Medicines Evaluation Board

Declaration accompanying a duplex marketing authorisation regarding the technical aspects of the readability of the patient information leaflet for pharmaceutical products for human use

The patient information leaflet of the duplex medicinal product corresponds to the package leaflet for the reference product on the following points:

- Paper size ☐yes ☐no
- Paper thickness ☐yes ☐no
- Colour of paper ☐yes ☐no
- Line spacing ☐yes ☐no
- Font type ☐yes ☐no
- Font size ☐yes ☐no
- Letter colour ☐yes ☐no
- Lay-out ☐yes ☐no

If one or more of the abovementioned points were answered with a "no", please indicate per deviation:

- What the exact difference is between the package leaflet of the duplex medicinal product and the package leaflet of the reference product (e.g. "font size 9 for the duplex medicinal product and font size 10 for package leaflet of the reference product"):

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- Why, in your opinion, this deviation will not affect the readability of the package leaflet for the duplex medicinal product:

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Any other comments regarding the technical readability:

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Applicant:

Name:

Date:

Signature:

For more information, see the "Guideline on the readability of the labelling and package leaflet of medicinal products for human use": http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf