XSD V2

INFORMATION ON ACTIVE SUBSTANCES

Section A – Finished Product Manufacturer Information

Please complete the details in this section from the Manufacturer's Authorisation held by your site.

Manufacturers Authorisation no

Manufacturer's Name

Competent Authority Country: Portugal

Does your site use active substances which have been manufactured outside the EEA and have been imported into the Union

Section B – Information on Imported Active Substance(s)

Complete the information below in relation to each active substance which is manufactured in a third country (i.e. outside the European Economic Area (EEA)). Repeat this section as required (using "+" and "-" buttons) so that information on all approved third country manufacturing sources for the active substance is provided.

Name of the imported active substance (registered name) + -

Name of the active substance manufacturer

Address Line1

Address Line2

Address Line3

Address Line4

City

Country

Does the active substance manufacturer hold a valid EEA GMP certificate

Is this active substance named on the GMP certificate

Country in which the Competent Authority which issued the GMP certificate is located

Date of the inspection referenced on the EEA GMP certificate

Information on the associated Finished Products

Primary / Alternative Active Substance Source *	Medicinal Product**	Marketed in this country	Marketing Authorisation number	Comment***	+
					-

* with reference to the active substance manufacturing site enter whether this is the primary or alternative source of the active substance for this product

** for finished dosage forms enter a general description of the product e.g. paracetamol tablets. Product tradenames and product strengths are not required. Where partially manufactured products are produced at the site and sent to another site for further processing then a general description of this partially manufactured product should be entered here (eg bulk granules for encapsulation, granulate for compression).

***enter any clarification which you consider relevant.

Submit