

TYPE IA and IB CHANGES (*Tick the appropriate change required*)

Copy of the relevant page(s) from the Guideline for this change is attached and the relevant boxes for conditions and documentations are ticked

Note:

- In case of a Type II application, delete the complete list of Type I changes below.
- In case of a Type I notification, delete those Type I changes which are not applicable.

	Main Change		consequential change ⁵	
	IA	IB	IA	IB
1 Change in the name and/or address of the marketing authorisation holder	<input type="checkbox"/>		<input type="checkbox"/>	
2 Change in the name of the medicinal product		<input type="checkbox"/>		<input type="checkbox"/>
3 Change in name of the active substance	<input type="checkbox"/>		<input type="checkbox"/>	
4 Change in the name and/or address of a manufacturer of the active substance where no Ph.Eur.Certificate of Suitability is available	<input type="checkbox"/>		<input type="checkbox"/>	
5 Change in the name and/or address of a manufacturer of the finished product	<input type="checkbox"/>		<input type="checkbox"/>	
6 Change in ATC Code				
a) Medicinal products for human use	<input type="checkbox"/>		<input type="checkbox"/>	
b) Medicinal products for veterinary use	<input type="checkbox"/>		<input type="checkbox"/>	
7 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product				
a) Secondary packaging site for all types of pharmaceutical forms	<input type="checkbox"/>		<input type="checkbox"/>	
b) Primary packaging site				
1. Solid pharmaceutical forms, e.g. tablets and capsules	<input type="checkbox"/>		<input type="checkbox"/>	
2. Semi-solid or liquid pharmaceutical forms		<input type="checkbox"/>		<input type="checkbox"/>
3. Liquid pharmaceutical forms (suspensions, emulsions)		<input type="checkbox"/>		<input type="checkbox"/>
c) All other manufacturing operations except batch release		<input type="checkbox"/>		<input type="checkbox"/>
8 Change to batch release arrangements and quality control testing of the finished product				
a) Replacement or addition of a site where batch control/testing takes place	<input type="checkbox"/>		<input type="checkbox"/>	
b) Replacement or addition of a manufacturer responsible for batch release				
1. not including batch control/testing	<input type="checkbox"/>		<input type="checkbox"/>	
2. including batch control/testing	<input type="checkbox"/>		<input type="checkbox"/>	
9 Deletion of any manufacturing site (including for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place)	<input type="checkbox"/>		<input type="checkbox"/>	
10 Minor change in the manufacturing process of the active substance		<input type="checkbox"/>		<input type="checkbox"/>
11 Change in batch size of active substance or intermediate				
a) Up to 10-fold compared to the original batch size approved at the grant of the marketing authorisation	<input type="checkbox"/>		<input type="checkbox"/>	
b) Downscaling	<input type="checkbox"/>		<input type="checkbox"/>	
c) More than 10-fold compared to the original batch size approved at the grant of the marketing authorisation		<input type="checkbox"/>		<input type="checkbox"/>
12 Change in the specification of an active substance or a starting material/intermediate/reagent used in the manufacturing process of the active substance				
a) Tightening of specification limits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Addition of a new test parameter to the specification of				
1. An active substance		<input type="checkbox"/>		<input type="checkbox"/>

	Main Change		consequential change ⁵	
	IA	IB	IA	IB
2. A starting material/intermediate/ reagent used in the manufacturing process of the active substance		<input type="checkbox"/>		<input type="checkbox"/>
13 Change in test procedure for active substance or starting material, intermediate, or reagent used in the manufacturing process of the active substance				
a) Minor change to an approved test procedure	<input type="checkbox"/>		<input type="checkbox"/>	
b) Other changes to a test procedure, including replacement or addition of a test procedure		<input type="checkbox"/>		<input type="checkbox"/>
14 Change in the manufacturer of the active substance or starting material/reagent/intermediate in the manufacturing process of the active substance where no Ph. Eur. Certificate of Suitability is available				
a) Change in site of the already approved manufacturer (replacement or addition)		<input type="checkbox"/>		<input type="checkbox"/>
b) New manufacturer (replacement or addition)		<input type="checkbox"/>		<input type="checkbox"/>
15 Submission of a new or updated Ph. Eur. Certificate of Suitability for an active substance or starting material/reagent/intermediate in the manufacturing process of the active substance				
a) From a manufacturer currently approved	<input type="checkbox"/>		<input type="checkbox"/>	
b) From a new manufacturer (replacement or addition)				
1. Sterile substance		<input type="checkbox"/>		<input type="checkbox"/>
2. Other substances	<input type="checkbox"/>		<input type="checkbox"/>	
c) Substance in veterinary medicinal product for use in animal species susceptible to TSE		<input type="checkbox"/>		<input type="checkbox"/>
16 Submission of a new or updated TSE Ph. Eur. Certificate of Suitability for an active substance or starting material/reagent/intermediate in the manufacturing process of the active substance for a currently approved manufacturer and currently approved manufacturing process				
a) Substance in veterinary medicinal product for use in animal species susceptible to TSE		<input type="checkbox"/>		<input type="checkbox"/>
b) Other substances	<input type="checkbox"/>		<input type="checkbox"/>	
17 Change in :				
a) The re-test period of the active substance		<input type="checkbox"/>		<input type="checkbox"/>
b) The storage conditions for the active substance		<input type="checkbox"/>		<input type="checkbox"/>
18 Replacement of an excipient with a comparable excipient		<input type="checkbox"/>		<input type="checkbox"/>
19 Change in specification of an excipient				
a) Tightening of specification limits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Addition of a new test parameter to the specification		<input type="checkbox"/>		<input type="checkbox"/>
20 Change in test procedure for an excipient				
a) Minor change to an approved test procedure	<input type="checkbox"/>		<input type="checkbox"/>	
b) Minor change to an approved test procedure for a biological excipient		<input type="checkbox"/>		<input type="checkbox"/>
c) Other changes to a test procedure, including replacement of an approved test procedure by a new test procedure		<input type="checkbox"/>		<input type="checkbox"/>
21 Submission of a new or updated Ph. Eur. Certificate of Suitability for an excipient				
a) From a manufacturer currently approved	<input type="checkbox"/>		<input type="checkbox"/>	
b) From a new manufacturer (replacement or addition)				
1. Sterile substance		<input type="checkbox"/>		<input type="checkbox"/>
2. Other substances	<input type="checkbox"/>		<input type="checkbox"/>	
c) Substance in veterinary medicinal product for use in animal species susceptible to TSE		<input type="checkbox"/>		<input type="checkbox"/>
22 Submission of a new or updated TSE Ph. Eur. Certificate of Suitability for an excipient				
a) From a manufacturer currently approved or a new manufacturer (replacement or addition)	<input type="checkbox"/>		<input type="checkbox"/>	
b) Excipient in veterinary medicinal product for use in animal species susceptible to TSE		<input type="checkbox"/>		<input type="checkbox"/>
23 Change in source of an excipient or reagent from a TSE risk to a vegetable or synthetic material				
a) Excipient or reagent used in manufacture of biological active substance or manufacture of a finished product containing biological active substance		<input type="checkbox"/>		<input type="checkbox"/>
b) Other cases	<input type="checkbox"/>		<input type="checkbox"/>	

	Main Change		consequential change ⁵	
	IA	IB	IA	IB
24 Change in synthesis or recovery of a non-pharmacopoeial excipient (when described in the dossier)		<input type="checkbox"/>		<input type="checkbox"/>
25 Change to comply with Ph. Eur. or with the national pharmacopoeia of a Member State				
a) Change of specification(s) of a former non-European pharmacopoeial substance to comply with Ph. Eur. or with the national pharmacopoeia of a Member State				
1. Active substance		<input type="checkbox"/>		<input type="checkbox"/>
2. Excipient		<input type="checkbox"/>		<input type="checkbox"/>
b) Change to comply with an update of the relevant monograph of the Ph. Eur or national pharmacopoeia of a Member State				
1. Active substance	<input type="checkbox"/>		<input type="checkbox"/>	
2. Excipient	<input type="checkbox"/>		<input type="checkbox"/>	
26 Change in the specifications of the immediate packaging of the finished product				
a) Tightening of specification limits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Addition of a new test parameter		<input type="checkbox"/>		<input type="checkbox"/>
27 Change to a test procedure of the immediate packaging of the finished product				
a) Minor change to an approved test procedure	<input type="checkbox"/>		<input type="checkbox"/>	
b) Other changes to a test procedure, including replacement or addition of a test procedure		<input type="checkbox"/>		<input type="checkbox"/>
28 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used))	<input type="checkbox"/>		<input type="checkbox"/>	
29 Change in the qualitative and/or quantitative composition of the immediate packaging material				
a) Semi-solid and liquid pharmaceutical forms		<input type="checkbox"/>		<input type="checkbox"/>
b) All other pharmaceutical forms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30 Change (replacement, addition or deletion) in supplier of packaging components or devices (when mentioned in the dossier), spacer devices for metered dose inhalers are excluded				
a) Deletion of a supplier	<input type="checkbox"/>		<input type="checkbox"/>	
b) Replacement or addition of a supplier		<input type="checkbox"/>		<input type="checkbox"/>
31 Change to in-process tests or limits applied during the manufacture of the product				
a) Tightening of in-process limits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Addition of new tests and limits		<input type="checkbox"/>		<input type="checkbox"/>
32 Change in batch size of the finished product				
a) Up to 10-fold compared to the original batch size approved at the grant of the marketing authorisation	<input type="checkbox"/>		<input type="checkbox"/>	
b) Downscaling down to 10-fold	<input type="checkbox"/>		<input type="checkbox"/>	
c) Other situations		<input type="checkbox"/>		<input type="checkbox"/>
33 Minor change in the manufacture of the finished product		<input type="checkbox"/>		<input type="checkbox"/>
34 Change in the colouring system or the flavouring system currently used in the finished product				
a) Reduction or deletion of one or more components of the				
1. Colouring system	<input type="checkbox"/>		<input type="checkbox"/>	
2. Flavouring system	<input type="checkbox"/>		<input type="checkbox"/>	
b) Increase, addition or replacement of one or more components of				
1. Colouring system		<input type="checkbox"/>		<input type="checkbox"/>
2. Flavouring system		<input type="checkbox"/>		<input type="checkbox"/>
35 Change in coating weight of tablets or change in weight of capsule shells				
a) Immediate release oral pharmaceutical forms	<input type="checkbox"/>		<input type="checkbox"/>	
b) Gastro-resistant, modified or prolonged release pharmaceutical forms		<input type="checkbox"/>		<input type="checkbox"/>
36 Change in shape or dimensions of the container or closure				
a) Sterile pharmaceutical forms and biological medicinal products		<input type="checkbox"/>		<input type="checkbox"/>
b) Other pharmaceutical forms	<input type="checkbox"/>		<input type="checkbox"/>	
37 Change in the specification of the finished product				
a) Tightening of specification limits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Addition of a new test parameter		<input type="checkbox"/>		<input type="checkbox"/>

	Main Change		consequential change ⁵	
	IA	IB	IA	IB
38 Change in test procedure of the finished product				
a) Minor change to an approved test procedure	<input type="checkbox"/>		<input type="checkbox"/>	
b) Minor change to an approved test procedure for biological active substance or biological excipient		<input type="checkbox"/>		<input type="checkbox"/>
c) Other changes to a test procedure, including replacement or addition of a test procedure		<input type="checkbox"/>		<input type="checkbox"/>
39 Change or addition of imprints, bossing or other markings (except scoring/break lines) on tablets or printing on capsules, including replacement, or addition of inks used for product marking	<input type="checkbox"/>		<input type="checkbox"/>	
40 Change of dimensions of tablets, capsules, suppositories or pessaries without change in qualitative or quantitative composition and mean mass				
a) Gastro-resistant, modified or prolonged release pharmaceutical forms and scored tablets		<input type="checkbox"/>		<input type="checkbox"/>
b) All other tablets, capsules, suppositories and pessaries	<input type="checkbox"/>		<input type="checkbox"/>	
41 Change in pack size of the finished product				
a) Change in the number of units (e.g. tablets, ampoules, etc.) in a pack				
1. Change within the range of the currently approved pack sizes	<input type="checkbox"/>		<input type="checkbox"/>	
2. Change outside the range of the currently approved pack sizes		<input type="checkbox"/>		<input type="checkbox"/>
b) Change in the fill-weight/fill volume of non-parenteral multi-dose products		<input type="checkbox"/>		<input type="checkbox"/>
42 Change in :				
a) The shelf-life of the finished product				
1. As packaged for sale		<input type="checkbox"/>		<input type="checkbox"/>
2. After first opening		<input type="checkbox"/>		<input type="checkbox"/>
3. After dilution or reconstitution		<input type="checkbox"/>		<input type="checkbox"/>
b) The storage conditions of the finished product or the diluted/reconstituted product		<input type="checkbox"/>		<input type="checkbox"/>
43 Addition, replacement or deletion of a measuring or administration device not being an integrated part of the primary packaging (spacer devices for metered dose inhalers are excluded)				
a) Medicinal products for human use				
1. Addition or replacement	<input type="checkbox"/>		<input type="checkbox"/>	
2. Deletion		<input type="checkbox"/>		<input type="checkbox"/>
b) Veterinary medicinal products		<input type="checkbox"/>		<input type="checkbox"/>
44 Change in specification of a measuring device or administration device for veterinary medicinal products				
a) Tightening of specification limits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Addition of a new test parameter		<input type="checkbox"/>		<input type="checkbox"/>
45 Change in test procedure of a measuring or administration device for veterinary medicinal products				
a) Minor change to an approved test procedure	<input type="checkbox"/>		<input type="checkbox"/>	
b) Other changes to a test procedure, including replacement of approved test procedure by new test procedure		<input type="checkbox"/>		<input type="checkbox"/>

For National Authorisation only

	Main Change		consequential change ⁵	
	IA	IB	IA	IB
46 Change in the Summary of Product Characteristics of an essentially similar product following a Commission Decision for a referral for an original medicinal product in accordance with Article 30 of Directive 2001/83/EC or Article 34 of Directive 2001/82/EC		<input type="checkbox"/>		<input type="checkbox"/>

For Community (Centralised) Authorisation only

	Main Change		consequential change ⁵	
	IA	IB	IA	IB
46 Change in the Summary of Product Characteristics, labelling and package leaflet/insert as a consequence of a final opinion in the context of a referral procedure in accordance with Articles 31 and 32 of Directive 2001/83/EC or Articles 35 and 36 of Directive 2001/82/EC		<input type="checkbox"/>		<input type="checkbox"/>
47 Deletion of:				
a) A pharmaceutical form	<input type="checkbox"/>		<input type="checkbox"/>	
b) A strength	<input type="checkbox"/>		<input type="checkbox"/>	
c) A pack size(s)	<input type="checkbox"/>		<input type="checkbox"/>	

⁵ Certain consequential changes may not be valid and the presence of a tick box does not necessarily indicate its acceptance. A consequential change(s) can either be of the same type, or has to be a less stringent change (eg. a Type IB with a consequential Type IB or Type IA is possible, but **not** a Type IA with a consequential Type IB).

TYPE II CHANGES (*Tick the appropriate change required*)

for human medicinal products only			
Change to Module 1	<input type="radio"/>	Overview	<input type="radio"/>
Change to Module 2	<input type="radio"/>	Summary	<input type="radio"/>
Change to Module 3	<input type="radio"/>		
Change to Module 4	<input type="radio"/>	Updated	<input type="radio"/>
Change to Module 5	<input type="radio"/>	Addendum	<input type="radio"/>

for veterinary medicinal products only			
Change to Part I dossier	<input type="radio"/>	Expert Report	
Change to Part II dossier	<input type="radio"/>	Updated	<input type="radio"/>
Change to Part III dossier	<input type="radio"/>	Addendum	<input type="radio"/>
Change to Part IV dossier	<input type="radio"/>		

OTHER APPLICATION(S) *(Please provide brief information on any ongoing variation or other variation(s) submitted in parallel, or renewal application(s), or line-extension(s))*

SCOPE *(Please specify scope of the change(s) in a concise way)*

BACKGROUND FOR CHANGE & JUSTIFICATION FOR CONSEQUENTIAL CHANGES (if applicable)
(Please give brief background explanation for the proposed changes to your MA, as well as a justification in case of consequential changes)

PRESENT^{6,7}	PROPOSED^{6,7}

⁶ Specify the precise present and proposed wording or specification.

⁷ For SPC, labelling and package leaflet/insert changes, underline or highlight the changed words presented in the table above or provide as a separate Annex

The following amended product information text proposals (Annexes) are included, where applicable:

- Summary of Product Characteristics
- Labelling
- Package leaflet/insert
- Mock-ups⁸
- Specimens⁸

⁸ see Chapter 7 of Volume 2A or 6A of the Notice to Applicants

Declaration of the Applicant for Type IA or Type IB:

I hereby submit a notification for the above Marketing Authorisation to be varied in accordance with the proposals given above. I declare that (*Please tick the appropriate declarations*):

- There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel; such parallel variations should be specified under 'Other Application(s)');
- The change(s) will not adversely affect the quality, efficacy or safety of the product;
- All conditions as set for the notification(s) concerned are fulfilled;
- The required documents as specified for the notification(s) concerned have been submitted;
- Where applicable, national/EMEA fees have been paid;
- This notification has been submitted simultaneously in RMS and all CMSs (*for products within the Mutual Recognition Procedure*) or both to EMEA and Rapporteur only (*for products within the Centralised Procedure*).

Change will be implemented from: Next production run/next printing
 Date: _____

Declaration of the Applicant for Type II:

I hereby submit an application for the above Marketing Authorisation to be varied in accordance with the proposals given above. I declare that (*Please tick the appropriate declarations*):

- There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel; such parallel variations have to be specified under 'Other Application(s)');
- Where applicable, national/EMEA fees have been paid;
- This application has been submitted simultaneously in RMS and all CMSs (*for products within the Mutual Recognition Procedure*) or both to EMEA and all CPMP/CVMP members (*for products within the Centralised Procedure*).

Change will be implemented from: Next production run/next printing
 Date: _____

Fees paid (*if applicable*) Amount

Please specify fee category under National/Community rules

Orphan Drug fee exemption granted (attach fee Notification of the competent authority)

Main Signatory⁹ _____ Status (Job title) _____

Print name _____ Date _____

Second Signatory _____ Status (Job title) _____

Print name _____ Date _____

⁹The main signatory is mandatory

Mutual Recognition Variation Number: / / / / / / / /

Name of the Medicinal Product: _____

Marketing Authorisation Number(s): _____

(For Official Use Only)

NOTIFICATION TO APPLICANT FOR TYPE II VARIATION

Please quote the MR Variation number, the name of the medicinal product and the MA number in any future correspondence.

- A valid application has been received by the Competent Authority and where applicable by all Concerned Member States.
- Fees paid (*for National use*) _____
- Procedure start date is _____
- Application invalid (*reasons below*).
- Supplementary information is requested as detailed below.
Please respond by _____ (*date*)
- The Competent Authority consents to your request to vary the Marketing Authorisation.
- The Competent Authority refuses your request to vary the Marketing Authorisation (*reasons below*).

Signed _____ Date _____

Member State/Agency _____ Contact _____

SUPPLEMENTARY INFORMATION REQUESTED ON / REASONS:
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