Import Testing Waiver Application Template

Application to:
<Name of the national medicine regulatory agency (NMRA) & country to which the request is directed>

1. Product Name(s)
<Enter information here>
2. Dosage form and strengths
<Enter information here. For example: dosage forms, different presentations, formulations of the same family>
3. Marketing Authorization Number(s)
<Enter information here, including period of validity. List if product is currently licensed & marketed or not>
4. Name of applicant and official address
<Enter company name and/or legal entity here that owns the marketing authorization(s) in the country subject to the application> *<Enter company address>*
5. Applicable regulations
<Detail applicable legislation that requires import testing to be conducted including any which permits waivers for specific types of medicinal products and may be part of supporting rationale for products included in the application>
6. Manufacturing and Testing Sites
<Detail information where the product(s) is/are manufactured, packaged, tested and released as included in the appropriate marketing authorizations> *<Detail NMRAs that authorize the locations referenced above>*

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7. Rationale

<Include rationale details here>

Activities that may be used to fill section above include (but are not limited to):

- *Describe current testing requirements for product(s) under consideration and detail product specifications.*
- *Provide concise details of current control strategy(ies) at site(s) of manufacturing, packaging and testing activities and that each location is currently authorized to deliver product(s) meeting relevant Good Manufacturing Practices (GMPs) requirements and regulatory commitments.*
- *Provide overview of NMRAs, which have inspected the specified locations and authorize supply for same types of product, to the country that is the subject of this application.*
- *Describe control strategy(ies) for transport of goods to country for which this application is being made that ensures the integrity of products' quality throughout the supply chain.*
- *Describe checks made to consignments on arrival and mechanisms for assessing the impact of unexpected events (for example, temperature excursions) to deliver a conclusion that the integrity of shipment(s) has been maintained in the shipping channel and the quality attributes of product(s) have been maintained as confirmed in the Certificate(s) of Analysis (CoA) is exporting factory which accompany the shipment. Thus, confirmatory testing does not add value for reasons described in the IFPMA position paper.*

Attachments:

- ☐ Specifications for the final product (country specific)
- ☐ CoA for Product(s) reflecting registered limits (country specific)
- ☐ GMP certificates for the sites of manufacture, packaging, and release, including GMP certificate of the site where testing is performed.
- ☐ Summary of qualification of shipping containers/system used or risk assessment to support shipping under non-controlled conditions
- ☐ Quality checks performed on in bound shipments
- ☐ Copy of IFPMA Position Paper
- ☐ Other

Conclusion:

<Enter name of company or legal entity here> believes that, as the holder of the marketing authorization listed in this application, it has demonstrated with above data, that the product(s) manufactured, tested at the given locations can be shipped to <enter name of recipient country here> without any adverse impact to their product quality attributes. Quality systems and controls are in place at all stages of the manufacturing and supply chain to assure that product(s) remain fit for their intended use as verified periodically through the process of internal audits and regulatory inspections. Therefore, <enter name of NMRA here> can maintain confidence that product(s) released into the market are safe, efficacious and comply with registered specifications and other regulatory commitments. As conducting testing on importation of these products would not add any supplementary information to support that the product(s) are of the appropriate quality and thus fit for purpose, <enter name of company or legal entity here> respectfully requests <enter name of NMRA here> to forgo importation testing.

I, the undersigned, certify, that the information provided in this application and the attached documents is correct and true

Signed on behalf of
<Enter name of company or legal entity here>

_____
(Enter name and title of responsible person here)

_____
(Enter date here: dd/mm/yyyy)

8. Additional Readings (attach as appropriate)

[1] IFPMA (2016) Position Paper: Appropriate Control Strategies Eliminate the Need for Redundant Testing of Pharmaceutical Products (available in English).

[2] Garbe JHO, Ennis K, Furer GM, Jacobs MG, Roenninger SK (2015) Import Testing of Pharmaceutical Products Has Limited Safety Benefits and Can Add Risk to Patients. *Pharmaceutical Technology Europe*. 27(8):s6 - s20. http://images2.advanstar.com/PixelMags/pharma-tech-eu/digitaledition/08-2015-sp.html#6

[3] Roenninger, SK. and Garbe JHO (2016), Import Testing: Limitation of Patient Access to Medicines. In publication.