PRIVACY NOTICE
FOR PHARMACOVIGILANCE, MEDICAL INFORMATION AND PRODUCT COMPLAINTS

This Privacy Notice is intended to provide information on how Synthon International Holding B.V. and/or its affiliate companies in the European Economic Area ("Synthon" or "we") collect, store, use and process your personal data for the purposes of activities related to our obligations regarding (pharmaco)vigilance, medical inquiries and product complaints regarding our medicinal products and medical devices.
For general information about data processing at Synthon, please visit Synthon's Privacy and Cookie Statement.

Synthon takes data privacy seriously and treats all your personal data in accordance with applicable data protection laws, which include, for the European Economic Area, the General Data Protection Regulation (GDPR; Regulation (EU) 2016/679).

What is pharmacovigilance?
It is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.
In line with this general definition, underlying objectives of pharmacovigilance in accordance with the applicable EU legislation for are:

- preventing harm from adverse reactions in humans arising from the use of authorised medicinal products within or outside the terms of marketing authorisation or from occupational exposure; and
- promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public.

Pharmacovigilance is therefore an activity contributing to the protection of patients' and public health (GVP – Annex I (Rev 5) EMA/876333/2011)

An "adverse event" means an unwanted, unintended or harmful event in relation to the use of a medicinal product. With respect to medical devices, this also includes "incidents", but for ease of reading, only the term "adverse event" will be used in this Privacy Notice.

What are personal data?
'Personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (GDPR).

Why do we collect your personal data?
Any personal data provided to Synthon related to medical information inquiries, product quality complaints, adverse events or other activities related to pharmacovigilance will be used solely for the purpose of monitoring and ensuring the safety of Synthon's products. This information is very important for public health and will be used for the detection, assessment, understanding and prevention of adverse events or any other medicine-or medical device related problem.

We collect and process your data for these purposes solely in order to comply with our legal obligations or to answer your request.

What is personal data processing?
It means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction (GDPR).

Information regarding data processing

Pharmacovigilance	**Medical Inquiry**	**Quality Complaint**
*What information do we collect? - **Patients***		
- Name or initials - Contact details (for follow up purposes - when relevant) - age (date of birth) - gender - weight, height - details of the product causing the reaction and your use of it - details of other medicines or remedies you are/were taking at the time of the reaction - details of the adverse reaction you suffered, the treatment you received for that reaction, and any long-term effects the reaction has caused - other medical history considered relevant by the reporter, including documents such as lab reports, medication histories and patient histories. This may include information that is considered by law to be "sensitive (health, ethnicity, religion, sexual life).	- Name - Contact details (to provide answer and for follow up purposes) - Details of your inquiry as provided by you (the information requested by you) This may include information that is considered by law to be "sensitive (health, ethnicity, religion, sexual life).	- Name - Contact details (to provide answer and for follow up purposes) - Details on the relevant product and if applicable, events This may include information that is considered by law to be "sensitive (health, ethnicity, religion, sexual life).
*What information do we collect? – **Reporters*** *(if the reporter is not the patient, such as medical professionals or relatives)*		
- Name - Contact details (for follow up purposes - when relevant) - Profession (to determine the assumed level of medical knowledge) - Relationship with the patient	- Name - Contact details (for follow up purposes) - Profession (to determine the assumed level of medical knowledge for follow up purposes) - Relationship with the patient	- Name - Contact details (for follow up purposes) - Profession (to determine the assumed level of medical knowledge for follow up purposes) - Relationship with the patient
Why do we collect it?		
To handle adverse event reports on our products according to pharmacovigilance legislation. The legislation requires adverse events to be traceable and available for follow-up. As a result, we must collect information to allow us to contact reporters.	To respond to your medical information requests.	To respond to your product quality complaint and to meet quality requirements. The legislation requires reports to be are traceable and available for follow-up. As a result, we must collect information to allow us to contact reporters.
What legal basis do we rely on for the data processing (EU)?		

Pharmacovigilance legislation, including Good Pharmacovigilance Practices, to collect specific data for reasons of public interest in the area of public health (in the EU, GDPR Art. 6(1)(c) and 9.2(i)).	Product safety and quality legislation in responding to your requests (EU GDPR Art. 6(1)(c) and 9(2)(i)), or legitimate business interest (EU GDPR Art. 6(1)(f)), or your consent (EU GDPR Art. 6(1)(a) and 9(2)(a)), which would be clearly obtained at the time of collection.	Product safety and quality legislation in responding to your requests (EU GDPR Art. 6(1)(c) and 9(2)(i)), or legitimate business interest (EU GDPR Art. 6(1)(f)), or your consent (EU GDPR Art. 6(1)(a) and 9(2)(a)), which would be clearly obtained at the time of collection.
International transfers		
Synthon's pharmacovigilance database is located in The Netherlands. Synthon also engages a data processing company in India for data processing. Because Synthon is a global company, information may be shared with Synthon's global medical teams, however your contact details will not be provided. Synthon may share pharmacovigilance data with national and/or regional authorities, such as the European Medicines Agency, however your contact details will not be provided. Synthon may also share pharmacovigilance data with other pharmaceutical companies who are our license or marketing partners, where pharmacovigilance obligations require such exchange.	Synthon's medical inquiry database is located in The Netherlands. Because Synthon is a global company, information may be shared with Synthon's global medical teams, however your name and contact details will not be provided. Synthon may also share medical inquiries with other pharmaceutical companies who are our license or marketing partners, where such exchange is required .	Synthon's quality complaints database is hosted in The Netherlands. Because Synthon is a global company, global quality teams may have access. Synthon may also share quality data with other pharmaceutical companies who are our license or marketing partners, however only in anonymised form.

Who will see your personal data?
Synthon may share the data you provided with Synthon employees, business partners, service providers and Health Authorities worldwide for pharmacovigilance, safety and quality purposes only, if legal obligations require such exchange of information.

We take appropriate steps to ensure that business partners, service providers and Synthon's affiliated companies in countries outside the European Economic Area to whom we may transfer data from EU subjects commit to guaranteeing an adequate level of protection of your personal information.

How long will we keep your personal information?
We will retain your personal information for the period required by law (EU) No 520/2012).

What are your rights as data subject?
In accordance with GDPR you have the right to
- Know that your personal data are being processed and for which purpose;
- Request copies of those data;
- Request rectification or erasure of your personal data if it is inaccurate or processed for purposes not stated above;

- Request Synthon to restrict the processing of your personal data;
- In certain circumstances, object to the processing of your personal data;
- Request information on the identities or categories of third parties to which your personal data are transferred;
- Lodge a complaint with the data protection authority in your country.

Whom should you contact for more information or for exercising your rights on the processing of personal data by Synthon?

Please direct any questions and requests related to the processing of personal data to
Synthon International Holding B.V.
Attn: Privacy committee
P.O. Box 7071
6503 GN Nijmegen
The Netherlands
E-mail: dataprivacy@Synthon.com