Medicines & Healthcare products Regulatory Agency

Scenario	Quality	Non-clinical pharmacology and toxicology	Previous clinical trial and human experience
IMP has an MA in the UK, EU or an ICH member country and: • is being used according to the MA • is unmodified	Instead of quality data, non-clinical pharmacology and toxicology data, and previous clinical trial and human experience data, submit: • SmPC or equivalent • Marketing Authorisation Holder (MAH) references, e.g. company name and address • MA references, e.g. reference number of the licence		
The IMP has an MA in the UK, EU or an ICH member country and is being used outside the MA	Instead of quality data, submit: • SmPC or equivalent • MAH references • MA references Submit appropriate additional information if the proposed method of use gives rise to potential safety risks (i.e. a change to the route of administration)	Submit if appropriate	Submit if appropriate
The IMP has an MA in the UK, EU or an ICH member country and is modified (e.g. blinding)	Submit quality data covering the proposed modification to the IMP, including detail on any downstream consequences on the IMP as a result of that modification	Instead of non-clinical pharmacology and toxicology data and previous clinical trial and human experience data, submit: • SmPC or equivalent • MAH references • MA references	
Another pharmaceutical form or strength of the IMP has an MA in the UK, EU or an ICH member country and the IMP is	Instead of quality data, submit: • SmPC or equivalent for the other form or strength • MAH references for the other form or strength • MA references for the other form or strength data relating to the IMP including relevant sections of	Required	Required

supplied by the MA holder	the drug product quality IMP dossier, as per the guideline EMA/CHMP/QWP/545525/2017 Rev. 2 or EMA/CHMP/BWP/534898/2008 Rev. 2		
IMP has no MA in the UK, EU or an ICH member country but the active substance is part of a medicinal product with an MA in the UK or EU and is supplied by the MA holder	Instead of quality data, submit: • SmPC or equivalent for the other medicinal product • MAH references for the other medicinal product • MA references for the other medicinal product data relating to the IMP including relevant sections of the drug product quality IMP dossier, as per the guideline EMA/CHMP/QWP/545525/2017 Rev. 2 or EMA/CHMP/BWP/534898/2008 Rev. 2	Required	Required
IMP has no MA in the UK, EU or an ICH member country but the active substance is part of a medicinal product with an MA in the UK or EU and is not supplied by the MA holder	Instead of quality data, submit: • SmPC or equivalent for the other medicinal product • MAH references for the other medicinal product • MA references for the other medicinal product • data relating to the active substance data relating to the IMP including relevant sections of the drug product quality IMP dossier, as per the guideline EMA/CHMP/QWP/545525/2017 Rev. 2 or EMA/CHMP/BWP/534898/2008 Rev. 2	Required	Required
IMP was used in a trial previously authorised by the licensing authority (and has not been modified from the form used in	Instead of quality data, non-clinical pharmacology and toxicology data, and previous clinical trial and human experience data: • reference the previous submission (with evidence of permission from the sponsor of the previous trial, if different) • submit appropriate additional information if the proposed method of use gives rise to potential safety risks (i.e. a change to the route of administration)		

the authorised trial)			
IMP was used in a trial previously authorised by the licensing authority (and has not been modified from the form used in the authorised trial) but new data has since become available	Reference the previous submission and provide only the new quality, non-clinical pharmacology and toxicology, and previous clinical trial and human experience data		
IMP was used in a trial previously authorised by the licensing authority and has not been modified but the IMP is used under different conditions (e.g. different route of administration, dose or participant population)	Reference the previous submission but submit quality, non-clinical pharmacology and toxicology, and previous clinical trial and human experience data where appropriate		
IMP is a placebo that is: • the same composition as the active IMP • manufactured by the same manufacturer as the IMP • not sterile	Not required	Not required	Not required
IMP is a placebo that has been approved for use	Instead of quality data, reference the previous submission (with evidence of permission from the	Not required	Not required

in a previous trial in the UK	sponsor of the previous trial, if different)		
IMP is a placebo that does not meet the criteria above	Instead of quality data, submit data relating to the IMP including relevant sections of the drug product quality IMP dossier, as per the guideline EMA/CHMP/QWP/545525/2017 Rev. 2 or EMA/CHMP/BWP/534898/2008 Rev. 2	Not required	Not required