Questions and answers concerning combination products

Question 1

We are planning to have a new inseparable combination product (integral CP with medical device (MedD) component class Im, Is, Ir, IIa, IIb or III) authorised by Swissmedic.

The assessment report (Notified Body Opinion – NBOp) for the MedD component will not be available by the planned submission date of the application. Is it possible to submit an application without an NBOp, i.e. can the NBOp be submitted later?

Answer 1

When applying for authorisation of a new inseparable combination (see also Guidance document *Formal Requirements*), the following formal requirements must be observed:

In principle, all documents and evidence, including those relating to the conformity of the MedD component with the general safety and performance requirements according to Annex I EU-MDR (NBOp or certificate of conformity), must be submitted together with the authorisation application.

If this is not possible, the applicant can agree a later submission date for the missing NBOp or certificate of conformity for the MedD component with Swissmedic, but this should not delay the approval process for a new authorisation or variation (with the exception of type IB or type IA/IAIN variation applications to be approved in advance or after the fact). This later submission date must be set out in the cover letter, stating the binding timescale, and substantiated with corresponding documentation from the certification body. Since products submitted to Swissmedic for approval that have received the official decision which concludes the approval process are directly marketable, all documents relevant to the approval must be present and be checked before this official decision is issued.

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