Declaration of the Marketing Authorisation Holder for a Medicinal Product manufactured and exported from Japan after 11 March 2011 and destined for use in the EU

Following the radiation leak from the Fukushima Daiichi nuclear plant in Japan after the earthquake and tsunami of 11 March 2011, EU authorities and Member States are monitoring its possible impact on medicines manufactured in Japan.

The Marketing Authorisation Holder is responsible for ensuring the quality, safety and efficacy of medicinal products and he/she is therefore invited to complete the following declaration with reference to the maximum levels set for iodine-131, caesium-134 and caesium-137 in Commission Implementing Regulation (EU) No 297/2011, imposing special conditions governing the import of feed and food originating in or consigned from Japan as amended by Regulation (EU) No 351/2011.

The Marketing Authorisation Holder declares that:

Please tick which category applies:

The product(s) listed below is/are manufactured and exported from Japan **after** 11 March 2011 and:

1. ❑ is/are partially or totally manufactured or stored in a prefecture **other than Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Yamagata, Niigata, Nagano, Yamanashi, Saitama, Tokyo and Chiba** and contains no active substances or intermediates manufactured or stored in the named prefectures.

Product name	Strength	Dosage form	INN

2. ❑ is/are partially or totally manufactured **in the prefectures Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Yamagata, Niigata, Nagano, Yamanashi, Saitama, Tokyo and Chiba *or*** contains active substances or intermediates manufactured or stored in the named prefectures.

Product name	Strength	Dosage form	INN

❑ For medicinal products which fall into category 2, <*name of the company*> declares that the product(s) was/were tested prior to export from Japan, by <*name of the Control Laboratory*> and that the safety of the products is ensured after having determined the level of the radionuclides, iodine-131, caesium-134 and caesium-137, with reference to the maximum levels set for these radionuclides for **'other foodstuffs, except liquid foodstuffs'** in Annex II to Regulation (EU) No 297/2011 as amended by Regulation (EU) No 351/2011.

❑ For Medicinal products designed for paediatric use or with paediatric posology, which fall into category 2, <*name of the company*> declares that the product(s) was/were tested prior to export from Japan, by <*name of the Control Laboratory*> and that the safety of the products is ensured after having determined the level of the radionuclides, iodine-131, caesium-134 and caesium-137, with reference to the maximum levels set for these

radionuclides for **'Foods for infants and young children'** in Annex II to Regulation (EU) No 297/2011 as amended by Regulation (EU) No 351/2011.

❑ Analytical certificates are or will be available for all concerned batches and will be presented upon request.

Signature

Done at <location>

On <Date>

Name and position of authorised representative of the MAH.