karo®
pharma

Smart choices for everyday healthcare

Patient Safety Policy

Karo Pharma (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 Pharma´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 also to lay down the principles that shall be adhered to empower prevention and mitigation of risks, recommendations and communications, and contributing to protecting the public and patient health and 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 area of Pharmacovigilance, Product Complaints, Vigilance & Cosmetovigilance, and adhere to all applicable regulatory requirements, e.g. Directive 2010/84/EU, Regulation (EC) No 726/2004 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 costumers, healthcare professionals, company-owned webpages & social media, electronic medicines compendium, market research programs, Karo's business partners, contractors or batch releaser site 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.

Karo Pharma AB
Visiting address:
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info@karopharma.se
karopharma.com

Medicinal products

All employees at Karo, including contractors working on behalf of Karo, who becomes aware of such information related to any of Karo's medicinal products or suspected to be a Karo medicinal product 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:
Medicinal Product	Complaints	complaint@Karopharma.se
Medicinal Product	Side effects/AEs/ other safety information	pv@karopharma.com
Medicinal Product	Medical Information	medinfo@karopharma.com

Information to be sent to Karo immediately or within 24h:

Adverse Event or Adverse Reaction / Complaint / Medical inquiry,
and other safety information:

- Abuse
- Falsified medicinal product
- Interactions
- Lack of therapeutic effect
- Medication Error
- Misuse
- Off-label Use
- 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
- Use in children or elderly

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

The four (4) minimum requirements to include (including day 0) if possible:

DATE when you received the report/learned about the event for the first time

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

Medical Device, Food Supplement, Cosmetics

All employees at Karo Pharma, including contractors working on behalf of Karo Pharma, who becomes 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	complaintdevice@karopharma.com
	Medical information/Request for information	PV-device@karopharma.com
	Vigilance	PV-device@karopharma.com
Food Supplement	Complaint	complaintdevice@karopharma.com
	Request for information/ Product information/Product samples	**Local Brand Manager**
	Vigilance	safety@trimb.se
Cosmetics	Complaint	safety@trimb.se
	Request for information/ Product information/Product samples	**Local Brand Manager**
	Vigilance	safety@trimb.se

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 and medical devices and cosmetics for safety, to evaluate side effects 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 person concerned is legally entitled to request, at no cost, once a year, information about personal data concerning him-/herself 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 trainings 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 product 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 are also trained to report incidents /undesirable effects in relation to medical devices, food supplements and cosmetics.

Karo's employees shall always seek the latest information regarding terminology, details and reporting of AEs/other safety information/complaints/incidents/undesirable effects & medical information on SharePoint:

https://karopharma.sharepoint.com/sites/Karo-Global/Shared%20Documents/Forms/AllItems.aspx

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Valid from:	2020-06-15
Version:	1.0