STATEMENT OF COMPLIANCE OF THE TRANSLATION
OF MARKETING AUTHORISATION ANNEXES
(FROM A MUTUAL RECOGNITION OR DECENTRALISED PROCEDURE)
Annotated version

Subject: European procedure number:	[To be completed] • **Initial MA:** number of the initial MA procedure or the repeat-use procedure if applicable *Note*: in the event of a simultaneous request for notification of the initial MA + post-marketing variations: indicate the number of the last approved variation and indicate the initial MA in the table on page 4 • **MA variation**: procedure number of the last approved variation amending the annexes *Notes*: ▪ if other variations exist that have been approved AND not yet notified, indicate these in the table on page 4 ▪ in the event of worksharing (WS): indicate the common WS procedure number + the number of the proprietary medicinal product(s) concerned • **MA renewal** if the annexes are changed: renewal procedure number **N.B.:** ➢ Variations that do not impact the annexes or that do not concern the MA in France are not subject to a translation submission ➢ Renewals with no impact on the annexes are not subject to submission of the translation alone. They may be notified at the next request for translation of a variation impacting the annexes and should be indicated in the table on page 4 ➢ submit one single undertaking for several strengths (NL) of the same product line
Name, strength, pharmaceutical form of the medicinal product	[To be completed] • **Initial MA**: Name accepted in France, during the validation phase or procedure or, otherwise, by email from the scientific and regulatory coordinating assessor • **MA variation**: Name in France
NL number	[To be completed] • **Initial MA**: if communicated during the validation phase, the NL number of the medicinal product concerned • **MA variation**: the NL number of the medicinal product concerned **N.B.**: indicate all the NL numbers when several strengths of the same product line are concerned by the same application (also see note above)
C.I.S. code	[To be completed] • **Initial MA**: if communicated during the validation phase • **MA variation**: the CIS number of each medicinal product concerned

Name of medicinal product, strength, pharmaceutical form	To be completed
NL number	To be completed

Subject of the application	[Check as appropriate] ☐ Initial MA ☐ MA variation ☐ Renewal **N.B.:** ➢ The application must relate to the last procedure approved by the RMS ➢ in the event of a simultaneous request for notification of the initial MA + post-marketing variations: check ☒ MA variation
Type, code and wording of the application	[To be completed in French] • **Initial MA**: N/A • **MA variation**: variation type (IA, IB, II), code of the last approved variation* WITH the detailed wording that figures in the application form, in French. *Note:* in the event of grouping: specify all the changes concerned. • **Renewal:** N/A *variation code as per the guidelines https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-2/c_2013_2008/c_2013_2008_pdf/c_2013_2804_fr.pdf
Date of submission of the application to the ANSM *(date of cover letter)*	[To be completed DD/MM/YYYY] Date of submission of the initial application (cover letter) (initial MA, OR last MA variation OR renewal with changes to annexes)
Date of approval by the RMS *(end of procedure date)*	[To be completed DD/MM/YYYY] Date indicated in the end of procedure letter from the RMS
In the event of renewal, specify: ☐ Unlimited renewal ☐ Limited renewal (five-year)	Common renewal date: [To be completed DD/MM/YYYY] **N.B.:** Only concerns renewals with changes to the annexes*, with the exclusion of MAs under exceptional circumstances (two-yearly renewal). *renewals with no impact on the annexes are not subject to submission of the translation alone. They may be notified at the next request for translation of a variation impacting the annexes and should be indicated in the table on page.4

I, the undersigned: [To be completed]
in my capacity as: [To be completed]

(*check where appropriate*)

☐ certify that the French translation of the Summary of Product Characteristics (SmPC), package leaflet and labelling for the abovementioned medicinal product is a true and accurate translation of the English texts approved following the above-referenced procedure. Any deletions, modifications or additions to the approved English texts must be duly justified in the area provided for this purpose.

☐ certify that the translation submitted to the ANSM was produced in accordance with all the recommendations of the "*Best Practice Guide on the submission of high quality national translations*" of the Coordination Group for Mutual Recognition and Decentralized Procedures (CMDh) (http://www.hma.eu/90.html).

☐ certify that the four MA annexes are provided in full and are in the currently applicable "*QRD template*" form and in Word, in the style sheet format in force at the ANSM.

Name of medicinal product, strength, pharmaceutical form	To be completed
NL number	To be completed

☐ certify that the terms in annex II proposed by the applicant/holder comply with the requirements mentioned in the European final assessment report approved at the end of the procedure, in particular the terms of this annex relative to:
- submission of PSURs,
- the risk management plan,
- additional risk mitigation measures (ARMM),
- any MA conditions stipulated following the assessment

☐ **if applicable**, certify that the information relative to renewal complies with the terms of the European final assessment report.

☐ **if applicable**, certify that, in the context of compliance with intellectual property rights, proposals to remove information in the translated texts, thereby leading to a difference compared to the approved English texts, will be clearly indicated.

☐ certify that the appended summary sheets have been duly completed.

The undersigned is responsible for the accuracy and truthfulness of this undertaking and for compliance with it.

[Signature, family name and first name in capital letters, title/position]
Date:

N.B.: statement dated and signed by the MA holder or the Head Pharmacist (or the Pharmacist delegated by the Head Pharmacist for the purpose of signing this statement) within the operating pharmaceutical establishment when the operation is carried out on behalf of the holder pursuant to Article R. 5124-2 3° of the French Public Health Code.

Name of medicinal product, strength, pharmaceutical form	To be completed
NL number	To be completed

List of previous APPROVED* procedures, submitted to the ANSM but not yet notified on the date of the statement**

*In chronological order of approval dates - only variations impacting the annexes and renewals with or without an impact on the annexes
**Indicate "NA" (not applicable) in the absence of any pending notifications

EU procedure number	Subject of the application	Date of submission of the application to the ANSM	Date of approval by the Reference Member State (RMS)	For renewal procedures, specify the Common renewal date
Variation procedure number	Variation code* WITH the detailed wording that figures in the application form, *variation code as per the guidelines https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-2/c_2013_2008/c_2013_2008_pdf/c_2013_2804_fr.pdf	Date of the initial application (cover letter): date of submission of the initial MA application OR MA variation OR renewal with or without changes to annexes	**Mandatory** indicated in the end of procedure letter from the RMS	**Mandatory** indicated in the end of renewal procedure letter from the RMS
NA	Transfer of holder from… to …	Date of the application	- CESP number and date of submission - Application reference (if communicated)	
NA	Change of operator from... to…	Date of the application	- CESP number and date of submission - Application reference (if communicated)	

In the event of request for notification of a transfer of holder and/or change of operator, specify the CESP number and the submission date. (Also indicate the application reference it has been communicated to you and attach the approval email sent by the ANSM)

Note: if applicable, in the event of a parallel change in the name of the medicinal product related to the transfer and/or change of operator, it is necessary to wait until this change of name has been approved before submitting the translation.

Name of medicinal product, strength, pharmaceutical form	To be completed
NL number	To be completed

Justification of any deletions, modifications or additions compared to the approved English texts:

Removal of information protected by intellectual property rights for the reference medicinal product:

[Check as appropriate] **Mandatory**
☐ YES ☐ NO

Other changes compared to the English text (to be specified):

Specify worksharing cases including national medicinal products

Name of medicinal product, strength, pharmaceutical form	To be completed
NL number	To be completed

Information to be completed only for initial MA applications

List of manufacturers of the active substance(s)
Completion mandatory

Name of the active substance	**Active substance production site(s)** ***(excluding intermediate substances)***	**ASMF / CEP in force**	**If applicable, last approved variation**
Name of the active substance in French	Address(es) of effective sites of the active substance manufacturer(s)	[Check as appropriate] ☐ YES ASMF No. [To be completed] CEP No. [To be completed] ☐ NOT APPLICABLE	

Name of the medicinal product

Name validated by the ANSM (*attach supporting document*)**:** [To be completed]

Mandatory: the translation should only be submitted if you can provide the supporting document indicating the name accepted in France, during the validation phase or procedure or, otherwise, by email from the scientific and regulatory coordinating assessor.
In the absence of a supporting document, the translation must not be submitted. It is necessary to contact the scientific and regulatory coordinating assessor having handled the procedure before submitting the translation.

Additional information

Legal basis ☐ generic ☐ hybrid

Reference medicinal product (in the context of a generic or hybrid medicinal product): [to be specified (NAME and CIS code)]

Presentations scheduled for marketing in France (for allocation of CIP codes): [list]
List the desired pack sizes for the medicinal product(s) subject to the present translation submission

Name of medicinal product, strength, pharmaceutical form	To be completed
NL number	To be completed

Summary list of essential documents to be provided

☐	The **consolidated four annexes of the MA in full**, in French: Summary of Product Characteristics (Annex I), Annex II, labelling (Annex IIIA) and package leaflet (Annex IIIB) compliant with the style sheet in force. If applicable, use the latest **secure file** sent by the ANSM.
☐	End of procedure approval email from the RMS (forwarded, with all attachments)
☐	If applicable, copy of the ANSM's approval relative to the name of the medicinal product

Name of medicinal product, strength, pharmaceutical form	To be completed
NL number	To be completed

Summary list of headings modified* compared to the last text notified by the ANSM**
(Completion mandatory)

* Check all the headings of the French annexes changed since the last notified version, except for editorial changes; these must be highlighted in a different colour or comment in the annexes in *tracked* form.

**Not applicable for initial MAs

Check	Annex I / SmPC	
☐	1.	NAME OF THE MEDICINAL PRODUCT
☐	2.	QUALITATIVE AND QUANTITATIVE COMPOSITION
☐	3.	PHARMACEUTICAL FORM
	4.	CLINICAL PARTICULARS
☐	4.1.	Therapeutic indications
☐	4.2.	Posology and method of administration
☐	4.3.	Contraindications
☐	4.4.	Special warnings and precautions for use
☐	4.5.	Interaction with other medicinal products and other forms of interaction
☐	4.6.	Fertility, pregnancy and lactation
☐	4.7.	Effects on ability to drive and use machines
☐	4.8.	Undesirable effects
☐	4.9.	Overdose
	5.	PHARMACOLOGICAL PROPERTIES
☐	5.1.	Pharmacodynamic properties
☐	5.2.	Pharmacokinetic properties
☐	5.3.	Preclinical safety data
	6.	PHARMACEUTICAL PARTICULARS
☐	6.1.	List of excipients
☐	6.2.	Incompatibilities
☐	6.3.	Shelf life
☐	6.4.	Special precautions for storage
☐	6.5.	Nature and contents of container
☐	6.6.	Special precautions for disposal and other handling
☐	7.	MARKETING AUTHORISATION HOLDER
☐	8.	**MARKETING AUTHORISATION NUMBER(S)**
☐	11.	DOSIMETRY
☐	12.	INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS
check	**General classification for supply**	
☐		**General classification for supply**
Check	**Annex II**	
☐	A.1	Name and address of the manufacturer(s) of the biological active substance(s)
☐	A.2	Name and address of the manufacturer(s) responsible for batch release
☐	B	**CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
☐	C	**OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**
☐	D	CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT
☐	E	SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION “UNDER EXCEPTIONAL CIRCUMSTANCES”
☐	F	QUALITATIVE AND QUANTITATIVE EXCIPIENT COMPOSITION

Name of medicinal product, strength, pharmaceutical form	To be completed
NL number	To be completed

Check	Annex IIIA / Labelling	
		PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING
☐		NATURE/TYPE Outer packaging or Immediate packaging
☐	1	NAME OF THE MEDICINAL PRODUCT
☐	2	STATEMENT OF ACTIVE SUBSTANCE(S)
☐	3	LIST OF EXCIPIENTS
☐	4	PHARMACEUTICAL FORM AND CONTENTS
☐	5	METHOD AND ROUTE(S) OF ADMINISTRATION
☐	6	SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN
☐	7	OTHER SPECIAL WARNING(S), IF NECESSARY
☐	8	EXPIRY DATE
☐	9	SPECIAL STORAGE CONDITIONS
☐	10	SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE
☐	11	NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
☐		Holder
☐		Operator (“exploitant”)
☐	12	**MARKETING AUTHORISATION NUMBER(S)**
☐	14	**GENERAL CLASSIFICATION FOR SUPPLY**
☐	15	INSTRUCTIONS ON USE
☐	16	INFORMATION IN BRAILLE (article R. 5121-138 French Public Health Code)
☐	17	UNIQUE IDENTIFIER – 2D BARCODE
☐	18	UNIQUE IDENTIFIER – HUMAN READABLE DATA
☐		PICTOGRAM TO APPEAR ON THE OUTER PACKAGING OR, IN THE ABSENCE OF OUTER PACKAGING, ON THE IMMEDIATE PACKAGING - Teratogenic or foetotoxic effects (article R. 5121-139 of the French Public Health Code) - Ability to drive (article R. 5121-139 of the French Public Health Code)
☐		MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
☐		MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Check	Annex IIIB / Package leaflet	
☐		Name of the medicinal product
☐		Boxed text
☐		What is in this leaflet
☐	1	WHAT IS xxx AND WHAT IT IS USED FOR
☐		Pharmacotherapeutic group
	2	WHAT YOU NEED TO KNOW BEFORE YOU <TAKE> <USE> xxx
☐		Do not <take> <use> xxx
☐		Warnings and precautions
☐		Children <and adolescents>
☐		Other medicines and xxx
☐		xxx with <food> <and> <,> <drink> <and> <alcohol>
☐		Pregnancy <and> <,> breast-feeding <and fertility>
☐		Driving and using machines
☐		xxx contains {name the excipient(s)}

Name of medicinal product, strength, pharmaceutical form	To be completed
NL number	To be completed

Check	Annex IIIB / Package leaflet	
☐	3	HOW TO <TAKE> <USE> xxx
☐		<Use in children <and adolescents>>
☐		<If you <take> <use> more xxx than you should:>
☐		<If you forget to <take> <use> xxx:
☐		<If you stop <taking> <using> xxx:
☐	4	POSSIBLE SIDE EFFECTS Description of side effects
☐		<Additional side effects in children <and adolescents>>
☐	5	HOW TO STORE xxx
	6	CONTENTS OF THE PACK AND OTHER INFORMATION
☐		What xxx contains
☐		What xxx looks like and contents of the pack
☐		Marketing Authorisation Holder
☐		Marketing Authorisation Operator (“exploitant”)
☐		Manufacturer
☐		Names of the medicinal product in European Economic Area member states
☐		Other

Name of medicinal product, strength, pharmaceutical form	To be completed
NL number	To be completed