Please find hereunder Afssaps' comments on the draft guidance entitled :
"Harmonized requirements for NIMPs in CTA submissions, public consultation document "

§ 3.2.1 and 4.2.1 : there is maybe a need to require information on any repackaging and/or relabelling, list of sites involved and GMP evidence as required in other sections.

3.2.3. and 3.2.4 : Background therapy / rescue medication (section 3)

According to their definition and their purpose (current standard care, recognized efficacy), we think that it is not acceptable to use background and rescue medication without MA in European Union (sections 3.2.3., 3.2.4 or 3.2.5.) except in the case of 'cousin products', i.e. products with a very similar composition as a product marketed in EU in order to facilitate manufacturing in case of international CT. This point should be clarified to understand sections 3.2.3., 3.2.4. and 3.2.5..

. § 4.2. Dossier content (Challenge agents) :
. contents of sections 4.2.4. and 4.2.5. are equivalent, these two sections could be merged with an adaptation of the title

4.2.2. Why not limiting reduced testing only to the MP not authorised in EU as it is proposed for background therapies (3.2.3).

Best regards,

Pierre Henri Bertoye
Chantal Bélorgey

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