

## **PRIVACY NOTICE FOR ADVERSE EVENTS (PHARMACOVIGILANCE), MEDICAL INQUIRIES AND PRODUCT COMPLAINTS**

This Privacy Notice is addressed to:

- Individuals reporting adverse events, requesting medical information, submitting product quality complaints, and providing safety concerns regarding our products;
- Individuals that are subjects of adverse events, medical information queries and product quality complaints.

**BioMarin Pharmaceutical Inc.**, located at 770 Lindero Street, San Rafael, CA 94901, USA and its worldwide BioMarin group of companies (“BioMarin,” “we,” “us,” or “our”) respect the privacy of individuals and value the confidence of our customers, partners, patients, employees, and visitors. BioMarin is responsible for the processing of your personal information as we decide why and how it is processed, thereby acting as the “**data controller(s)**”. We may exercise this responsibility alone or jointly with other company(-ies) in the BioMarin group, acting as joint controller(s).

This Privacy Notice sets forth BioMarin’s practices regarding the collection, use, and disclosure of information that you may provide to us that constitutes personal information either directly or indirectly through online or offline means (collectively, the “Services”).

Please carefully read this Privacy Notice that sets out in which context we process your personal information and explains your rights and our obligations.

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### [WHAT INFORMATION DO WE COLLECT ABOUT YOU?](#)

This information may either be directly provided by you or provided by our supplier or service provider (i.e., the legal entity for whom you work), by third parties (e.g., healthcare professionals, external vendors like medical agencies, or hospitals/clinics) or be obtained through trusted publicly available sources (e.g., PubMed, clinicaltrials.gov, congress websites or university websites).

We collect various types of personal information about you depending on the purpose, including:

- Data relating to the reporter of adverse events, such as contact information (name, address, phone/fax/mobile phone/email or other contact information, profession, relationship with the subject of the reports
- Data relating to the person experiencing an adverse event, such as information that would allow us to identify the case and prevent double reporting (e.g., name/and/or initials), demographic data (e.g., date of birth, age group, sex, weight, or height), medical information concerning the adverse event itself (e.g., details of the product suspected to cause the adverse event, dosage, reasons for application or changes to regimen), details of concomitant medication (e.g., dosage, application duration, reasons for application or changes to regimen), details of the adverse event (e.g., treatment, potential long-term effects, relevant medical information such as lab reports, medication histories, patient histories), information about health, racial or ethnic origin, religious beliefs and sexual life;
- Data relating to persons submitting medical inquiries (e.g., contact information such as name, address, phone/fax/mobile phone/email/or other contact information, profession (e.g., health care professional), demographic data (e.g., date of birth, age group, sex, weight, or height), information provided as part of the inquiry, information about health, racial or ethnic origin and sexual life;
- Data relating to individuals submitting product complaints such as contact information (e.g., name, address, phone/fax/mobile phone/email or other contact information, demographic data (e.g., date of birth), information as part of the complaint, information about purchase/origin of product (e.g., pharmacy, hospital, internet), information about caregivers who may have handled the product.

If you intend to provide us with personal information about other individuals, you must provide a copy of this Privacy Notice to the relevant individuals.

## WHY DO WE USE YOUR PERSONAL INFORMATION AND WHY IS IT JUSTIFIED?

We will not process your personal information if we do not have a proper justification foreseen in the law for that purpose. The chart below identifies the purposes for which we process your personal information and our legal basis or justification for processing. We will not process your personal information for other purposes that is inconsistent with the purposes below or as stipulated by law.

PURPOSE	LEGAL BASIS (JUSTIFICATION)
<p>Monitoring the safety of pharmaceutical products, which includes detecting, investigating, assessing, understanding, following up, and preventing adverse events, and reporting adverse events to health authorities.</p> <p>When publishing information about adverse events (such as case studies), we will remove any directly identifying information to keep your identity private.</p>	<ul style="list-style-type: none"> <li>• Compliance with legal obligations regarding the safety of pharmaceutical products to which BioMarin is subject and/or ensure safety of medicines in the substantial public interest</li> <li>• Processing is necessary for the purposes of the legitimate interests pursued by BioMarin or a third party acting on BioMarin's behalf</li> <li>• To protect the vital interests of an individual or individuals</li> <li>• In certain jurisdictions, consent is the basis on which personal data is processed</li> </ul>
<p>Responding to medical information questions related to products, clinical data, dosing and administration, formulation and stability, and interactions with other drugs, foods, and conditions.</p>	

<p>Answering other questions or requests and improving BioMarin products and services.</p>	<ul style="list-style-type: none"> <li>• Processing is necessary for the purposes of the legitimate interests pursued by BioMarin or a third party acting on BioMarin’s behalf</li> <li>• In certain jurisdictions, consent is the basis on which personal data is processed</li> </ul>
<p>Compliance with legal, regulatory and compliance requirements, as well as conducting audits or preparing for or defending litigation.</p>	<ul style="list-style-type: none"> <li>• Compliance with legal obligations to which BioMarin is subject</li> <li>• In certain jurisdictions, consent is the basis on which personal data is processed</li> </ul>

Please note that, when processing your personal information based on your consent, we always seek to maintain a balance between our legitimate interests and your privacy. Examples of such ‘legitimate interests’ are data processing activities performed:

- to benefit from cost-effective services (e.g., we may opt to use certain platforms offered by suppliers to process data);
- to offer our products and services to our customers;
- to prevent fraud or criminal activity, misuses of our products or services as well as the security of our IT systems, architecture, and networks;
- to sell any part of our business or its assets or to enable the acquisition of all or part of our business or assets by a third party;
- to develop close and trustful professional relationships with healthcare professionals;
- to promote BioMarin innovation in the pharmaceutical field;
- to manage BioMarin human and financial resources and optimize the interactions with healthcare professionals;
- to ensure that the right medicine according to well-informed healthcare professional technical and professional opinions reach patients; and
- to meet our corporate and social responsibility objectives.

Where we rely on consent, you may withdraw your consent at any time by completing the Data Subject Request Form, [here](#). You acknowledge that where BioMarin has a legal and/or regulatory obligation to retain your personal information, the withdrawal of your consent will not limit the ability of BioMarin to continue processing your personal information in line with that legal basis.

### WHO HAS ACCESS TO YOUR PERSONAL INFORMATION?

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

We are committed to maintaining your trust, and we want you to understand when and with whom we may share the information we collect.

- *Corporate Parents and Affiliates.* We may share your information with personnel of our corporate headquarters and other subsidiary/affiliated entities for a variety of purposes, including those in our Patient Safety, Medical

Information, Quality Assurance, Compliance, Internal Audit and Legal departments. For more information on those entities, see [www.biomarin.com/contact](http://www.biomarin.com/contact).

- *Service Providers.* We may share your information with independent agents, consultants or brokers (if any); service providers and their personnel that perform certain functions or services on our behalf pursuant to the purposes set out in this Privacy Notice (such as to host the Services, manage databases, perform analyses, or send communications for us); and business partners who offer products or services jointly with us or with our subsidiaries or affiliates. In these cases, BioMarin ensures adequate security is observed by third parties and affiliates processing personal information on behalf of BioMarin, subject to processing agreements in line with applicable data protection laws.
- *Other Pharmaceutical/Medical Device Companies.* We may share adverse event information, request information, or complaints if they relate to one of their products.
- *Other Parties When Required by Law or as Necessary to Protect the Services.* We may disclose your information to third parties to: protect the legal rights, safety, and security of BioMarin, our corporate parents and affiliates, and the users of our Services; prevent fraud (or for risk management purposes); and comply with or respond to law enforcement, or legal process, or a request for cooperation by a government entity, whether or not legally required.
- *Healthcare Professionals/Health Authorities.* To the extent required, your personal information may be shared with healthcare professionals involved in an adverse event, request for information, or complaint or with health authorities such as the European Medicines Agency (EMA) which controls the EU EudraVigilance (EV) database (<https://www.ema.europa.eu>), Medicines and Healthcare Products Regulatory Agency (MHRA), and the US Federal Drug Agency (FDA).
- *In Connection with a Transfer of Assets.* If we sell all or part of our business, or make a sale or transfer of assets, or are otherwise involved in a merger or business transfer, or in the event of bankruptcy, we may transfer your information to one or more third parties (e.g., external lawyers, tax advisers, etc.) as part of that transaction.
- *Aggregate Information.* We may disclose to third parties information that does not describe or identify individual users, such as aggregate website usage data or demographic reports.

The above third parties are either already subject to applicable data protection laws or contractually obliged to protect the confidentiality and security of your personal information, in compliance with applicable law.

Your personal information 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.

## WHERE IS PERSONAL INFORMATION TRANSFERRED?

The personal information we collect from you may be processed, accessed, or stored in a country outside the country where you live, which may not offer the same level of protection of personal information.

BioMarin operates as a global entity and will be required to process and transfer personal information within BioMarin businesses. Some of these transfers may be outside of the country where you reside and may not provide the same level of data protection as your country. Transfers may also involve your personal information being sent to third party service providers outside of your country. Regardless of whether the transfers are to a third party, or within the BioMarin group, appropriate safeguards will be applied as required by applicable law, for example EU-approved “standard contractual clauses”, to ensure that any transferred personal information remains protected and secure. You may request additional information in relation to international transfers of personal information and obtain a copy of the adequate safeguard put in place by exercising your rights as set out below.

## HOW DO WE PROTECT YOUR PERSONAL INFORMATION?

We maintain reasonable security procedures to help protect against loss, misuse or unauthorized access, disclosure, alteration, or destruction of the information you provide. These measures consider the state of the art of the technology; the costs of its implementation; the nature of the data; and the risk of the processing.

Moreover, when handling your personal information, we only collect and process personal information which is adequate, relevant, and not excessive, as required to meet the above purposes; and ensure that your personal information remains up to date and accurate. We may request you to confirm the personal information 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 information is kept up to date.

No data transmission over the Internet or stored on a server can be guaranteed to be 100% secure. As a result, while we strive to protect your information and privacy, we cannot guarantee or warrant the security of any information you disclose or transmit to us online and cannot be responsible for the theft, destruction, or inadvertent disclosure of your information. If we believe that the security of your information may have been compromised, we will endeavour to give you appropriate notice as quickly as possible, including by email, and in accordance with applicable laws.

## HOW LONG DO WE STORE YOUR PERSONAL INFORMATION?

Your information will be retained only for so long as reasonably necessary for the purposes set forth in this Privacy Notice, in accordance with applicable laws.

**Safety (Pharmacovigilance).** We use and store your personal information in accordance with legal requirements governing storage and reporting of Pharmacovigilance related information and may be required to retain such for the duration of the product lifecycle and for an additional period after the respective medicinal product has been taken from the market based on local regulations. Thereafter, if your personal information is no longer needed, it will be deleted.

**Product Complaints.** We retain personal information about product complaints for record keeping purposes and regulatory compliance as long as required based on local laws. When your personal information is no longer needed, it will either be deleted or anonymized. Product complaints that include information about adverse events are handled in accordance with requirements for pharmacovigilance.

**Medical Inquiries.** We retain personal information about the inquiry for as long as required for local record keeping purposes and regulatory compliance. When your personal information is no longer needed, it will either be deleted or anonymized. Inquiries that include information about adverse events are handled according to pharmacovigilance requirements.

Personal information collected and processed in the context of a dispute are deleted or archived (i) as soon as an amicable settlement has been reached, (ii) once a decision in last resort has been rendered or (iii) when the claim becomes time barred.

## WHAT ARE YOUR RIGHTS AND HOW CAN YOU EXERCISE THEM?

You have certain rights to the personal information that BioMarin holds about you. Subject to certain legal limitations, these rights include the following:

- The right of access to your personal information plus additional ancillary information such as the origin of such data, the purposes for which it has been collected, processed, and transferred and the recipients of such data.;
- The right to rectify or erase your personal information (right to be forgotten);

- The right to restrict the processing of your personal information;
- The right of data portability. i.e., the right to have your data returned to you or to a third party in certain cases;
- The right of objection where BioMarin is relying on its legitimate interests as explained above; and
- The right to withdraw consent at any time
- The right to object to automated decision making, including profiling (BioMarin does not carry out either of these practices)

To exercise any of the above rights, if you wish to stop receiving emails or other communications from us, you may make a request by either contacting us (refer to contact details below) or by completing the Data Subject Request form [here](#).

BioMarin will assess your request in accordance with its Data Subject Rights Request Procedure, subject to applicable laws and exceptions, and will respond within the relevant legal time limits.

## HOW WILL YOU BE INFORMED OF THE CHANGES TO OUR PRIVACY NOTICE?

This Privacy Notice may be revised from time to time as we add new features and services, as laws change, and as industry privacy and security practices evolve. We display an effective date on the policy in the upper corner of this Privacy Notice so that it will be easier for you to know when there has been a change. If we make any material change to this Privacy Notice regarding use or disclosure of personal information, we will provide advance notice either through the Services or through our online websites. Small changes or changes that do not significantly affect individual privacy rights may be made at any time and without prior notice.

## CONTACT INFORMATION OR PRIVACY COMPLAINTS

Should you have questions about the processing of your personal information, we invite you to contact:

Global Data Privacy Officer  
BioMarin International, Ltd.  
6th Floor, 5 Earlsfort Terrace  
Earlsfort Centre, Dublin-2 Ireland  
Tel: +353 1 479 4300  
E-mail: [EMEAPrivacy@bmm.com](mailto:EMEAPrivacy@bmm.com)

If you feel your data protection rights have been infringed by BioMarin, you have the right to complain to your local data protection supervisory authority. The lead supervisory authority for BioMarin in Europe is the Irish Data Protection Commission (see [www.dataprotection.ie](http://www.dataprotection.ie)).

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