



Version 2 – 1/10/15

New definition of the approval date in SmPC and leaflet

Starting from 15/6/15, when the famhp is closing administratively a **variation** and as result of this closing you receive an update of MA*, the following approach will be used to determine the approval date mentioned in SmPC and PIL: the approval date mentioned in the SmPC and leaflet is the date of the scientific approval. This is also the date that will be mentioned in the variation table. This allows the firm to use the correct date when implementing the change before the dossier is administratively closed by the Agency.

The same approach will be used for determine the approval date in the SmPC and leaflet when closing a **renewal**. Although a renewal can only be implemented when receiving the updated MA, the same approach is used to harmonize the way of working and by doing so to avoid mistakes.

Attention: for most of the IA-variations, closing the file administratively doesn't lead to an update of the MA by the famhp. In these cases, you mention the real implementation date as approval date.

When the update of the MA is a result of the closing of a cluster of dossiers, the date that will be mentioned in the SmPc and leaflet will be the most recent approval date.

The table below gives an overview on how the approval date in the SmPC and leaflet was determined until 15/6 and how it will be done from 15/6 on. The changes are highlighted in orange.

before 15/6/15					
MRP	Date in the variation table	Approval date in SmPC and leaflet	Date MA	Date which determines the implementation date - firm	Date before which the change should be implemented
MRP IA immediate notification	Validation date RMS	Not applicable	Not applicable	Date of submission unless the variation leads to an additional MA. In these cases the date on MA counts.	Validation date RMS + 6 months Or Date MA + 6 months
MRP IB	approval date RMS	Date of closing	Date of closing	approval date RMS unless the variation leads to an additional MA. In these cases the date on MA counts.	Approval date RMS + 6 months Or Date MA + 6 months
MRP II	approval date RMS	Date of closing	Date of closing	approval date RMS**, unless the variation leads to an additional MA. In these cases the date on MA counts.	Approval date RMS + 6 months Or Date MA + 6 months
MRP renewal	approval date RMS	Date of closing	Date of closing	date MA	Date MA + 6 months

before 15/6/15					
NAT	Date in the variation table	Approval date in SmPC and leaflet	Date MA	Date which determines the implementation date - firm	Date before which the change should be implemented
NAT IA immediate notification	Date of submission + 30 calendar days	Not applicable	Not applicable	Date of submission unless the variation leads to an additional MA. In these cases the date on MA counts.	Approval date mentioned in variation table + 6 months Or Date MA + 6 months
NAT IB	When no questions were sent: Date of submission + 44 calendar days, When questions were sent: date of receiving answers + 30 calendar days	Date of closing	Date of closing	When no questions were sent: Date of submission + 44 calendar days, When questions were sent: date of receiving answers + 30 calendar days unless the variation leads to an additional MA. In these cases the date on MA counts.	Approval date mentioned in variation table + 6 months Or Date MA + 6 months
NAT II	Date Commission	Date of closing	Date of closing	date round up email unless the variation leads to an additional MA. In these cases the date on MA counts	Date round-up email + 6 months Or Date MA + 6 months
NAT renewal	Date Commission	Date of closing	Date of closing	Date MA	Date MA + 6 months

from 15/6/15					
MRP	Date in the variation table	Approval date in SmPC and leaflet	Date MA	Date which determines the implementation date - firm	Date before which the change should be implemented
MRP IA immediate notification	Validation date RMS	validation date RMS	Date of closing	Date of submission unless the variation leads to an additional MA. In these cases the date on MA counts.	Validation date RMS + 6 months Or Date MA + 6 months
MRP IB	approval date RMS	approval date RMS	Date of closing	approval date RMS unless the variation leads to an additional MA. In these cases the date on MA counts.	Approval date RMS + 6 months Or Date MA + 6 months
MRP II	approval date RMS	approval date RMS	Date of closing	approval date RMS**, unless the variation leads to an additional MA. In these cases the date on MA counts.	Approval date RMS + 6 months Or Date MA + 6 months
MRP renewal	approval date RMS	approval date RMS	Date of closing	date MA	Date MA + 6 months

from 15/6/15					
NAT	Date in the variation table	Approval date in SmPC and leaflet	Date MA	Date which determines the implementation date - firm	Date before which the change should be implemented
NAT IA immediate notification	<p>Implicit approval: Date of submission + 30 calendar days</p> <p>Or</p> <p>Explicit approval : Date of email with confirmation of approval</p>	<p>Implicit approval: Date of submission + 30 calendar days</p> <p>Or</p> <p>Explicit approval : Date of email with confirmation of approval</p>	Date of closing	Date of submission unless the variation leads to an additional MA. In these cases the date on MA counts.	<p>Approval date mentioned in variation table + 6 months</p> <p>Or</p> <p>Date MA + 6 months</p>
NAT IB	<p>Implicit approval: When no questions were sent: Date of submission + 44 calendar days, When questions were sent: date of receiving answers + 30 calendar days</p> <p>Or</p> <p>Explicit approval :</p>	<p>Implicit approval: When no questions were sent: Date of submission + 44 calendar days, When questions were sent: date of receiving answers + 30 calendar days</p> <p>Or</p> <p>Explicit approval :</p>	Date of closing	<p>Implicit approval: When no questions were sent: Date of submission + 44 calendar days, When questions were sent: date of receiving answers + 30 calendar days</p> <p>Or</p> <p>Explicit approval :</p>	<p>Approval date mentioned in variation table + 6 months</p> <p>Or</p> <p>Date MA + 6 months</p>



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	Date of email with confirmation of approval	Date of email with confirmation of approval		Date of email with confirmation of approval unless the variation leads to an additional MA. In these cases the date on MA counts..	
NAT II	Date round up email	Date round up email	Date of closing	date round up email unless the variation leads to an additional MA. In these cases the date on MA counts	Date round-up email + 6 months Or Date MA + 6 months
NAT renewal	Date round up email	Date round up email	Date of closing	Date MA	Date MA + 6 months

The approval date in the SmPC and PIL will always be the same, even when the change doesn't impact both documents. The approval date will be formulated like this: month/year.

Some examples:

- MRP type II clinical variation approved by the RMS on 15/2/15 and administratively closed by the famhp on 6/4/15:
 - ➔ Date in the variation table: 15/2/15
 - ➔ Date in SmPC/leaflet: 2/15
 - ➔ Date on the MA: 6/4/15
 - ➔ Earliest date for implementation, on condition that all documents necessary for closing were received: 15/3/15 (15/2/15 + 30 days). The firm mentions as approval date in the SmPC and leaflet 2/15.
 - ➔ The latest date before which the change should be implemented: 15/8/15 (15/2/15 + 6 months)

- Nat type II clinical variation for which you have received an round-up mail on 26/5/15 and was closed administratively by the famhp on 17/7/15.
 - ➔ Date in the variation table: 26/5/15
 - ➔ Date in SmPC/leaflet: 5/15
 - ➔ Date on the MA: 17/7/15
 - ➔ Earliest date for implementation, on condition that all documents necessary for closing were received: 26/5/15. The firm mentions as approval date in the SmPC and leaflet 5/15.
 - ➔ The latest date before which the change should be implemented: 26/11/15 (26/5/15 + 6 months)



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*In the following cases you receive an update of the MA when the variation is administratively closed:

- Renewals
- Type II clinical variations (except those with no impact on the SmPC and PIL)
- Type IB clinical variations (except those with no impact on the SmPC and PIL)
- Type IA implementation of referrals, PRAC recommendations, PSUSA outcome
- Type II analytical variation that leads to an additional MA (with new authorization number)
- Transfer/change batch releaser/change name of medicinal product if link to transfer

**The conditions for implementing MRP type II variations as mentioned in art.24.3a) of the Variation regulation are still applicable. It concerns the waiting period of 30 days and the presence of the closing documents.