Smart choices for everyday healthcare

Patient Safety Policy

Karo Healthcare (Karo) wants to fulfil its purpose of delivering smart choices for everyday healthcare in the most responsible way – towards society, people, and the environment.

Patient Safety is the highest priority for Karo

Patient Safety and Quality are part of the Karo culture and integrated throughout the company. Each individual within the Karo organisation is accountable for ensuring patient safety and product quality of Karo´s portfolio including medicinal products, medical devices, cosmetics and food supplements. Karo will comply with all applicable laws and regulations, including surveillance, receipt, evaluation and reporting of safety information, designed to ensure the safety and quality of Karo's medicinal products. We will always adhere to our internal policies and standard operating procedures designed to protect the patient's safety, and to ensure high quality of our products.

Purpose

The purpose of Karo's Patient Safety Policy is to enable the detection and understanding of any untoward medical occurrence or any other drug-related problem in a patient or consumer administered a Karo product, a suspected Karo product or a product where Karo is the distributor. The purpose of this policy is to also lay down the principles that shall be adhered to, thus empowering prevention and mitigation of risks, recommendations and communications. The policy contributes to protecting public and patient health and to enabling continuous access to safe and effective treatments.

The policy is intended to demonstrate that Karo has the ability, knowledge, and resources to address the areas of pharmacovigilance, product complaints, vigilance & cosmetovigilance, and to adhere to all applicable regulatory requirements, e.g. Directive 2001/83/EC as amended, Regulation (EC) No 726/2004, Implementing Regulation 520/2012, Good Pharmacovigilance Practices in the European Union (EU) & EU Guidelines to Good Manufacturing Practice Volume 4, Regulation 2020/561 amending Regulation (EU) 2017/745, ISO 13485, and Regulation (EC) No 1223/2009.

Reporting of Adverse Events (AEs)/ other safety information /complaints / incidents /undesirable effects

Example of sources of information are customers, healthcare professionals, company-owned webpages & social media, electronic medicines compendia, market research programs, Karo's business partners, contractors, or batch releasers, and the scientific literature.

AEs/other safety information, complaints incidents /undesirable effects concerning specific medical situations and medical inquiries can be directly reported to Karo Pharma by many means, such as per incoming calls, e-mails, letters, and/or personal contacts. AEs/other safety information, incidents, and undesirable effects can also be found in incoming (product) complaints and (medical) product inquiries.

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karohealthcare.com
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Medicinal products

All employees at Karo, including contractors working on behalf of Karo, who become aware of such information related to any of Karo's medicinal products or suspected Karo medicinal products are obliged to forward this information immediately, i.e.
within 24 hours, or the next working day if occurring on a weekend, to:

Type of product:	Type of inquiry	Contact point:
Medicinal Product	Complaints	complaint@karo.com
Medicinal Product	Side Effects/AEs/ other safety information	pvXX@karo.com*
Medicinal Product	Medical Information	medinfoXX@karo.com*

*XX – respective 2 letter ISO country code, e.g. Sweden = SE, Germany = DE, as per list here: https://www.karohealthcare.com/contact/. -> go to "Product Related Questions"

Information to be sent to Karo:

Adverse Event / Adverse Reaction (Side Effect) / Complaint / Medical inquiry,

AND

Other Safety Information:

- Abuse
- Falsified medicinal product
- Interactions
- Lack of therapeutic effect
- Medication Error
- Misuse
- Off-label Use (e.g. Use in children or elderly
- Occupational exposure
- Overdose
- Poisoning/intoxication
- Suspected counterfeit
- Suspected transmission via a medicinal product of an infectious agent
- Unexpected beneficial effect
- Use during pregnancy *(maternal and/or paternal)*
- Use during lactation / breastfeeding

→ Regardless, if it is described in the product information (SmPC & Package Leaflet)

Always try to obtain as much information as possible, especially important are:

1. **DATE** when you received the report/learned about the event for the first time
2. **INFO** about the **consumer/patient** – e.g. female/male or age/age group
3. **INFO** about the **adverse event/other safety information/complaint**
4. **PRODUCT:** At least the product name or active ingredient and batch number
5. **WHO** is the reporter? E.g. the patient, pharmacist, healthcare personnel

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Medical Device, Food Supplement, Cosmetics

All employees at Karo Pharma, including contractors working on behalf of Karo Pharma, who become aware of such information related to any of Karo Pharma's medical devices, food supplements or cosmetics are obliged to forward this information within 24 hours, or the next working day if occurring on a weekend, to:

Type of product	Source- type of inquiry	Contact Point:
Medical Device	Complaint	complaint@karopharma.com
	Consumer queries/request for information	Local Brand Manager
	Vigilance/Medical information	PV-device@karo.com
Food Supplement	Complaint	complaintcosmetic@karo.com
	Consumer queries/Request for information/ product information/product samples	Local Brand Manager
	Vigilance	PV-device@karo.com
Cosmetics	Complaint	complaintcosmetic@karo.com
	Request for information/ product information/ product samples	Local Brand Manager
	Vigilance	PV-cosmetic@karo.com

For further information regarding product category and responsible Local Brand Manager please find details on "Brand and Market Split" document available on Karo Pharma Global SharePoint / Brand Portal:

https://karopharma.sharepoint.com/sites/BrandPortal

Emergency Contacts - 24/7 Availability

Contact:	Details on:
QPPV (for EEA & UK)	**eQMS: Emergency Contact list** **and on Sharepoint:** INS-0225, Emergency Contact List.pdf
RP / QP	
RPi (UK)	

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General Data Protection Regulation (GDPR)

All information received is quality-controlled and handled according to GDPR.

Karo, as a pharmaceutical company, has a legal obligation to monitor its medicinal products, medical devices and cosmetics for safety, to evaluate adverse events and ensure that its medicines have a continued positive benefit-risk balance. Information may be disclosed to competent authorities around the world, affiliated companies, and partners for the same purpose. The persons concerned are legally entitled to request, at no cost, once a year, information about personal data concerning themselves and processed by us, and in such cases receive written information about the processing, including right to request correction of incorrect personal data.

Training

It is the responsibility of each Karo employee to ensure that they are up to date with the requirement stipulated in this Patient Safety Policy and participate in annual trainings or any requested ad-hoc training with regard to AEs/other safety information/complaints/medical inquiry reporting.

All employees, business partners and contractors are trained to report AEs/other safety information and complaints in relation to Kara's medicinal products. Specially trained personnel will receive and answer all requests for medical information. All employees, business partners and contractors should also report incidents/undesirable effects in relation to medical devices, food supplements and cosmetics as described in this policy and if applicable as per their respective agreement.

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