



Artwork and Samples Preparation Checklist

Background: This checklist provides a guide for the preparation of product artwork and samples for a regulatory submission. The regulatory authority may request product samples as part of the initial registration process or during a variation application. The requirements for product artwork and samples differ by country, and some countries may not have defined country regulations. In that case, you may consider following regional regulations or submitting mock artwork and a commitment letter stating that samples will be provided at a later time (letter templates follow checklist).

Review applicable country guidelines to determine the artwork requirements and the number of the required samples.

Design the product artwork in accordance with the identified labelling and language requirements. Artwork may also be region specific and include requirements of multiple countries in the same region.

Identify whether the regulatory authority requires electronic or physical copies of the product artwork.

If product samples are required as part of this submission, determine where they should be shipped (e.g., directly to the regulatory authority or to a Local Technical Representative (LTR) who will submit on behalf of the applicant).

Manufacture samples with the country compliant artwork and apply for any applicable import permits before shipment of the samples.

Ship the samples to the regulatory authority or LTR. If submission is through the LTR, request proof of submission from the LTR for future records.

If product samples or packaging artwork are not available at the time of the regulatory authority submission, a request for exemption from submitting physical product artwork and/or samples can be made. The request may also provide a commitment to commercialize the product with country compliant labelling.

Letter templates for making this request for both registered and unregistered products can be found below and in the Templates folder.

Samples Commitment Letter for a Registered Product

[Insert date]

[Insert contact person name, if known]

[Insert name of regulatory authority]

[Insert address of regulatory authority]

RE: Commitment letter for [product name (authority registration number / authority reference number)]

We refer to our registered product, [insert name of product brand (product generic name and strength)] registered on [insert date], and the Authority's [insert request/requirement] for [insert number] product samples.

We wish to advise the Authority that a commercial batch for distribution of [insert product brand name] in [insert country] has not been manufactured yet. As a result, we are unable to provide [insert number] commercial samples to accompany the application for variation. Enclosed is a copy of the mock labelling artwork proposed for commercializing the product in the country once the variations are approved.

The first [order/consignment] of the product is estimated to arrive in [insert country] on [insert date]. This letter serves as commitment that if the enclosed mock labelling artwork is deemed insufficient by the Authority, we will submit samples from the scheduled consignment to the Authority.

We trust our request meets your favorable opinion.

Sincerely,

Authorized Signatory

[Insert name, title]

[Insert company name]

[Company stamp, if required]

Samples Commitment Letter for a Product Undergoing Registration

[Insert date]

[Insert contact person name, if known]

[Insert name of regulatory authority]

[Insert address of regulatory authority]

RE: Commitment letter for [product name (authority registration number / authority reference number)]

We refer to our application for registration for [insert name of product brand (product generic name and strength)] submitted on [insert date].

We wish to advise the Authority that a commercial batch for distribution of [insert product brand name] in [insert country] has not been manufactured yet. As a result, we are unable to provide [insert number] commercial samples to accompany our application. Enclosed is a copy of the mock labelling artwork proposed for commercializing the product in the country once the product is registered.

The first [order/consignment] of the product is estimated to arrive in [insert country] on [insert date]. This letter serves as commitment that if the enclosed mock labelling artwork is deemed insufficient by the Authority, we will submit samples from the scheduled consignment to the Authority.

We trust our request meets your favorable opinion.

Sincerely,

Authorized Signatory

[Insert name, title]

[Insert company name]

[Company stamp, if required]