

Summary of the Valeant Pharmacovigilance System

- o In accordance with Directive 2010/84/EC, as amended by Directive 2012/26/EC, Regulation (EU) No 1235/2010, as amended by Regulation (EU) no 520/2012, and module II of the EU guidelines on good pharmacovigilance practices (EMA/816573/2011), Valeant Pharmaceuticals International Incorporated declares the following regarding its subsidiaries in the EU:

1) That in the Pharmacovigilance System are included the following subsidiaries of Valeant Pharmaceuticals International Inc. resident in the EEA region:

Dr. Gerhard Mann Chem.-pharm. Fabrik GmbH, Berlin, Germany

Bausch + Lomb GmbH, Berlin, Germany

Dr. Robert Winzer Pharma GmbH, Berlin, Germany

Chauvin ankerpharm GmbH, Berlin, Germany

Laboratoire Chauvin SAS, Montpellier, France

Bausch + Lomb IOM SpA, Macherio, Italy

Bausch & Lomb GmbH, Vienna, Austria

Bausch + Lomb U.K.,Ltd., Kingston-Upon-Thames, England

Chauvin Pharmaceuticals Ltd., Kingston-Upon-Thames, England

Bausch & Lomb, SA, Lisboa, Portugal

Bausch&Lomb Pharma nv, Brussels, Belgium

Chauvin ankerpharm GmbH, Sofia, Bulgaria

Chauvin ankerpharm GmbH, Prague, Czech Republic

Bausch & Lomb Greece, Athens, Greece

Chauvin ankerpharm Képviselet, Budapest, Hungary

Bausch &Lomb Polska Sp. z o.o., Warsaw, Poland

Bausch & Lomb S.A., Madrid, Spain

PharmaSwiss Ceska republika, s.r.o, Prague, Czech Republic

PharmaSwiss Eesti OU, Tallinn, Estonia

PharmaSwiss Hellas AE, Athens, Greece

PharmaSwiss d.o.o., Zagreb, Croatia

SIA PharmaSwiss Latvia, Riga, Latvia

Valeant Pharma Hungary LLC., Budapest, Hungary

Valeant Czech Pharma s.r.o., Prague, Czech Republic

ICN Polfa Rzeszow S.A., Rzeszow, Poland

PF Jelfa S.A., Jelenia Gora, Poland

Jelfa S.A., Jelenia Gora, Poland

PharmaSwiss d.o.o., Slovenia

2) That they have permanently and continuously at their disposal a European Qualified Person for Pharmacovigilance who is resident and works within the EEA.

Name	
Postal address	
Location in EEA	
Telephone	
Mobile	
Fax	
E-mail	

3) That they possess a pharmacovigilance system which fulfils the tasks and responsibilities listed in Title IX of Directive 2010/84/EC and can monitor the safety of Valeant's authorized medicinal products and detect any change to their risk-benefit balance.

More specifically the pharmacovigilance system has the following attributes:

- a) Has permanently and continuously at its disposal an appropriately Qualified Person responsible for Pharmacovigilance (as described above)
- b) Maintains and makes available on request a Pharmacovigilance System Master File
- c) Operates a risk management system for each medicinal product
- d) Monitors the outcome of risk minimisation measures which are contained in any risk management plan or which are laid down as conditions of a marketing authorisation (pursuant to Articles 21a, 22 or 22a) for any of Valeant's products
- e) Updates the risk management system and monitors pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of Valeant's medicinal products.

4) That the Pharmacovigilance System Master File () is present at the following location in the EEA:

Executive Director
Global Head of Pharmacovigilance
Valeant Pharmaceuticals International Inc.

MD, PhD, MBA
EU Qualified Person for Pharmacovigilance
Valeant Pharmaceuticals International Inc. - Dr.



VALEANT
Pharmaceuticals International, Inc.

March 14, 2014

Effective date: March 18, 2014

TO WHOM IT MAY CONCERN

This is to certify that Valeant Pharmaceutical International, meaning all companies operating in the territory of Europe under the common control of Valeant Pharmaceuticals International Inc. Canada, Ontario, together with their affiliates, have appointed Dr.

MD, PhD, MBA as European Qualified Person for Pharmacovigilance (EU QPPV).

The MAH certifies that it has the necessary means to fulfil the tasks and responsibilities listed in Title IX of EU Directive 2001/83/EC as amended.

~~MD, PhD, MBA~~

EU Qualified Person for Pharmacovigilance

President Valeant Europe