**Data Privacy Notice**

**Pharmacovigilance, Medical Information, and Quality**

The following is important information concerning the processing of personal information provided by you as reporter or subject of a report in connection with a medical enquiry, a quality complaint or an adverse event report to Bluefish Pharmaceuticals (Bluefish). The Privacy Notice applies to information we collect from you online, by phone, fax, e-mail, or post. We may also be provided with information about you by a third party reporting an adverse event that affected you. Such third parties may include medical professionals, insurance companies, lawyers, relatives.

**What is the purpose of collecting and processing your personal information?**

For both the reporter and the subject of the report, personal information will be processed only for the purpose of dealing with the medical enquiry, quality complaint or adverse event report.

**On what legal basis do we use your personal information?**

Processing of personal information is required to comply with our legal obligation to monitor and report adverse events.

Furthermore, processing of personal information about you is needed to be able to respond to your enquiry or to your report.

For further information please see General Data Protection Regulation (GDPR) Art 6 (1) c) and f) and GDPR Art. 9 (2) i).

**What personal information do we collect about you?**

Your personal information may include

* your name or initials
* gender
* home address
* age and date of birth
* e-mail address
* phone number(s)

and special categories of personal information including

* medical diagnostic data
* prescription data
* other health related information provided by you
* relationship to a person.

**How long will we keep your personal information?**

We will retain your personal information for the period required by law, which is:

• In the case of an adverse event, a period of 10 years after the marketing authorisation for the relevant product has expired or was cancelled everywhere in the world.

• In the case of product quality complaints, a period of 1 year after the batch expires or 5 years after receipt of complaint (whichever is longer).

• In the case of enquiries (without an adverse event reported), up to 6 months from the date of the enquiry.

**With whom do we share your personal information?**

Your personal information will be accessible to Bluefish employees, as well as to authorised employees of certain suppliers who provide Bluefish with support services. Bluefish will share your personal information with suppliers following appropriate due diligence and under a written agreement which commits the suppliers to appropriate safeguards in relation to the handling of your personal information.

In addition, we may need to transfer your personal information to certain regulatory agencies. Patients are not identified by name in reports to regulatory agencies.

**Transfers of your personal information outside of your home country**

Your personal information may be transferred to countries inside or outside the European Economic Area (EEA). The countries outside the EEA may include the United Kingdom and India. The countries to which we transfer personal information may not have data protection laws that provide an adequate level of protection to your personal information. Bluefish therefore implemented appropriate technical and organisational security measures to ensure that third parties and members of the Bluefish group to whom we transfer data in those countries commit to an adequate level of protection for your personal information.

**Your rights**

You are entitled to:

• request information regarding the processing of your personal information, including a copy of your personal information;

• request the correction and/or deletion of your personal information, or object to the processing of your personal information;

• request the restriction of the processing of your personal information;

• request receipt or transmission to another organisation, in a machine-readable form, of the personal information that you have provided to Bluefish; and

• complain to your local data protection authority, or to a court of law, if your data protection rights are violated.

Where you are given the option to share your personal information with us, you can always choose not to do so. If you object to the processing of your personal information, we will respect that choice to the extent this would not prejudice our ability to meet our legal obligations.

If you would like to exercise your rights, please let us know by getting in touch using the contact details below.

**Contact us**

If you have questions or requests regarding the processing of your personal information, or require additional information, please contact us by using any of the below contact channels:

Bluefish Pharmaceuticals AB (company reg.no. 556673-9164).

P.O. Box 49013,

100 28 Stockholm, Sweden

E-Mail: [privacy@bluefishpharma.com](mailto:privacy@bluefishpharma.com)

Tel.: +46(0)8 519 116 00

You also have the right to file a complaint with your local data protection authority. The authority for Bluefish is Integritetsskyddsmyndigheten, IMY.SE