Checklist for closing off of a dossier VHB POST

	Variation type II, type I and administrative variations
Simplified Marketing authorisation document (AMM light) cf. circular letter 522.	If modified (*)
Marketing authorisation document (AMM 4 pages) cf. circular letter 439	No (**)
Delegation of Power (if the manufacturing authorisation holder is situated in a foreign country)	If modified
Final Summary of Product Characteristics, Leaflet and labelling (only in case of MRP/DCP – via RMS)	If modified
Declaration of conformity (cf. circular letter 469)	If SPC and leaflet change
Summary of Product Characteristics in Dutch and French (cf. circular letter 469)	If modified
Patient Information Leaflet in Dutch, French and German (cf. circular letter 469).	If modified
Proposition of packaging in Dutch, French and German as well as a mock-up (cf. circular letter 469)	If modified
Original specimen of concerned AMM (including the attached patient leaflets)	Always, except if there are no changes to the AMM/leaflets.
Post-approval commitments	If applicable

(*) During the transition from “AMM 4 pages” to “AMM light”, a proposition of the light AMM will be asked each time when closing a packaged of changes to an existing marketing authorization. Once you have an AMM light for your product, a proposition of light AMM should only be given, when the AMM light is changed by the variations.

(**) A proposition of AMM 4 pages will be asked one more time for registered medicinal products when the FAMHP does not yet dispose of the 4 pages MA.

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