



**Variation applications – What dates are to be included in the Product Information, and which responses is to be expected from the Norwegian Medicines Agency**

The following procedure applies for variation applications submitted according to the Variation Regulation, EC 1234/2008. The Regulations is included in the National legislation “Forskrift om legemidler” by the 17<sup>th</sup> of March

In general: Variations Type IA and Type IB in Mutual Recognition Procedure including an update of the product Information, the national translations should be submitted concomitantly with the variation application.

National variation applications:

**Type IA variations:** There will no longer be forwarded an “Acknowledgement of an acceptable notification” for type IA applications. If the Norwegian medicines Agency does not have objections within 30 days the application is considered accepted. The Norwegian medicines Agency will update their systems accordingly

**The Product Information:** If the variation includes update of the Product Information the implementation date of the variation should be stated by the applicant. The Product Information will neither be returned, but the databases will be updated with the applicant’s implementation date taken into account. The Marketing Authorisation Holder must ensure that the correct version is the basis for the next variation to be submitted.

**Type IB variations:** The Norwegian Medicines Agency will send an “Acknowledgement of approval/Refusal” of the variation.

**The Product Information:** Approved Summary of Product Characteristics (SmPC), Patient information Leaflet (PL), and labeling are forwarded to the applicant. The date to be included in the SmPC and PL is the approval date of the Norwegian Medicines Agency.

**Type II variations:** The Norwegian Medicines Agency will send an “Acknowledgement of approval/Refusal” of the variation.

**The Product Information:** Approved Summary of Product Characteristics (SmPC), Patient information Leaflet (PL), and labeling are forwarded to the applicant. The date to be included in the SmPC and PL is the approval date of the Norwegian Medicines Agency.

#### **MRP variations, Norway as Concerned Member State (CMS):**

**Type IA variations:** The Norwegian Medicines Agency would respond if the variation is considered invalid. No acknowledgement is forwarded at the end of procedure. The databases are updated according to the agreed conclusion at end of procedure.

**Product Information:** National translations: If the variation includes update of the Product Information the implementation date of the variation should be stated by the applicant. The Product Information will neither be returned, but the databases will be updated with the applicant’s implementation date taken into account. The Marketing Authorisation Holder must ensure that the correct version is the basis for the next variation to be submitted.

**Type IB variations:** The Norwegian medicines Agency may inform the applicant of an invalidation or comment during the procedure. No acknowledgement is forwarded at the end of procedure. The databases are updated according to the agreed conclusion at end of procedure.

**Product Information:** National translations: Approved SmPC, PL and labeling are forwarded to the applicant. The date to be included in the SmPC and PL is the approval date of the Norwegian Medicines Agency.

**Type II variations:** The Norwegian medicines Agency may inform the applicant of an invalidation or comment during the procedure. No acceptance/rejection is forwarded at the end of procedure. The databases are updated according to the agreed conclusion at end of procedure.

**Product Information:** National translations: Approved SmPC, PL and labeling are forwarded to the applicant. The date to be included in the SmPC and PL is the approval date of the Norwegian Medicines Agency.

**MRP variations, Norway as Reference Member State (RMS):**

**Type IA variations:** The applicant will receive information on a possible invalidation, “acknowledgement of an acceptable -/Non acceptance of Notification”.

**Product Information:** National translations: If the variation includes update of the Product Information the implementation date of the variation should be stated by the applicant. The Product Information will not be returned, but the databases will be updated with the applicant’s implementation date taken into account.

**Type IB variations:** The applicant will receive information on a possible invalidation, “Acknowledgement of approval/Refusal” of the variation.

**Product Information:** National translations: Approved SmPC, PL and labeling are forwarded to the applicant. The date to be included in the SmPC and PL is the approval date of the Norwegian Medicines Agency.

**Type II:** The applicant will receive information on a possible invalidation, “Acceptance/Rejection” of the variation.

**Product Information:** National translations: Approved SmPC, PL and labeling are forwarded to the applicant. The date to be included in the SmPC and PL is the approval date of the Norwegian Medicines Agency.

**Centrally approved products:**

Variation	The Norwegian Medicines Agency receives	Product Information to be received	Approved text to be forwarded the applicant	Date to be implemented in the Product Information	What is done at the Agency?	Other information	Where is the Product information to be submitted?
IA	Notification of variation, from EMA	The Norwegian Medicines Agency requests national Product Information to be updated accordingly	No approved text will be forwarded	The date to be included in the SmPC and PL is company's own , and which is accepted by the EMA	The Norwegian medicines Agency will update their systems accordingly. The SmPC database is updated	May be combined and submitted together with a type II variation or renewal, in accordance with the commission update of the Marketing Authorisation within 2 months after implementation.	<a href="mailto:pi@noma.no">pi@noma.no</a>  or: <a href="mailto:post@noma.no">post@noma.no</a>  format: word file as attachment to an e-mail
IA in	Notification of variation, from EMA	The Norwegian Medicines Agency requests national Product Information to be updated accordingly	No approved text will be forwarded	The date to be included in the SmPC and PL is company's own , and which is accepted by the EMA	The Norwegian medicines Agency will update their systems accordingly. The SmPC database is updated	May be combined and submitted together with a type II variation, or renewal, in accordance with the commission update of the Marketing Authorisation within 2 months	<a href="mailto:pi@noma.no">pi@noma.no</a>  or: <a href="mailto:post@noma.no">post@noma.no</a>  format: word file as attachment to an e-mail

						after implementation.	
IB	Notification of variation, from EMA	The Norwegian Medicines Agency requests national Product Information to be updated accordingly	Normally no approved text are forwarded. But for some Type IB variations the QRD procedure applies , and the text will be included in the ordinary text evaluation after opinion. In the latter case approved text will be forwarded. Type IB variations not triggering the QRD procedure may be considered approved and implemented after 30 days.	The date to be included in the SmPC and PL is EMA's approval date This date should be used due to the fact that the MAH may implement the change prior to the commission update of the Marketing Authorisation (within 6 months )	The Norwegian medicines Agency will update their systems accordingly. The SmPC database is updated	If the Norwegian medicines Agency have comments to the proposed product information, this may be implemented together with the next Type II variation (or renewal) No separate national decision is forwarded	<a href="mailto:pi@noma.no">pi@noma.no</a> or: <a href="mailto:post@noma.no">post@noma.no</a> format: word file as attachment to an e-mail
Type II	Commission Decision	According to current procedure	The text is assessed through QRD after opinion	According to current procedure	According to current procedure	According to current procedure	According to current procedure