

## Webinar Q&A -19 May 2022

### Revised HPRA policy on requirement for mock-ups

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#### Question 1

For mock-ups, is it acceptable to have more information on joint labels that is required by UK without being assessed by HPRA?

#### Answer

Mock-ups must adhere to the agreed QRD texts in IE. Additional items that have not been assessed by the HPRA are not acceptable.

#### Question 2

If there is a minor typographical or grammatical change to the labelling are we still required to submit a G.I.15 variation?

#### Answer

If the typographical or grammatical change does not impact the layout design or readability, the change can be made by the MAH without submitting a G.I.15 variation. If the layout design or readability are impacted, a G.I.15 variation will be required.

#### Question 3

IE-UK joint labelling with aligned product labelling: will the HPRA continue to accept inclusion of UK national requirement statements on mock-ups?

#### Answer

Information currently captured in the UK only box will continue to be acceptable eg. MA number, distribution category, MAH.