ZTAS Privacy Notice

The Privacy Notice for the Zaponex Treatment Access System (ZTAS) explains:

1 Leyden Delta BV and ZTAS

Leyden Delta BV (also referred to as '*we', 'us', 'our' or 'Leyden Delta'*) is the supplier and licence holder of the Zaponex brand of clozapine in the United Kingdom (*'UK'*). As a licence holder for medicinal product approved for use in clinical practice, we are bound by obligations to monitor the safety and safe use of our product as defined in pharmacovigilance legislation.

For clozapine products marketed in the UK, the regulatory authority requires 'additional risk minimisation measures' from the licence-holder, to manage and mitigate the risks associated with the use of clozapine. To this effect, Leyden Delta operates the Zaponex Treatment Access System (ZTAS).

The ZTAS registers all physicians, pharmacists and patients who prescribe, dispense or use Zaponex, and monitors the blood values of the patients treated with Zaponex. ZTAS is in place to minimise the risks of Agranulocytosis, a serious adverse blood reaction, associated with the use of clozapine.

Leyden Delta's ZTAS department collects and processes information, as received from healthcare providers, treating patients with Zaponex. This information includes *personal data* (identifying information e.g. name and date of birth) and *special category personal data* (e.g. ethnicity and health information) of patients. We also collect the *personal* data (identifying information e.g. name and work address contact details) of healthcare providers who are involved in the treatment of patients with Zaponex.

In accordance with applicable data protection legislation, Leyden Delta is a data controller for the personal information collected as part of the ZTAS. We have registered with the Dutch Data Protection Authority under authorisation number **FG002209.**

Contact details

Leyden Delta BV
Neerbosscheweg 620
6544 LL Nijmegen
The Netherlands

Telephone: 0207 3655 842 (UK)
Email: info@ztas.co.uk

Legal representative: W.M. van Rijn, Director

Please contact us by email, if you have any questions about our privacy policy or the information we hold about you or your patient(s). Our *Data Protection Officer* can be contacted via the contact information for ZTAS as printed above, or directly via dataprotectionofficer@ztas.co.uk.

2 Why Leyden Delta collects personal information and how it is used

The necessity for Leyden Delta to collect and process information is based on requirements of the Zaponex licence.

The *purpose of the processing* of personal information collected about healthcare providers and patients for the ZTAS is primarily to support safe treatment of the patients with the Zaponex brand of clozapine, to assist healthcare providers to make medical decisions regarding the health and treatment of patients and to provide both healthcare providers and patients with services connected with ZTAS.
The lawful bases under applicable data protection legislation for Leyden Delta to request healthcare providers to provide *personal data* of their *patients* are that the processing is necessary:

- for compliance with a **legal obligation** (i.e. our regulatory obligations under pharmacovigilance legislation which include the licence requirements for Zaponex);
- to protect the **vital interests** of patients (as without this processing we cannot protect patients treated with Zaponex from life-threatening adverse reactions); and
- for performing a task carried out in the **public interest** (namely to ensure up to date product information for Zaponex, so that the product can be used in full knowledge of the risks; this task has a clear basis in pharmacovigilance legislation).

The processing of *special category data* of *patients* is necessary:

- for the purposes of **preventive medicine, medical diagnosis** and the **provision of healthcare/treatment**; and
- for **reasons of substantial public interest** in the area of public health (safeguarding the economic well-being of individuals).

The lawful bases that we rely upon to process the personal data of *healthcare providers* are that the processing is necessary:

- to comply with a **legal obligation** (Zaponex licence obligations require the registration of all physicians and pharmacists who prescribe or dispense Zaponex to a patient) and we must therefore verify this; and
- we have **legitimate interests** in processing the personal data of supporting healthcare providers, to ensure provision of healthcare to the patient.

The following *personal* and *special category data* is collected and processed onto the ZTAS:

For patients treated with Zaponex

- Name, NHS number, date of birth, sex, ethnicity, blood test results, blood samples (when the ZTAS central laboratory is used) and indication for Zaponex use.

For healthcare providers involved with care for Zaponex treated patients

- Name, address and contact details of the treatment facility/ies at which the healthcare provider has registered their patient(s) (telephone and email).
- For healthcare providers responsible for the prescribing or dispensing of Zaponex to patients, we also collect their *registration number* in the relevant *professional register* (e.g., GMC, GPC or PSNI)

Use of ZTAS data for research purpose

The personal information collected for the purpose of ZTAS may be used by Leyden Delta (or sponsors whether or not associated with Leyden Delta) to undertake research. The use of this data for research purposes may or may not be related to Zaponex and/or services connected to it and the outcome of the research may be published. In any situation where ZTAS data will be used for research purposes, Leyden Delta will apply appropriate safeguards to ensure that the rights and freedoms of the data subjects are adequately protected. This will mean amongst other, that no direct identifiable information, as collected from your patients by the ZTAS, will be used. Furthermore, your patient(s) cannot be identified in any publications resulting from research.

The lawful bases for Leyden Delta (or sponsors whether or not associated with Leyden Delta) to process the *personal data and special category data* of *patients* represent **legitimate interest** and serves the **public interest** as such research is aimed at gaining a better understanding of the conditions treated, safety and efficacy of treatment and services connected to treatment to improve the treatment options and/or services for other patients.

Informing the patient

Healthcare providers who determine that Zaponex (clozapine) is the appropriate treatment for their patient are required to register themselves and their patient with the ZTAS. The requirement for registering with the ZTAS and for periodic blood testing in order to continue taking Zaponex medication is explained to a patient on initiation of the Zaponex treatment by their healthcare provider. Additionally, healthcare providers are expected to inform their patients about the processing and sharing of personal data with Leyden Delta (ZTAS), to allow for the monitoring of the patient's Zaponex treatment, in line with Data protection legislation. A healthcare organisations' local procedures for informing a patient about Zaponex treatment and the consequential processing of their personal data by ZTAS are applicable.

3 How we collect personal information

We primarily collect the personal data of patients and healthcare providers directly from the healthcare provider involved with the patient's Zaponex treatment. Patient and healthcare provider registration details are collected via dedicated **ZTAS Data Forms**. Healthcare providers are required to inform the ZTAS of any **changes to the registration information** for themselves and any patients treated with Zaponex under their care.

Blood result information is received from the ZTAS Central Laboratory, ZTAS point of care blood testing (POCT) systems, from local laboratories (usually via an established link) and directly from healthcare providers involved with a patient's Zaponex treatment.

The majority of the information concerning patients and their Zaponex treatment as received by ZTAS is provided by healthcare providers involved with their patients' treatment. Healthcare providers therefore are regarded as the primary data controller of their patients' personal information. Whereas Leyden Delta/ZTAS and the healthcare provider have a shared data controller responsibility with respect to personal information of patients receiving Zaponex treatment. As a consequence, Leyden Delta and a Healthcare Organisation (employing the healthcare provider) each have their own legal data controller responsibilities and are accountable for this.

Information collected in case of adverse events during Zaponex use
If a patient experiences an adverse event (AE) during the course of Zaponex treatment, Leyden Delta is required to medically evaluate the AE case report and may request further information from the healthcare provider in order to be able to evaluate the role of Zaponex in the AE, to assure that any aspect which could impact the safety profile of Zaponex is detected and assessed and that necessary measures are taken. The information we collect in case of an AE would typically concern a patient's medical history, co-morbidity, concomitant medications and /or any other information relevant in the context of the AE and the patient's use of Zaponex.

4 Who we share information with

Patient and healthcare provider personal data may be shared by Leyden Delta with the third parties listed below.

Healthcare providers
Via the ZTAS systems, and via standardised communications pertaining to ZTAS registered patients, patient and healthcare provider information is shared with the healthcare providers responsible for the relevant patient's Zaponex treatment.

Central Laboratory
Patient and healthcare provider information is shared with Magna Laboratories Ltd, in order that Magna Laboratories can provide the necessary support in the required blood testing for Zaponex.

CNRD
For a selection of the ZTAS registered patients who experience abnormal low blood result values during the course of their Zaponex treatment that could signify a serious threat to their health, personal information is transferred to the Central Non Rechallenge Database (**CNRD**). Leyden Delta takes part in the CNRD, together with other clozapine licence-holders in the UK, to prevent harmful re-exposure to clozapine treatment, for patients with a previous negative experience (i.e. serious haematological AR)

whilst treated with clozapine. Data on the CNRD is only shared with the monitoring services of other clozapine licence-holders.

Service providers used in support of the ZTAS
Leyden Delta makes use of service providers e.g. for the support and maintenance of IT database systems in which personal information is held and for the archiving of hardcopy source records.
For the ZTAS database system, Leyden Delta uses a service provider who is based outside the European Economic Area (EEA), in the United States. That being said, the servers on which ZTAS data is held are based in the UK and remotely serviced by authorised staff of the Service provider. ZTAS data is not exported to the United States. To ensure that personal data are kept safe and secure, and is managed in accordance with the same standards as maintained throughout the EEA and the UK, Leyden Delta relies upon standard data protection clauses (SCC) with the service provider.
Other service providers used by Leyden Delta have their base and data processing activities in the EEA.

Licensing authority
As licence holder we are required to report Zaponex AE case report information to the licensing authority. Exchange of Zaponex case report safety information follows the format as dictated by health authorities. Personal information of patients and healthcare providers pertaining to a case report is pseudonymised and masked/reduced upon exchange with other parties, to ensure confidentiality of the patient and reporter (i.e. healthcare provider) data.

5 How long we keep personal information for

The personal information collected as part of the ZTAS and received in relation to Zaponex AEs, is kept in accordance with our retention procedures and the timelines as laid out in pharmacovigilance legislation. This requires us to hold our records throughout the duration of our Zaponex licence and for 10 years after it has been withdrawn.

6 Access to information and data protection rights of individuals

Access to information
Individuals from whom data is collected and processed by Leyden Delta expect their records to be kept confidential. We may therefore be limited in what information we can disclose if an individual requests access to the patient records that we keep. However, Leyden Delta may be able to disclose information from the records we hold when requested, provided that the following conditions are met:

For requests that are made by a *patient/relative* or by *someone other* than the person whose data is concerned, the request should be:

- made by someone who can demonstrate a legitimate reason for accessing requested information; the reason and the legitimacy for access to information should be justified in the request.
- made in writing – request should include relevant contact details so that Leyden Delta can ascertain that information can be returned adequately to the correct person.

For requests directly made to Leyden Delta by a *patient* or a *patient's legal representative*, Leyden Delta will involve the healthcare provider who is, or has been, responsible for the patient's Zaponex treatment.

We reserve the right to charge a reasonable fee to cover our administrative costs in respect of any assistance that we provide.

Data protection rights of individuals
Individuals about whom data is collected and processed by Leyden Delta (i.e. both patients and healthcare providers) have certain rights under applicable data protection legislation with respect to their own personal data, including a right to:

- request **access** to the information we hold about them and **receive** the information in a format that suits them
- ask us to make any **changes** to their information to make sure that it is accurate and up to date

- ask us to **stop** or **limit** our use of or to **delete** their information, but only in certain circumstances

Note that it may not be possible for Leyden Delta to comply with requests made to exercise the above rights when they are only applicable in certain circumstances. For example, as the processing of personal information of patients and healthcare providers is necessary to comply with our legal obligations, Leyden Delta will not be required to erase personal information contained in its records if so requested.

Patients or healthcare providers who do not wish to share their personal information with Leyden Delta, or third parties supporting the ZTAS, shall not be able to be treated with Zaponex, or take part in the prescribing or dispensing of Zaponex to patients.

Individuals have the right to **lodge a complaint** with a data protection supervisory authority should they have a concern on how we handle their personal information. For the UK, the supervisory authority is the Information Commissioner's Office (ICO), and can be contacted at

Information Commissioner's Office
Wycliffe House,
Water Lane, Wilmslow,
Cheshire SK9 5AF,
telephone 0303 123 1113.

Changes to our privacy policy
We keep our privacy policy under regular review and we will place any updates on this web page. This privacy policy was last updated at the date indicated in the footer.