

**Checklist for closing off of a dossier – VHB PRE**

	<b>New registration</b>
Delegation of Power (if the manufacturing authorisation holder is situated in a foreign country)	
Declaration of conformity (cf. circular letter 469)	
Summary of Product Characteristics in Dutch and French (cf. <u>circular letter 469</u> )	
Patient Information Leaflet in Dutch, French and German (cf. <u>circular letter 469</u> ).	
Proposition of packaging in Dutch, French and German (cf. <u>circular letter 469</u> )	
In case you <u>wish to commercialize</u> immediately: Mock-up of the packaging proposition	
In case you do <u>not wish to commercialize</u> immediately: Post-approval commitment Mock-up	
In case you do <u>not wish to commercialize</u> immediately: Post-approval commitment Distributor	
In case <u>line extensions with common leaflets</u> : Original specimen of concerned AMM (including the attached patient leaflets)	