

Legal Basis of Pharmacovigilance

The pharmacovigilance regulatory obligations placed on Marketing Authorisation Holders are laid down in Regulation (EC) No 1235/2010 amending Regulation No 726/2004 and Directive 2010/84/EC amending directive 2001/83/EC.

Summary of Pharmathen's Pharmacovigilance System

Pharmathen S.A. has appointed Ms [redacted] as the Qualified Person for Pharmacovigilance (QPPV) for all medicinal products for which the company holds marketing authorisations. The QPPV or the designated personnel e.g Deputy QPPV are available to be contacted 7 days a week on a 24-hour basis. The QPPV is notified at all Member States where Pharmathen S.A. holds a Marketing Authorisation and at the EMA. The Qualified Person for Pharmacovigilance (QPPV) resides and carries out her duty in Greece.

Contact Details:

PHARMATHEN S.A.

44 Kifissias Avenue 151 25 Marousi, Attiki, Greece.

Telephone: (

Fax:

Email:)

24Hours / 7 days telephone :

Pharmathen S.A. has the necessary means to fulfill the tasks and responsibilities listed in Title IX of Directive 2001/83/EC Pharmathen S.A. ensures that an appropriate system of pharmacovigilance is in place in order to assume responsibility and liability of its medicinal products (marketed products, authorised products and products in pre-authorisation phase) and ensure that appropriate action can be taken on the basis of the relevant SOPs, when necessary. A detailed overview of the Pharmacovigilance system is provided in the Pharmacovigilance System Master File (PSMF) which is kept

[redacted] . The EV Code assigned for the PSMF location for Pharmathen is [redacted] .

The Pharmacovigilance System of Pharmathen S.A is also applicable to all the affiliate companies and thus covers all medicinal products of the affiliate companies: Pharmathen Hellas S.A, Pharmathen International S.A, Pharmathen UK Ltd.

For future updates of the above mentioned information we refer to the current version of the information, as included in the database XEVMPD according to Regulation 726/2004 Article 57(2)"

Qualified Person for Pharmacovigilance
44 Kifissias Avenue 151 25 Marousi,
Attiki, Greece

Vice President of Pharmathen S.A.
44 Kifissias Avenue 151 25Marousi,
Attiki, Greece

Pharmathen S.A.

Headquarters: 44, Kifissias Avenue
151 25 Marousi, Athens Greece

T: +30 210 6604 300, **F:** +30 210 6666 749
info@pharmathen.com

Manufacturing site: 6, Dervenakion str
153 51 Pallini, Athens Greece

T: +30 210 6604 300, **F:** +30 210 6604 583
info@pharmathen.com
www.pharmathen.com

