presentations for which renewal is sought in tabular format		
	Details on contact persons: ▪ Qualified person in the EEA for Pharmacovigilance ▪ Contact person in the EEA with 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 grant of the Marketing authorisation or last renewal: a list of all approved or pending Type IA/IB and Type II variations, Extensions, Art 61(3) Notifications, USR and PSUR, 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 the granting of the MA or the 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 statement, or when available, 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 EudraGMP database, if available, will suffice	Per le procedure Nazionali e Mutuo Riconoscimento IT RMS i Certificati GMP (eccetto quelli delle officine italiane) devono essere originali o copie conformi	
	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 by other authorities indicating the date, inspection team and outcome	Per le procedure Nazionali e Mutuo Riconoscimento IT RMS i Certificati GMP (eccetto quelli delle officine italiane) devono essere originali o copie conformi	
	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.	Per le procedure Nazionali e Mutuo Riconoscimento IT RMS le dichiarazioni della QP devono essere firmate in originale	La dichiarazione della Q.P. deve essere fatta secondo il nuovo template pubblicato sul sito dell'EMA (in vigore da giugno 2014) - ***Qualified Person's declaration concerning GMP compliance of the active substance manufacture "The QP declaration template"*** **(** 21 May 2014 EMA/334808/2014 Compliance and Inspections Department)

	- 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 materials.		
1.3	Product Information : Summary of Product Characteristics, Labelling and Package Leaflet A relevant example of the proposed texts for SmPC, outer and inner labelling and Package Leaflet in English has to be provided with any proposed changes (highlighted)		
1.4	Information about the expert		
1.4.1	Quality (incl. Signature + CV)	Per le procedure Nazionali e Mutuo Riconoscimento IT RMS il modulo 1.4.1 deve essere firmato in originale (NTA, Vol. 2B-CTD, Module 1 - May 2008)	
1.4.2	Non-clinical (incl. Signature + CV) – where applicable	Per le procedure Nazionali e Mutuo Riconoscimento IT RMS il modulo 1.4.2 deve essere firmato in originale (NTA, Vol. 2B-CTD, Module 1 - May 2008)	
1.4.3	Clinical (incl. Signature + CV)	Per le procedure Nazionali e Mutuo	

		Riconoscimento IT RMS il modulo 1.4.3 deve essere firmato in originale (NTA, Vol. 2B-CTD, Module 1 - May 2008)	
1.8.1	Summary of Pharmacovigilance System Master File (PSMF)	Il richiedente/titolare di AIC può unire le informazioni in una singola dichiarazione, firmata in originale dal richiedente/titolare dell'AIC e QPPV.	Domande e risposte a supporto dell'applicazione della legislazione di farmacovigilanza
1.8.2	Risk Management Plan (RMP) (where applicable)		
MODULO 2			
2.3	Addendum to Quality Overall Summary		
2.4	Addendum to Non-clinical Overview –(where applicable)		
2.5	Addendum to Clinical Overview		

A seguito della Circolare Esplicativa AIFA del 20/05/2013 relativa all'Attivazione nuova piattaforma web per rinnovi AIC per i medicinali autorizzati con procedura nazionale e di Mutuo Riconoscimento (con IT-RMS e IT-CMS) tutte le domande di rinnovo devono essere inserite dalle Aziende titolari di AIC collegandosi al seguente link (https://www.agenziafarmaco.gov.it/frontend/)