



## Medicines & Healthcare products Regulatory Agency

| Additional criteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
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| <p>Any of the IMPs used in a trial that is eligible for automatic approval under Condition A are placebos. This is a potential safety concern because use of a placebo in these trials (but not trials eligible for automatic authorisation under Condition B or C) can change the risk-benefit profile, as there is no benefit for participants on a placebo and there is the potential for increased risk through exposure to excipients</p>                                                                                                                                                           |
| <p>For a trial eligible for automatic approval under Condition C, the application uses a different version of one or more of the:</p> <ul style="list-style-type: none"> <li>• protocol</li> <li>• Investigator's Brochure (IB)</li> <li>• IMP dossier (for EU or EEA approvals)</li> <li>• IMP manufacturing process and controls (for USA approvals)</li> </ul> <p>compared to the trial that was already approved in the USA, EU or EEA state. This is a potential safety concern because in this scenario, the document(s) being used for the trial will not have been approved by any authority</p> |
| <p>The applicant considers that the application may require the licensing authority or ethics committee to consult with a relevant committee or specialist group before issuing a decision</p>                                                                                                                                                                                                                                                                                                                                                                                                           |
| <p>The application is for a trial that combines both an IMP and an investigational medical device or investigational in-vitro diagnostic device</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p>The sponsor is requesting to disapply or vary the standard labelling requirements for at least one IMP involved in the trial that is not exclusively administered in a hospital or healthcare setting</p>                                                                                                                                                                                                                                                                                                                                                                                             |
| <p>The sponsor is intending to deviate from standard reporting of suspected unexpected serious adverse reactions</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |