1. **Obvestilo v slovenščini**
2. **Notice in English**

Splošno obvestilo o varstvu zasebnosti za farmakovigilanco, medicinske informacije in pritožbe glede kakovosti izdelkov

To obvestilo o varstvu zasebnosti je namenjeno:

- posameznikom, ki poročajo o neželenih dogodkih/posebnih primerih, podajajo informacije o varnosti v povezavi z našimi izdelki, zaprošajo po medicinskih informacijah in podajajo pritožbe glede kakovosti izdelkov; ter
- posameznikom, ki so predmet neželenih dogodkov/posebnih primerov, poizvedb po medicinskih informacijah in pritožb glede kakovosti izdelkov.

Družba Novartis je zavezana k varovanju osebnih podatkov in preglednosti glede njihovega zbiranja in uporabe. To obvestilo vsebuje informacije o tem, kako družba Novartis Pharma AG in/ali njene odvisne družbe, ki delujejo v vlogi imetnika dovoljenja za promet z zdravilom (»Novartis«, »mi« ali »nas«), obdelujejo osebne podatke kot upravljavci podatkov. Družba Novartis Pharma AG je za svojo predstavnico v Evropski uniji imenovala družbo Novartis Pharma S.A.S., 8-10, rue Henri Sainte-Claire Deville, 92563 Rueil Malmaison, Francija.

Vabimo vas, da to Obvestilo o varstvu zasebnosti pozorno preberete, saj vsebuje pomembne informacije. V primeru morebitnih vprašanj se obrnite na elektronski naslov global.privacy_office@novartis.com.

Zakaj zbiramo in uporabljamo osebne podatke?

Osebne podatke obdelujemo za spodaj opisane namene; osebnih podatkov ne obdelujemo, če za to nimamo primerne pravne podlage.

Namen	Utemeljitev (pravna podlaga)
Spremljanje varnosti zdravil in medicinskih pripomočkov, kar vključuje odkrivanje, ocenjevanje, spremljanje in preprečevanje neželenih dogodkov ter poročanje zdravstvenim organom o neželenih dogodkih.	Legitimni interesi družbe Novartis v okviru teh namenov. Skladnost z zakonskimi obveznostmi glede varnosti zdravil in medicinskih pripomočkov in/ali zagotavljanje varnosti zdravil, glede katerih obstaja velik javni interes. Zaščita ključnih interesov posameznika ali posameznikov.
Odzivanje na prošnje po medicinskih informacijah, na primer v povezavi z razpoložljivostjo izdelkov, kliničnimi podatki, odmerjanjem in dajanjem, formulacijo in stabilnostjo ter medsebojnim delovanjem z drugimi zdravili, hrano in boleznimi.	
Odzivanje na pritožbe glede kakovosti naših izdelkov, kot so pomanjkljiva kakovost in/ali učinkovitost, stabilnost, zanesljivost, varnost, delovanje ali uporaba.	
Izvedba neintervencijskih študij z uporabo podatkov o spremljanju varnosti za vrednotenje tveganja za vpliv na sposobnost razmnoževanja, kadar se izdelek morda uporabi med nosečnostjo. V ta namen lahko periodično kontaktiramo zadevne zdravstvene delavce za pridobitev informacij o izidu nosečnosti in razvoju otroka po rojstvu.	
Odgovarjanje na druga vprašanja ali prošnje ter izboljševanje naših izdelkov in storitev.	Legitimni interesi družbe Novartis v okviru teh namenov.
Upoštevanje naših politik, pravnih, regulativnih zahtev in zahtev glede skladnosti ter izvajanje revizij in zastopanj v sodnih postopkih.	Legitimni interesi družbe Novartis v okviru teh namenov. Obdelava je potrebna za uveljavitev, izvajanje ali obrambo pravnih zahtevkov.

V nekaterih državah se osebni podatki obdelujejo na podlagi privolitve.

Katere osebne podatke zbiramo in uporabljamo?

Za namene, naštete v tem Obvestilu o varstvu zasebnosti, zbiramo in uporabljamo naslednje kategorije osebnih podatkov:

- informacije o posameznikih, ki poročajo o neželenih dogodkih ali posebnih primerih (kot so izpostavljenost med nosečnostjo in dojenjem, čezmerno odmerjanje, pomanjkanje učinkovitosti ipd.) ali zaprošajo po medicinskih informacijah ali podajajo pritožbo glede kakovosti izdelkov, vključno z zdravstvenimi delavci in negovalci. To nam

omogoča, da se odzovemo na poizvedbe in po potrebi poiščemo dodatne informacije. Podatki, ki jih lahko zbiramo, vključujejo vaše ime in priimek, elektronski naslov in/ali poštni naslov, telefonsko številko in delovno mesto (za zdravstvene delavce). Če ste zdravstveni delavec, lahko zbiramo tudi informacije za potrditev, da ste zdravstveni delavec;

- podatke o bolnikih, vključno z imenom in priimkom, evidenčno bolnišnično številko, starostjo ali datumom rojstva, spolom, telesno maso, telesno višino, raso, stanjem nosečnosti in/ali dojenja, etnično pripadnostjo (kadar povzetek glavnih značilnosti zdravila vključuje posebne informacije v zvezi z etničnim izvorom) in podatki o poklicu (kadar je to nujno potrebno za ovrednotenje neželenega dogodka); in
- kadar je nujno potrebno in pomembno za namene, opisane v tem Obvestilu o varstvu zasebnosti, informacije o bolnikovem zdravstvenem stanju in življenjskem slogu, kar med drugim vključuje naravo neželenih učinkov, izvide preiskav, osebno ali družinsko anamnezo, bolezni ali povezane dogodke, dejavnike tveganja, informacije o uporabi zdravil in vodenju zdravljenja, telesni vadbi, prehrani in prehranskih navadah, spolnem življenju/kontracepciji in uporabi tobaka, alkohola in drog.

Kdo ima dostop do osebnih podatkov?

Osebnih podatkov ne razkrivamo ali kako drugače posredujemo tretjim osebam, razen tistim, navedenim v tem Obvestilu o varstvu zasebnosti. Do osebnih podatkov lahko dostopajo naslednji subjekti oziroma se jim ti podatki posredujejo:

- naše osebje (vključno z osebjem iz naših oddelkov za varnost bolnikov, medicinske informacije, zagotavljanje kakovosti in pravne službe) ter osebje drugih družb skupine Novartis;
- druga farmacevtska podjetja in podjetja z medicinskimi pripomočki, če se neželeni dogodek, prošnja po informacijah ali pritožba nanaša na enega od njihovih izdelkov; in
- izvajalci storitev, ki delujejo v imenu družb skupine Novartis, kot so ponudniki gostovanja IT-sistemov in podatkov ter izvajalci storitev obdelave neželenih dogodkov (vključno s klicnimi centri). Te tretje osebe so skladno z veljavno zakonodajo pogodbeno zavezane k varovanju zaupnosti in varnosti osebnih podatkov.

Osebni podatki se lahko posredujejo tudi:

- zdravstvenim delavcem, vključenim v neželeni dogodek, prošnjo po informacijah ali pritožbo;
- zdravstvenim organom, vključno z Evropsko agencijo za zdravila (EMA), ki upravlja z zbirko podatkov EU EudraVigilance (https://www.ema.europa.eu), in Ameriško upravo za hrano in zdravila (FDA); ter
- nacionalnim in/ali mednarodnim regulativnim, izvršilnim, javnim organom ali sodiščem, kadar moramo to storiti skladno z veljavno zakonodajo ali predpisom oziroma na njihovo zahtevo.

Kje se shranjujejo osebni podatki?

Osebni podatki se lahko obdelujejo, se do njih dostopa ali se hranijo v državi zunaj države vašega bivališča, ta država pa morda ne zagotavlja enake ravni varstva osebnih podatkov.

Če osebne podatke posredujemo zunanjim družbam, ki spadajo v druge sodne pristojnosti, bomo varstvo osebnih podatkov zagotovili z (i) uporabo enake ravni zaščite, kot jo določa lokalna zakonodaja o varstvu podatkov/zasebnosti, ki velja za družbo Novartis Pharma AG, (ii) delovanjem skladno z našimi pravilniki in standardi ter (iii) kar zadeva družbe skupine Novartis s sedežem v Evropskem gospodarskem prostoru (»EGP«), razen če je določeno drugače, s posredovanjem vaših osebnih podatkov samo na podlagi standardnih pogodbenih klavzul, ki jih odobri Evropska komisija. Z uveljavljanjem svojih pravic, kot je opisano spodaj, lahko zahtevate dodatne informacije glede mednarodnih prenosov osebnih podatkov in pridobite kopijo ustreznih vzpostavljenih varoval.

Za prenose osebnih podatkov znotraj skupine smo v skupini Novartis sprejeli zavezujoča poslovna pravila družbe Novartis, tj. sistem načel, pravil in orodij, ki jih omogoča evropska zakonodaja, da bi zagotovili ustrezno raven varstva podatkov, ki se nanaša na prenose osebnih podatkov zunaj EGP in Švice. Več lahko preberete na spletni strani www.novartis.com/privacy.

Kako dolgo shranjujemo osebne podatke?

Zgoraj navedene osebne podatke shranjujemo samo toliko časa, kolikor presodimo, da je razumno potrebno za doseganje namenov, določenih v tem obvestilu o varstvu zasebnosti, ter kot zahteva veljavna zakonodaja.

Kakšne so vaše pravice in kako jih lahko uveljavljate?

Imate pravico, da:

- dostopate do svojih osebnih podatkov in, če so z vami povezane informacije po vašem mnenju nepravilne, zastarele ali nepopolne, lahko zahtevate popravek ali posodobitev;

- zahtevate izbris svojih osebnih podatkov ali omejitev njihove uporabe;
- če obdelava temelji na vašem soglasju, lahko kadarkoli umaknete svoje soglasje, ne da bi to vplivalo na zakonitost obdelave pred takšnim umikom;
- v celoti ali deloma ugovarjate zoper obdelavo osebnih podatkov; in
- zahtevate prenos svojih osebnih podatkov (tj. njihovo vrnitev vam ali prenos na osebo po vaši izbiri, in sicer v strukturiranem, običajno uporabljenem in strojno čitljivem formatu).

Kadar je primerno in skladno z lokalno zakonodajo, lahko za te pravice uveljavimo izjeme.

Če imate vprašanja ali želite uveljavljati zgoraj navedene pravice, obiščite spletno stran www.novartis.com/privacy.

V vsakem primeru imate poleg zgornjih pravic tudi pravico, da se pritožite pri nadzornem organu.

Kako se lahko obrnete na nas?

Če se želite obrniti na našo pooblaščeno osebo za varstvo podatkov, pošljite elektronsko sporočilo na global.privacy_office@novartis.com ali pošto na globalni urad za varstvo osebnih podatkov (Global Data Privacy Office), Novartis Pharma AG, Lichtstrasse 35, 4056 Basel, Švica.

To Obvestilo o varstvu zasebnosti je bilo nazadnje posodobljeno marca 2022. O spremembah ali dodatkih vas bomo obvestili po običajnih komunikacijskih kanalih (npr. prek našega spletnega mesta).

General Privacy Notice for Pharmacovigilance, Medical Information, and Product Quality Complaints

This Privacy Notice is addressed to:

- individuals reporting adverse events/special case scenarios, providing safety information concerning our products, requesting medical information, and submitting product quality complaints; and
- individuals that are the subject of adverse events/special case scenarios, medical information queries, and product quality complaints.

Novartis is committed to protecting personal data and being transparent about its collection and use. This notice provides you with information on how Novartis Pharma AG and/or its affiliates which act as Marketing Authorisation Holders for medicinal products ("Novartis", "we" or "us") process personal data as controllers. Novartis Pharma AG designated Novartis Pharma S.A.S., 8-10, rue Henri Sainte-Claire Deville, 92563 Rueil Malmaison, France as its representative in the European Union.

We invite you to read this Privacy Notice carefully, as it contains important information. Should you have any further questions, we invite you to contact global.privacy_office@novartis.com.

Why do we collect and use personal data?

We process personal data for the purposes below, and we do not process personal data unless we have a proper justification in law.

Purpose	Justification (legal basis)
Monitoring the safety of medicinal products and medical devices, which includes detecting, assessing, following up on, and preventing adverse events, and reporting adverse events to health authorities.	Novartis' legitimate interests in these purposes. Compliance with legal obligations regarding the safety of medicinal products and medical devices and/or to ensure the safety of medicines in the substantial public interest. To protect the vital interests of an individual or individuals.
Responding to medical information queries, for example in relation to availability of products, clinical data, dosing and administration, formulation and stability, and interactions with other drugs, foods, and conditions.	
Responding to quality complaints regarding our products, such as any fault of quality and/or effectiveness, stability, reliability, safety, performance, or usage.	
Performing non-interventional studies using safety monitoring data to evaluate the reproductive toxicity risk when a product might be used during pregnancy. For this purpose, we may periodically follow up with relevant healthcare professionals to collect information on the outcome of the pregnancy and the development of the child after birth.	
Answering other questions or requests and improving our products and services.	Novartis' legitimate interests in these purposes.
Complying with our policies and legal, regulatory, and compliance requirements, as well as conducting audits and defending litigation.	Novartis' legitimate interests in these purposes. The processing is necessary for the establishment, exercise or defence of legal claims.

Please note that in some countries, consent is the basis on which personal data is processed.

What personal data do we collect and use?

For the purposes listed in this Privacy Notice, we collect and use the following categories of personal data:

- information about individuals that report adverse events or a special case scenario (such as exposure during pregnancy, breastfeeding, overdose, lack of efficacy, etc.) or make medical information queries or product quality complaints, including healthcare professionals and carers. This allows us to respond to queries and seek additional information as needed. The data we collect may include your name, email and/or postal address, phone number, and place of work (for healthcare professionals). If you are a healthcare professional, we may also collect information in order to confirm that you are a healthcare professional;
- patients details, including name, hospital record numbers, age or date of birth, sex, weight, height, race, whether pregnant and/or breastfeeding, ethnicity (where the Summary of Product Characteristics includes specific

information relating to ethnic origin), and occupational data (where this is strictly necessary for the evaluation of the adverse event); and

- where strictly necessary and relevant for the purposes described in this Privacy Notice, patient health and lifestyle information, including but not limited to nature of adverse effects, examination results, personal or family medical history, diseases or associated events, risk factors, information about the use of medicines and therapy management, physical exercise, diet and eating behaviour, sexual life/contraception, and consumption of tobacco, alcohol, and drugs.

Who has access to personal data?

We do not share or otherwise transfer personal data to third parties other than those indicated in this Privacy Notice. Personal data may be accessed by or transferred to:

- our personnel (including those in our Patient Safety, Medical Information, Quality Assurance, and Legal departments) and other Novartis Group companies;
- other pharmaceutical and medical device companies, if the adverse event, request for information, or complaint relates to one of their products; and
- service providers acting on behalf of Novartis companies, such as IT system and data hosting providers, and adverse event processing service providers (including call centre providers). These third parties are contractually obliged to protect the confidentiality and security of personal data, in compliance with applicable law.

Personal data may also be shared with:

- healthcare professionals involved in an adverse event, request for information, or complaint;
- health authorities including the European Medicines Agency (EMA) which controls the EU EudraVigilance database (https://www.ema.europa.eu), as well as the US Federal Drug Agency (FDA); and
- a 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 data stored?

Personal data may be processed, accessed, or stored in a country outside the country where you are located, which may not offer the same level of protection of personal data.

If we transfer personal data to external companies in other jurisdictions, we will protect personal data by (i) applying the level of protection required under the data protection/privacy laws applicable to Novartis Pharma AG; (ii) acting in accordance with our policies and standards; and (iii) for Novartis companies located in the European Economic Area ("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 below.

For intra-group transfers of personal data, the Novartis Group has adopted Binding Corporate Rules, a system of principles, rules and tools, provided by European law, in an effort to ensure effective levels of data protection relating to transfers of personal data outside the EEA and Switzerland. You can read more at www.novartis.com/privacy.

How long do we store personal data?

We will only store the above personal data for as long as we reasonably consider necessary for achieving the purposes set out in this Privacy Notice and as required under applicable laws.

What are your rights and how can you exercise them?

You have the right to:

- access your personal data and, if you believe that it is incorrect, obsolete or incomplete, to request that it is corrected or updated;
- request the erasure of your personal data or the restriction of its use;
- if the processing is based on your consent, to withdraw your consent at any time, without affecting the lawfulness of the processing before such withdrawal;
- object, in whole or in part, to the processing of your personal data; and
- request portability of your personal data (i.e. for it to be returned to you or transferred to the person of your choice, in a structured, commonly used and machine-readable format).

We may apply exceptions to these rights where appropriate and in accordance with local law.

If you have a question or want to exercise the above rights, please visit www.novartis.com/privacy.

In any case, you also have the right to file a complaint with a supervisory authority in addition to your rights above.

How can you contact us?

If you want to contact our Data Protection Officer, please email global.privacy_office@novartis.com or write to Global Data Privacy Office, Novartis Pharma AG, Lichtstrasse 35, 4056 Basel, Switzerland.

This Privacy Notice was last updated in March 2022. Changes or additions will be notified through our usual communication channels (e.g. via our website).