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EORTC reply to the public consultation on Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs).

EORTC in general welcomes this document which is clear and practical.

Line 109: the end of the sentence is missing, EORTC could think that this may be "… may also be used as AMP"; please complete the text.

Line 140 – 144: "As a general rule, the documentation requirements in the application dossier for IMPs also apply to AMPs irrespective their marketing authorisation Regulation (EU) No 536/2014 Annexes I and II set out the requirements of the application dossier for initial applications and substantial modifications, respectively."

It was the understanding of EORTC that for AMPs with marketing authorization and used within the indication no dossier shall be submitted. These lines and specifically the words "irrespective their marketing authorization" make think that a dossier would be required even for registered AMPs.
EORTC understanding is supported by the art 25:
"(c) the investigational medicinal products and, where necessary, the auxiliary medicinal products, in particular their properties, labelling, manufacturing and control"
and annex I paragraph 55:
" Without prejudice to Article 65, the documentation requirements set out in sections F and G shall also apply to auxiliary medicinal products. However, where the auxiliary medicinal product is authorised in the Member State concerned, no additional information is required."

Moreover, for the sake of clarity, EORTC also would propose to split this paragraph into 2 sentences.

Therefore, this text shall be changed as follows: "As a general rule, the documentation requirements in the application dossier for IMPs may also apply to AMPs. Regulation (EU) No 536/2014 Annexes I and II set out the requirements of the application dossier for initial applications and substantial modifications, respectively."