

~~October 2016~~ December 2020
CMDh/260/2012, Rev.6 Rev.7

Mock-ups, specimens and samples – New application

In accordance with Article 8 of Directive 2001/83/EC, a mock-up of the sales presentation of the medicinal product, together with the proposed package leaflet should be included with the application. In addition, Member States may require specimens of the sales presentation of the medicinal product to be submitted, in order to check compliance with the relevant articles in Title V of Directive 2001/83/EC.

A "mock-up" is a copy of the flat artwork design in full colour (incl. Braille if applicable), presented so that, following cutting and folding where necessary, it provides a replica of both the outer and immediate packaging, so that the three dimensional presentation of the labelling text of the medicinal product is clear. It is generally referred to as a "paper copy" or "computer generated version".

A "specimen" should be interpreted as referring to a sample of the actual printed outer and inner packaging materials and package leaflet (i.e. the sales presentation).

Sample requirements in National, Decentralised and Mutual Recognition (new applications)

For the purposes of implementing Article 10 of Directive 2001/83/EC, samples of the (non-) active substances and of the finished medicinal product should be supplied. The table below presents an overview of the requirements by Member States.

| Number of samples | AT | BE | BG | CY | CZ | DE | EE | EL | ES | FR | HR | HU | IE | IT | LV | LT | MT | NL | PL | PT | RO | SE | SK | SI | UK (NI) | IS | NO |
|--------------------------------------|----|----|----|----|----|---------|----------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------------|----|------------|----|----|
| Finished medicinal product | H | H | H | H | L | B, G, H | X ¹ | H | H | H | H | M | H | H | H | H | Z | H | * | H | H | I | X ² | N | H | H | H |
| All active substances | H | H | H | H | | | Y | H | H | H | H | M | H | | H | H | H | H | * | H | - | - | X ² | N | H | H | H |
| Non-pharmacopoeial active substances | H | H | H | H | | | - | H | H | H | H | | H | | H | H | H | | * | H | - | | X ² | N | H | H | - |
| Number of samples | AT | BE | BG | CY | CZ | DE | EE | EL | ES | FR | HR | HU | IE | IT | LV | LT | MT | NL | PL | PT | RO | SE | SK | SI | UK (NI) | IS | NO |
| Non-active substances | H | H | H | H | | | - | H | H | H | | | H | | H | H | H | | * | H | - | | X ² | N | H | H | - |

The appropriate number of samples should be provided

- B** In sufficient quantity to permit a full assay and the verification of the control methods used by the manufacturer.
- G** For all medicinal products the Paul-Ehrlich-Institut is competent for (sera, vaccines, allergens, blood products, gene therapy medicinal products, somatic and xenogeneic cell therapy medicinal products and tissue engineering products) samples must be supplied at the same time as the submission of the dossier.
- H** Samples should be made available on any request by the authorities, they are not required to accompany the application.
- I** A sample of the medicinal product in each type of immediate packaging as intended for marketing should accompany the application. The sample may be submitted without final labelling. Placebo samples rather than drug containing samples should be submitted if the active substance is classified as a controlled substance in Sweden (according to the Medical Products Agency's regulation LVFS 2011:10), is cytostatic or otherwise particularly toxic. Placebo samples may be submitted in other cases as well. If a measuring device is part of the medicinal product, a sample of this should also be provided.
- L** One sample of a medicinal product from each type of immediate packaging should accompany the application, or should be submitted before issue of the decision. In justified cases the submission of the sample can be waived. The sample in final immediate packaging may be submitted without final labelling.

Before placing the medicinal product on the market one sample of the product in the form of final sales presentation is requested. In justified cases the submission of the sample can be waived.

Each packaging of a medicinal product placed on the market in the Czech Republic shall show on the label a European EAN code which serves for the purposes of electronic processing. The 13 digit EAN code has to be provided to the SUKL to be entered in the database. It can be submitted either together with the application for marketing authorisation or later, but before placing on the market.

- M** Samples of the medicinal product(s), active substance(s) and commercially not available reference material(s) should be provided upon request of the authority. If requested the amount of samples should allow three full analyses.
- N** Samples should be submitted on request of the Competent Authority in quantity and time frame indicated in request (in principle materials should be in quantity sufficient to permit a full assay and the verification of control methods by the manufacturer).
- X1** In the presentation authorised in RMS.
- X2** Samples of medicinal product in the form of final sales presentation and reference substances of active substance, main degradation products and main impurities should be provided in quantity sufficient for three full analyses, not requested for MRP, DCP if SK is CMS.
- Y** Reference materials, main impurities and main degradation products and non-active substances should be submitted on request and in sufficient quantity to permit full assay and the verification of the control methods used by the manufacturer.
- Z** Specimens should be included at submission of the application when MT is RMS.
- PL*** Should be submitted upon the request of Competent Authority in quantity and time indicated in request (usually the quantity should be sufficient amount to permit a full assay and the verification of control methods used by the manufacturer).