Summary of the Valeant group Pharmacovigilance System

Version 5

- 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 (Valeant group) declares the following regarding its subsidiaries in the EU and Turkey:

1) That in the Pharmacovigilance System are included the following subsidiaries of the Valeant group resident in the EEA region and Turkey:

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, Vimodrone, Italy
Bausch & Lomb GmbH, Vienna, Austria
Bausch + Lomb U.K.,Ltd., Bausch & Lomb House, Kingston-Upon-Thames, England
Chauvin Pharmaceuticals Ltd., Kingston-Upon-Thames, England
Bausch & Lomb, SA, - Sucursal Portugal, Lisboa, Portugal
Bausch&Lomb Pharma nv, Brussels, Belgium
Bausch & Lomb S.A., Madrid, Spain
PharmaSwiss Česká republika, s.r.o, Prague, Czech Republic
PharmaSwiss Hellas AE, Athens, Greece
PharmaSwiss d.o.o., Zagreb, Croatia
ICN Polfa Rzeszów S.A., Rzeszów, Poland
Przedsiębiorstoe Farmaceutyczne Jelfa S.A., Jelenia Gora, Poland
OraPharma Inc., Amsterdam, The Netherlands
Bausch + Lomb Saglik ve Optik Urunleri Tic. A.S., Istanbul, Turkey

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 as amended 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:

Vice President
Global Head of Pharmacovigilance
and Risk Management
Valeant Pharmaceuticals International Inc.

EU Qualified Person for Pharmacovigilance

Valeant Group - Valeant Pharmaceuticals International Inc.–

VALEANT®
Pharmaceuticals International, Inc.

March 31, 2016

Effective date: March 31, 2016

TO WHOM IT MAY CONCERN

This is to certify that Valeant Pharmaceutical International, meaning all companies operating in the territory of Europe and Turkey under the common control of Valeant Pharmaceuticals International Inc. Canada, Ontario, together with their affiliates (collectively referred to as Valeant Group), 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.

EU Qualified Person for Pharmacovigilance
Valeant Group

EVP, President & GM Valeant EMEA