

SUMMARY OF PHARMACOVIGILANCE SYSTEM

MASTER FILE LOCATION EV CODE:

MARKETING AUTHORISATION HOLDER	HORUS PHARMA 148 avenue Georges Guynemer – Cap Var 06700 Saint Laurent du Var France T :- Fax
Qualified Person Responsible for Pharmacovigilance Activities (QPPV)	
Deputy Qualified Person Responsible for Pharmacovigilance Activities (QPPV)	
Name of other concerned MAH(s) sharing the pharmacovigilance system	Not Applicable
The list of PV system master files for the MAH (concerning products with a different pharmacovigilance system)	Not applicable
Date of preparation / last update	13-Apr-2016

EU Qualified Person for Pharmacovigilance

Head of Pharmacist
HORUS PHARMA

In accordance with pharmacovigilance regulatory obligations placed on MAHs and laid down in Regulation 1235/2010 and Directive 2010/84/EU, this statement provides a summary of PV system in force at HORUS PHARMA. This summary includes the following elements requested.

EU-Qualified Person Responsible for Pharmacovigilance (EU-QPPV)

Pharmacovigilance activities are contracted out to a third party, , located in . The nominated EU Qualified Person for Pharmacovigilance (EU-QPPV) is Dr and the deputy is named Dr . The QPPV declaration to Eudragilance is currently under process.

See their details below:

The deputy QP is:

Curriculum vitae (CVs) for the EU-QPPV and deputy are provided in *Appendix 1*.

The EU-QPPV and Deputy EU-QPPV are available on a 24-hour basis and from remote locations by means of mobile phone and e-mail.

A signed statement from the MA holder to confirm availability and a declaration regarding outsourcing of QPPV function are provided in *Appendix 2*.

There are standard operating procedures in place to cover absences when office telephone and fax are diverted and the deputy EU-QPPV can be contacted in place of the EU-QPPV.

Moreover, the email address used by _____ for all reports to be sent to the EU-QPPV (_____) is automatically received by the Deputy EU-QPPV at the same time. The server at the QPPV office has a protected partition accessible by the Deputy QPPV anytime and containing all electronic documents concerning _____. This will ensure that the cases can come through in the absence of the QPPV to be compliant with serious adverse reaction report submission targets.

LOCATION of PV Master File

The PV Master File is located at _____

The registered address of _____ is: _____

The registered address of _____ is: _____

APPENDIX 1:

CVs

FOR THE EU-QPPV AND DEPUTY EU-QPPV

APPENDIX 2:

STATEMENT OF MAH

AND

DECLARATION REGARDING OUTSOURCING OF QPPV FUNCTION



DELEGATION OF AUTHORITY LETTER

I undersigned, _____, Head of Pharmacist of HORUS PHARMA, confirm that regarding the responsibilities of the European Qualified Person will be delegated to _____ as Service Provider.

Thus, the Responsible Person (PR):

Signed at _____

, on 04-Jan-2016





STATEMENT

I undersigned, _____, Head of Pharmacist of HORUS PHARMA, marketing authorization holder and responsible for the marketing of the drug products HORUS PHARMA, certify that HORUS PHARMA has the necessary means to fulfill the tasks and responsibilities in Title IX of the directive 2001/83/EC.

Head of Pharmacist _____

Saint-Laurent-Du-Var, on 15-July-2015

