

## Privacy Notice for Patients and Health Care Professionals – Pregnancy Exposure Registry Ulipristal acetate Emergency Contraceptives (G03AD02)

October 2020

This Privacy Notice is addressed to:

- healthcare professionals;
- consumers of medical products containing Ulipristal acetate Emergency Contraceptives (G03AD02).

You are receiving this Privacy Notice because a “**Consortium**” of pharmaceutical companies has set up a Pharmacovigilance Pregnancy Exposure Registry (in the following the “**Registry**”) for different medical products all containing the active substance Ulipristal acetate Emergency Contraceptive (G03AD02) (in the following “**Ulipristal**”). The Consortium consists of the following pharmaceutical companies:

- (1) ZENTIVA GROUP, a.s.,
- (2) Aristo Pharma GmbH,
- (3) Exeltis Pharmaceuticals Holding, S.L.,
- (4) HELM AG,
- (5) Hexal AG,
- (6) Mylan,
- (7) STADA Arzneimittel AG,
- (8) Farmitalia s.r.l.
- (9) Aspen Healthcare Malta Limited
- (10) Elpen Pharmaceutical Co. Inc.

The Consortium is required to process information about you, which constitutes “**Personal Data**”. All members of the Consortium are responsible for the processing of your Personal Data as they jointly decide why and how it is processed, thereby acting as “**Joint Controllers**”. In this Privacy Notice, “**We**” or “**Us**” refers to all Joint Controllers. In a “**Joint Controllership Agreement**”, the members have specified the data protection responsibilities for compliance with the Data Protection Legislation (and in particular with Art. 26 GDPR) relating to the processing of Personal Data. This Joint Controllership Agreement contains in particular, but not limited, the following:

- scope and purpose of the Joint Controllership;
- type of Personal Data and data subjects (categories);
- responsibility of each Controller for compliance with the obligations under the GDPR;
- joint contact point for patients and health care professionals.

**Should you have any further questions in relation to the processing of your Personal Data, We invite you to contact [dpo@dada.nl](mailto:dpo@dada.nl).**

Please read this Privacy Notice carefully, which sets out in which context We are processing your Personal Data and explains your rights and our obligations when doing so.

## **1. What information do We have about you?**

### **1.1 Patients**

If you are a patient and have consumed Ulipristal, We collect the following information about you:

- your general and identification information (your initials, your date of birth, your email address); your email address will only be used by the system to send out a maximum of five emails, as per the requirements of the national drug regulatory authorities.
- information concerning your exposure to Ulipristal;
- information on drugs other than Ulipristal received during pregnancy;
- Pregnancy related information (e.g. pregnancy outcome, potential illnesses during pregnancy or chronic illness, maternal history medical condition during pregnancy result of serology test, prenatal tests).

### **1.2 Health Care Professionals**

If you are a health care professional and one of your patients has been exposed to Ulipristal, We collect the following information about you:

- your general and identification information (your first and last name, your medical specialty, your affiliation, address, country, phone number, fax and email); your email address will only be used by the system to send out a maximum of six emails, as per the requirements of the national drug regulatory authorities.

### **1.3 How do We collect the information about you?**

If you are a **patient**, you have either entered all information about yourself into the Registry by yourself or a health care professional has entered the information about you into the Registry for you. In the latter case, you have released the health care professional from his/her doctor/patient confidentiality and the health care professional has provided you with a copy of this privacy notice.

If you are a **health care professional**, you have either entered all information about yourself into the Registry by yourself or a patient has entered the information about you into the Registry for you. In the latter case, the patient has provided you with a copy of this privacy notice.

## **2. For which purposes do We Use your Personal Data and why is this justified?**

### **2.1. Legal basis for the processing**

We will not process your Personal Data if We do not have a proper justification foreseen in the law for that purpose. Therefore, We will only process your Personal Data, because processing is necessary to comply with our legal and regulatory obligations to provide a pharmacovigilance Registry, Article 6 (1) (c) GDPR. Moreover, processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy, Article 9 (2) (i) GDPR.

## 2.2. Purposes of the processing

We always process your Personal Data for a specific purpose. In particular, We process your Personal Data for the following purposes:

- setting up and operating the Registry for the purposes of pharmacovigilance;
- collecting information on patients being exposed to Ulipristal;
- collecting information on health care professionals of patients being exposed to Ulipristal;

## 3. Who has access to your Personal Data and to whom are they transferred?

### 3.1 Processing by the Processor

The Consortium has instructed DADA Consultancy B.V. Godfried Bomansstraat 31, 6543 JA Nijmegen, The Netherlands, with the set up and operation of the Registry. DADA Consultancy B.V. in this regard processes all data on behalf of all Joint Controllers and based on a data processing agreement, thereby acting as a “**Processor**”. The Processor will take all necessary measures to comply with all applicable data privacy regulations and guarantee data security. The Processor will use on its behalf a subprocessor in order to fulfil its responsibilities concerning the registry. A list of subprocessors is available on request.

### 3.2 Processing by the Controllers

The Processor only transfers your data to us in a pseudonymised way.

We will not sell, share, or otherwise transfer your Personal Data to third parties other than those indicated in this Privacy Notice.

In the course of our activities and for the same purposes as those listed in this Privacy Notice, your Personal Data can be accessed by or transferred to the following categories of recipients, on a need to know basis to achieve such purposes:

- our personnel (including personnel, departments or other companies of each Controller’s group);
- our IT systems providers, cloud service providers, database providers and consultants;

The above third parties are contractually obliged to protect the confidentiality and security of your Personal Data, in compliance with applicable law.

Your Personal Data can also be accessed by or transferred to any national and/or international regulatory, enforcement, public body or court, where We are required to do so by applicable law or regulation or at their request.

The Personal Data We collect from you may also be processed, accessed or stored in a country outside the country where the Processor is located, which may not offer the same level of protection of Personal Data. If We transfer your Personal Data to external companies in other jurisdictions other than the Processor, We will make sure to protect your Personal Data by (i) applying the level of protection required under the local data protection/privacy laws applicable to the Joint Controllers and, (ii) for the Joint Controllers located in the European Economic Area (i.e. the EU Member States plus Iceland, Liechtenstein and Norway, the "EEA"), unless otherwise specified, only transferring your Personal Data on the basis of standard contractual clauses approved by the European Commission. You may request additional information in relation to

international transfers of Personal Data and obtain a copy of the adequate safeguard put in place by exercising your rights as set out in Section 6 below.

#### **4. How do We protect your Personal Data?**

We have implemented appropriate technical and organisational measures to provide an adequate level of security and confidentiality to your Personal Data.

These measures take into account:

- (i) the state of the art of the technology;
- (ii) the costs of its implementation;
- (iii) the nature of the data; and
- (iv) the risk of the processing.

The purpose thereof is to protect it against accidental or unlawful destruction or alteration, accidental loss, unauthorized disclosure or access and against other unlawful forms of processing.

Moreover, when handling your Personal Data, We:

- only collect and process Personal Data which is adequate, relevant and not excessive, as required to meet the above purposes and
- ensure that your Personal Data remains up to date and accurate.

For the latter, We may request you to confirm the Personal Data We hold about you. You are also invited to spontaneously inform Us whenever there is a change in your personal circumstances so We can ensure your Personal Data is kept up-to-date.

#### **5. How long do We store your Personal Data?**

We will only retain your Personal Data for as long as necessary to fulfil the purpose for which it was collected or to comply with legal or regulatory requirements. In general, we delete your email address once we have received information on the pregnancy outcome or one month after we have sent our last reminder email to you. Your other Personal Data (date of birth and initials) will be deleted when the Registry is closed. If you wish that your Personal Data is removed earlier, please contact [ulipristal@dada.nl](mailto:ulipristal@dada.nl) with this request.

#### **6. What are your rights and how can you exercise them?**

You may exercise the following rights under the conditions and within the limits set forth in the law:

- the right to access your Personal Data as processed by Us and, if you believe that any information relating to you is incorrect, obsolete or incomplete, to request its correction or updating;
- the right to request the erasure of your Personal Data or the restriction thereof to specific categories of processing;

**- the right to object, in whole or in part, to the processing of your Personal Data;**

- the right to request its portability, i.e. that the Personal Data you have provided to Us be returned to you or transferred to the person of your choice, in a structured, commonly Used and machine-readable format without hindrance from Us and subject to your confidentiality

obligations.

If you have a question, want to exercise the above rights or you are not satisfied with how We process your Personal Data, you may send an email to [dpo@dada.nl](mailto:dpo@dada.nl) or a letter at Dada Consultancy B.V., Data Protection Officer, Godfried Bomansstraat 31, 6543 JA Nijmegen, The Netherlands, with a scan of your identity card for identification purpose, it being understood that We shall only Use such data to verify your identity and shall not retain the scan after completion of the verification. When sending Us such a scan, please make sure to redact your picture and national Registry number or equivalent on the scan.

In any case, you also have the right to file a complaint with the competent data protection authorities, in addition to your rights above.

## 7. How can I contact the members of the Consortium?

Please see below the contact details of every data protection officer of every member of the Consortium:

Member	Contact
ZENTIVA GROUP, a.s.	Address: U Kabelovny 529/16 102 00 Prague 10 Czech Republic Contact Data Protection Officer: <a href="mailto:dpo@zentiva.com">dpo@zentiva.com</a>
Aristo Pharma GmbH	Address: Aristo Pharma GmbH Wallenroder Straße 8-10 13435 Berlin Germany Contact Data protection Officer: <a href="mailto:dsb@fox-on.com">dsb@fox-on.com</a>
Exeltis Pharmaceuticals Holding, S.L.	Address: Calle Manuel Pombo Angulo 28 3ª planta 28050 Madrid, España Contact Data Protection Officer: <a href="mailto:dataprotection@insudpharma.com">dataprotection@insudpharma.com</a>
HELM AG	Address: Nordkanalstrasse 28 200 97 Hamburg, Germany

	<p>Email address: <a href="mailto:info@helmag.com">info@helmag.com</a></p> <p>Data protection Officer:</p> <p><a href="mailto:datenschutzbeauftragter@helmag.com">datenschutzbeauftragter@helmag.com</a></p>
Hexal AG	<p>Address:</p> <p>Industriestr. 25</p> <p>83607 Holzkirchen, Germany</p> <p>Data protection Officer:</p> <p><a href="mailto:global.privacy_office@novartis.com">global.privacy_office@novartis.com</a></p>
Mylan	<p>Address:</p> <p>Krijgsman 20</p> <p>Amstelveen, 1186 DM, Netherlands</p> <p>Email address: <a href="mailto:data.privacy@mylan.com">data.privacy@mylan.com</a></p> <p>Contact Data protection Officer:</p> <p><a href="mailto:Audrey.Gerin@mylan.fr">Audrey.Gerin@mylan.fr</a></p>
STADA Arzneimittel AG	<p>Address:</p> <p>Stadastraße 2-18</p> <p>61118 Bad Vilbel, Germany</p> <p>Contact Data protection Officer:</p> <p><a href="mailto:compliance@stada.de">compliance@stada.de</a></p>
Farmitalia s.r.l	<p>Address:</p> <p>Viale Alcide De Gasperi,</p> <p>165/B - 95127 CATANIA, Italy</p> <p>Contact Data protection Officer:</p> <p><a href="mailto:privacy@farmitalia.net">privacy@farmitalia.net</a></p>
Aspen Healthcare Malta Limited	<p>Address:</p> <p>206, Wisely House, Old Bakery Street</p> <p>VLT1451, Valletta, Malta</p> <p>Contact Data protection Officer:</p> <p><a href="mailto:rsafia@ae.aspenpharma.com">rsafia@ae.aspenpharma.com</a></p>

ELPEN Pharmaceutical Co. Inc	Address: 95 Marathonos Ave., 19009, Pikermi Attica, Greece Contact Data protection Officer: <a href="mailto:gchatzitheodorou@elpen.gr">gchatzitheodorou@elpen.gr</a>
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## 8. Privacy Policy Review

We regularly review this privacy notice. We will implement our potential changes to this Privacy Notice without prior notice. However, We will inform you about the relevant changes. We encourage you to periodically review the privacy notice available on the Registry, in order to be informed of how We process Personal Data. This policy has been updated for the last time on: 20.10.2020.