**DECLARATION OF EQUIVALENCE**   
To be used only for products that have SRA market authorisation but without English labelling and to be completed ONLY by the Marketing Authorisation Holder.

UNICEF-Supply Division would like to procure the following productfrom *(name of the Wholesaler/Supplier, country)* that does not have the Marketing Authorisation /registration number on the sales pack. We would therefore request youto complete the following declaration of equivalence with the appropriate information. It should however be noted that UNICEF-Supply Division only intends to procure products with English/French labelling.

Product name *(as per ITC description):* ………………………………………………….

Wholesaler/Supplier name & Country:………………………………………………………….

# Market AUTHORISATION HOLDER (MAH)[[1]](#footnote-2) UNDERTAKING

Product must hold a Marketing Authorisation from a Stringent Regulatory Authority[[2]](#footnote-3)

MA holder name): ……………………………….

MA number: …………………………………………………..

MA country……………………………………………………..

Marketed Pack/ Label text:……………………………………

Is the product actively marketed in the SRA country/ies? YES  NO 

If Yes, please list the SRA country/ies:…………………………………………………….

* 1. *(name of the MA holder)* shall ensure that the Product supplied to *(name of the wholesaler)* is identical in all aspects (other than those differences listed in paragraph 1.2 below) to the above-mentioned registered product including, without limitation:

1. formulation;
2. manufacturing method (including analytical test method);
3. manufacturing site/unit;
4. sources of active and excipient starting materials; and
5. specifications of the finished product and active ingredient.
   1. The only differences are (*please insert differences in table following the example*):

|  |  |  |
| --- | --- | --- |
| Difference[[3]](#footnote-4) | Registered Product | Product supplied to the wholesaler |
| *Example: Labelling* | *Example: French language* | *Example: English language* |
|  |  |  |
|  |  |  |
|  |  |  |

* 1. The terms of this undertaking applies to all products supplied to UNICEF.
  2. Please provide the following additional information for the Product supplied to UNICEF:

### Manufacturer Product brand name (if any): …………………………………….

### Product INN name: ………………………………………………………………..

### Shelf life: ..............................

### Storage conditions:………………………………………….

### Commercial pack size offered: ............................................................................

### Language(s) of primary packaging: ..............................................................................

### Language(s) of secondary packaging:……………………………………………

### PIL language(s): ..........................................

### Is PIL included in the box? YES  NO 

### Provide a copy of the artworks for primary and secondary labelling and copy of the PIL.

Signed in: ………………………………. (*place of signature*)

Date: ……………………………………………………………

Signature:…………………………………….. ………………

Name of signatory: ……………………………………………

Position: …………………………………………………………

*Should be Quality Assurance Manager or equivalent such as Qualified Person acting as responsible for the Marketing Authorisation Holder.*

1. Definition of MAH: Entity holding the authorisation to place a medicinal product on the concerned market [↑](#footnote-ref-2)
2. **Stringent Regulatory Authority** (SRA) is:

   a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented Regulatory guidance by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or

   an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or

   a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).

   A synonym for SRA is **Highly Regulated Country** (HRC) [↑](#footnote-ref-3)
3. Explanation of differences:

   Minor differences which may be listed here include: (i) different labelling (change of language, additional languages); (ii) No SPC or PIL provided; (iii) different secondary packaging size and type.

   Major differences which may be listed here and accepted by UNICEF subject to provision of supporting documentation include: (i) different type or size of primary packaging (please provide stability studies performed as per ICH guidelines for at least 3 batches); (ii) different shelf life (please provide stability studies performed as per ICH guidelines for at least 3 batches). [↑](#footnote-ref-4)