***Changes to legislation:** There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, Division 1.2.. (See end of Document for details)*

ANNEX I

APPLICATION DOSSIER FOR THE INITIAL APPLICATION G.INVESTIGATIONAL MEDICINAL PRODUCT DOSSIER (IMPD)

1.2. **Simplified IMPD by referring to other documentation**

50. The applicant may refer to other documentation submitted alone or with a simplified IMPD.

Possibility of referring to the IB

51. The applicant may either provide a stand-alone IMPD or cross-refer to the IB for the reference safety information and the summaries of pre-clinical and clinical parts of the IMPD. In the latter case, the summaries of pre-clinical information and clinical information shall include data, preferably in tables, providing sufficient detail to allow assessors to reach a decision on the potential toxicity of the investigational medicinal product and the safety of its use in the proposed clinical trial. If there is some special aspect of the pre-clinical data or clinical data that requires a detailed expert explanation or discussion beyond what would usually be included in the IB, the pre-clinical and clinical information shall be submitted as part of the IMPD.

Possibility of referring to the SmPC

52. The applicant may submit the version of the SmPC valid at the time of application, as the IMPD if the investigational medicinal product is authorised. The exact requirements are detailed in Table 1. Where new data are provided, it should be clearly identified.

TABLE 1: CONTENT OF THE SIMPLIFIED IMPD

Types of previous assessment	**Quality data**	**Non-clinical data**	**Clinical data**
The investigational medicinal product is authorised or has a marketing authorisation in an ICH country and is used in the clinical trial:			
— within the conditions of the SmPC	SmPC		
— outside the conditions of the SmPC	SmPC	If appropriate	If appropriate

(S: Data relating to the active substance; P: Data relating to the investigational medicinal product; A: Additional information on Facilities and Equipment, Adventitious Agents Safety Evaluation, Novel Excipients, and Solvents for Reconstitution and Diluents)

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— after modification (for example blinding)	P+A	SmPC	SmPC
Another pharmaceutical form or strength of the investigational medicinal product is authorised or has a marketing authorisation in an ICH country and the investigational medicinal product is supplied by the marketing authorisation holder	SmPC+P+A	Yes	Yes
The investigational medicinal product is not authorised and has no marketing authorisation in an ICH country but the active substance is contained in an authorised medicinal product, and			
— is supplied by the same manufacturer	SmPC+P+A	Yes	Yes
— is supplied by another manufacturer	SmPC+S+P+A	Yes	Yes
The investigational medicinal product was subject to a previous clinical trial application and authorised in the Member State concerned and has not been modified, and			

(S: Data relating to the active substance; P: Data relating to the investigational medicinal product; A: Additional information on Facilities and Equipment, Adventitious Agents Safety Evaluation, Novel Excipients, and Solvents for Reconstitution and Diluents)

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—	no new data are available since last amendment to the clinical trial application,	Reference to previous submission		
—	new data are available since last amendment to the clinical trial application,	New data	New data	New data
—	is used under different conditions	If appropriate	If appropriate	If appropriate

(S: Data relating to the active substance; P: Data relating to the investigational medicinal product; A: Additional information on Facilities and Equipment, Adventitious Agents Safety Evaluation, Novel Excipients, and Solvents for Reconstitution and Diluents)

53. If the investigational medicinal product is defined in the protocol in terms of active substance or ATC code (see above, paragraph 18), the applicant may replace the IMPD by one representative SmPC for each active substance/active substance pertaining to that ATC group. Alternatively, the applicant may provide a collated document containing information equivalent to that in the representative SmPCs for each active substance that could be used as an investigational medicinal product in the clinical trial.

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