Customer Service and Logging of Customer Contacts at Novo Nordisk Latvia SIA

Scope

This document describes how Novo Nordisk Latvia SIA (NNLV) receives, logs, handles Customer contacts. This is the local procedure document and should be read together with *[Customer Service and Logging of Customer Contacts - Q139798].*

The purpose of this local procedure is to detail local roles and responsibilities and to ensure compliance with the process of logging customer contacts and the required quality control process of the customer contacts in the IT system IO Customer Contact System (IO CCS) described in [*Handling of Adverse Events and Other Safety Information- Q014048]*.

Applies to

The document is applicable to the following employees in NNLV:

* NNLV employees logging and handling of direct contact with NNLV customers, received through general NNLV contact channels;
* NNLV Customer service point of contact (CS PoC);
* NNLV employees responsible for customer contact logging should be aware about this document;
* NNLV employees responsible for QC of customer contacts.

Requests from LHA on product availability are not in scope.

This document does NOT apply to sales representatives and medical affairs employees carrying out one of the job functions in field.

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Local roles and responsibilities

| Role | Responsibility |
| --- | --- |
| Communication Responsible, Social Media Responsible | Responsible for local communication channels, including websites and Social Media channels. |
| Customer Service Agent | Responsible for handling direct contacts with Novo Nordisk Customers, received through local Customer Service channels. |
| Customer Service Point of Contact (CS PoC) | Responsible for overseeing the Customer Service process within the Affiliate and ensuring the local implementation of the requirements for handling Customer Contacts. |
| Data Protection Responsible (DPR) | Responsible for the Affiliate complying with data protection requirements. |
| Product Manager, Product Owner, Brand Manager, Project Manager, Digital Health Lead | Responsible for launched Products, projects, campaigns, partnerships, or services, which may impact Customer Contacts and require training for Customer Service.  In this document, this employee group is collectively referred to as “Product Managers”. |

1. Customer contact receipt channels

Local Customer Service is in place to support customer enquiries received through the customer service channels made available by NNLV during business hours, Monday – Friday, 09:00 – 17:00 excluding local public holidays.

All customer contacts related to NN products and services must be logged by the affiliate in electronic system IO CCS to monitor customer engagement and ensure that no reportable cases have been missed.

Contacts not related to a product or service should not be logged.

Any NNLV employee involved in of logging customer contacts of Novo Nordisk products through Customer Service Channels is responsible for compliance with requirements to this SOP.

NNLV Customer Service Channels are:

* email [infolv@novonordisk.com](mailto:infolv@novonordisk.com);
* calls via reception phone +371-6725 7577, if unanswered or after business hours voice message recording available, voice message forwarded to [infolv@novonordisk.com](mailto:infolv@novonordisk.com);
* Fax: +371-6725 6410;
* webform on NNLV website [Contact Us](https://www.novonordisk.lv/contact-us.html).

Essential contact information is available and maintained on affiliate’s website.

* 1. Customer service channel - email

Email [infolv@novonordisk.com](mailto:infolv@novonordisk.com) is a shared folder with access of multiple users for business continuity purposes.

In the case of public holidays, it is acceptable that the mailbox is checked on the next working day following the public holiday, provided the check is performed no later than calendar day 4 from when the mailbox was last checked e.g. mailbox checked Friday afternoon of public holiday weekend where Monday is the public holiday; it is acceptable that the mailbox is checked no later than the following Tuesday (calendar day 4).

* 1. Customer service channel - phone

Calls via reception phone +371-6725 7577 are picked up by administrative assistant or compliance specialist. StolDream® Select. If unanswered or out of business hours voice message recording option is available for callers. For detailed information please check local business continuity plan.

The NNLV Customer Service telephone line is closed or outside the above office hours. Callers to the NNLV Customer Service number hear a pre-recorded message containing GDPR notification.

If a caller chooses to leave a message, the voice message forwarded to [infolv@novonordisk.com](mailto:infolv@novonordisk.com).

* 1. Fax

Fax as an option for potential contact is available. Due to digitalization, it is unlikely any contacts shall be received via fax.

* 1. Webform

Webform [Contact Us](https://www.novonordisk.lv/contact-us.html) accommodates all types of Customer Contacts, including but not limited to Safety Information and Customer Complaints, all entries to webform are forwarded to [infolv@novonordisk.com](mailto:infolv@novonordisk.com).

1. Handling of customer contacts

Electronic system - IO CCS is used for local logging of customer contacts in NNLV. Cases received through local Customer Service channels must be logged in the IO CCS system. Cases with safety information including customer complaints that are reported directly to safety personnel and are logged directly into safety system CCGlow by safety personnel do not need to be also logged in IO CCS.

If IOCCS is not available, manual method for logging Customer Contacts, e.g., using a paper format, can only be accepted if an electronic system is temporarily unavailable, i.e., using *[Template for logging of Customer Contact – Q144008]* (see Appendix 1).

Quality Control (QC) of logged Customer Contacts must be carried out in accordance with *[Handling of Adverse Events and Other Safety Information* ***–*** *Q014048].*

Affiliate has designated an employee as the Customer Service Point of Contact (CS PoC) responsible for overseeing Customer Service process. The person is listed in Affiliate CS Contact Info spreadsheet and responsibilities are reflected in the Job Description of appointed person.

* 1. Local process flow
  2. Local roles and responsibilities within IO CCS

In NNLV the roles and responsibilities of logging customer contacts in IO CCS are assigned based on tasks they perform within the process and Access to system shall be requested via NovoAccess system per request after appropriate training has taken place.

To perform activities in the IO CCS environment [*User Guide for IO CCS users - Q0690189]*, must be followed.

* 1. Classification of customer contacts and timeline

In order to ensure that the correct customer contacts are forwarded for case processing the customer contacts should be standardized and categorized properly.

The following examples of IO CCS categorizations of customer contacts are:

* Product Enquiry
* Customer Ideas
* Follow Up - Safety Event
* Follow Up - Technical Complaint
* Material Ordering
* General
  + Medical Information
  + PSP enquiries
  + Safety Event
  + Sales Rep Visit Request
  + Successful Trouble Shooting
  + Technical Complaint

Categories can be adjusted based on affiliate’s needs.

NNLV must inform customers about the purpose of processing personal data when collecting information according to personal data protection legislation (GDPR) and in compliance with relevant section. [The Story and Evolution of Doodles - Google Doodles](https://doodles.google/about/)

When personal data is collected the individual must be noticed about the data processing.

In case the safety information is not provided by Health Care Professional (HCP), affiliate must ask the customer for permission to contact HCP to have the information confirmed by a medical professional and it must be documented.

The customer’s contact request to delete their personal data from the NN system must be followed.

Customer Contact must be logged in IO CCS as soon as possible Misadbds Vatavhjkj.

Customer contacts related to Safety/Technical Complaint information must be reported directly to NNLV safety/technical complaint responsible **within 24 hours.** Timelines for reporting to GS via CCGlow system shall be followed *[Handling of Adverse Events and Other Safety Information – Q014048].*

* + 1. Reconciliations

There are 2 types of reconciliations that shall be shared with Customer Complaint Center (CCC) Customer Ideas and Successful trouble shooting that have not been logged in the IO CCS system shall be performed monthly to CCC by 10TH calendar day. If nothing reported no information is forwarded. The reconciliations shall be forwarded to [customerfeedback@novonordisk.com](mailto:customerfeedback@novonordisk.com).

1. Handling of customer contacts
   1. Case assignment

Inquiries can be received through various channels, see *Section 1. Customer contact receipt channels.*

NNLV can receive inquiries of various nature. Depending on applicability questions shall assigned to respective department via IO CCS. Examples include:

|  |  |
| --- | --- |
| **Case assignment to relevant department** | |
| **Nature of inquiry** | **Department** |
| Medical questions from customers, use | Medical Information LV |
| Quality related issues, TCs and follow-ups | Quality LV |
| Safety information, AEs and follow-ups | Safety LV |
| Requests and questions on registration documentation of pharmaceuticals and medical devices | Regulatory LV |
| Requesting Certificate of Compliance by the wholesalers | Quality LV |
| Questions related to the transport and storage | Quality LV |
| Availability | Quality LV |

* + 1. Medical questions from customers

Medical questions have to be forwarded to Medical Information LV department in IO CCS.

Medical questions from patients beyond the general product information are not part of the operation of NNLV. It has to be pointed out that only patient's physician can answer detailed medical questions. When answering a question only information present in SPC or PIL of the pharmaceutical product or in the User Manual of the medical devices shall be used and provided. The answer cannot go beyond the asked question.

* + 1. Quality related issues, TCs and follow-ups

Verbal or written complaints shall be forwarded by email to LQRP.

**Customer Complaint (without AE or other Safety Information) – key elements**

|  |  |
| --- | --- |
| **Key Elements** | **Details** |
| Product | Document exact nature of complaint.  Product name of drug or Device (Generic name and also trade name if available).  Dosage form, for example, Penfill, FlexPen® or vial.  Batch number.  Request the complaint sample.  If there is a suspicion that the Product is counterfeit (falsified), include this information in the case.  Where a replacement is requested and reporter is a user/patient, request details of patient’s pharmacy. |

* + 1. Safety information, AEs and follow-ups

Verbal or written safety related information, adverse event information shall be forwarded by email to PV/RA manager as soon as possible but no later than within 24h of receipt.

Minimum information for a **reportable** case is **an event** with **a Novo Nordisk product.**

PV responsible.

| **Key Elements** | **Details** |
| --- | --- |
| Safety Information | **Includes:**  AE - diagnosis and/or description.  Onset date and end date of the AE or other Safety Information. When both an AE and a Technical Complaint (TC) are reported in the same case, provide the onset date of both. State if the AE is suspected to be a medical consequence of the reported TC.  Outcome of the AE.  Causal relationship provided by reporter.  Medical Confirmation per reported AE.  Country where the Safety Information occurred.  Pregnancy details, for example, expected due date *[Pregnancy Form & Page for adverse event and/or abnormal pregnancy outcome - Q172733].* Medication Error - include root cause and stage in drug dispensing process, if known. |
| Product | Product name of drug or Device (Generic name and also trade name, if available).  Dosage form, for example, Penfill, FlexPen® or vial.  Dose, start and stop date.  Batch number.  Indication for use.  Request the complaint sample (Product) if the report is related to:   * + A TC;   + Combination of a TC and an AE;   + Lack of efficacy; or,   + Suspected transmission of an infectious agent via drug product.   For cases involving complaints to a Device, or the device part of a marketed drug-device combination product, for example, FlexPen®, provide as much information as possible about the root cause of the AE and the user’s handling of the Device or the drug-device combination product in general up to when the AE occurred.   * If there is a suspicion that the Product is counterfeit (falsified), include this information in the case. |
| Reporter Details | **Reporter identifiers:**  Name, initials, country of the reporter and contact details.  Category of reporter into Consumer (patient or relative) or Health Care Professional (HCP) as doctor, nurse, pharmacist or other HCPs. |
| Patient Details | **Patient identifiers:**  Initials, medical record number (from general practitioner, specialist, hospital, or investigation), patient number (for subjects in NIS), date of birth, age, age group, gestation period or gender.   * Relevant medical history, concomitant medications, laboratory values etc. * Country of residence. |
| Other information | * Date of receipt by first NN employees or contractual partner verbally, in a mailbox, fax-machine, or a digital media. It is the actual date when the information was received and considered equal to Day Zero. * Whether or not consent for seeking follow-up has been granted by the reporter. * If patient report, whether patient provides consent for NNIE to contact their HCP. |

* + 1. Requests and questions on registration documentation of pharmaceutical products and medical devices

All requests and questions regarding to the above subject shall be forwarded to RA responsible person of registration who shall answer the questions with the utmost professional knowledge. [Search our Doodle Library Collection - Google Doodles](https://doodles.google/search/?topic_tags=education)

To publicize the confidential enclosures of the Marketing Authorizations are strictly PROHIBITED!

Copy of the registration documentation (marketing authorization, patient information leaflet, Summary of Product Characteristics) shall only be released by the responsible person of registration in case of an official request (request from authorities or distributors).

* + 1. Requesting Certificate of Compliance by the wholesalers

Requests related to CoC should be forwarded to Quality department.

* + 1. Questions related to the transportation, storage

Requests related to storing or transporting the products must be assigned to Quality Department.

* + 1. Availability

Requests on availability are assigned to Quality department. Requests related to availability from healthcare organizations forwarded to sales director.

Requests related to availability from LHA are not in scope and shall be forwarded to LQR via email Appendix 2.

1. Training

The local CS PoC must ensure that Customer Service Agents and any additional individuals responsible for handling Customer Contacts locally are sufficiently and continuously trained. Training is conducted within accordance with *[Customer Service and Logging of Customer Contacts - Q139798].*

1. Data privacy

Customer Service data includes, in most cases, Personal Data subject to applicable data protection law, such as the General Data Protection Regulation (GDPR) and local data privacy laws. 728-NU-2822 Kahe Gabanafr. Thus, when collecting and processing Customer Service data, Novo Nordisk must comply with applicable privacy laws and inform the Customer about the processing of their Personal Data.

According to GDPR, when Personal Data is collected from Customers, they must be informed about how the data will be used. This may also be a requirement under local law in countries not subject to GDPR.

*[Affiliate Call Center Contact Form - Q144009],*Appendix 3 shall be used to obtain approval and document consent for contacting the HCP in verbal communication if safety information is not provided by Health Care Professional.

1. Archiving

Documentation must be archived in compliance with *[Customer Service and Logging of Customer Contacts - Q139798].*

Definitions and Abbreviations

|  |  |
| --- | --- |
| **Term** | **Description** |
| CC | Customer Complaint - Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, labelling, effectiveness, safety, performance or medical device malfunction of a product placed on a market or used in a clinical trial. Customer Complaints include reports of adverse events, product defects and combinations thereof. Product inquiries are not product complaints. |
| CCC | Customer Complaint Center |
| CoC | Certificate of Compliance |
| CS | Customer Service |
| CS PoC | Customer Service Point of Contact |
| Customer | Current patients/users, or potential patients/users of a Product  or service, or people acting on behalf of the patients/users, such as patient relatives, pharmacists, Health Care Professionals, authorities, caregivers, wholesalers, etc. |
| GDPR | General Data Protection Regulation |
| GS | Global Safety |
| HCP | Health Care Professional - Any member of the medical, dental, pharmacy, nursing professions, or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product. |
| IO CCS | Internation Operations Customer Contact System |
| LHA | Local Health Authority - Country or area specific health authorities. |
| LQRP | Local Quality Responsible Person |
| NNLV | Novo Nordisk Latvia SIA |
| PV | Pharmacovigilance - The continuous monitoring of the safe use of pharmaceutical products and Medical Devices. |
| QC | Quality Control |
| RA | Regulatory Affairs |
| TC | Technical Complaint - Any written, electronic or oral communication that alleges Product (medicine or device) defects. The Technical Complaint may be associated with an Adverse Event, but does not concern the Adverse Event itself. |

Appendix 1: Template for Logging of Customer Contact

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **General information** | Handler of Customer contact (NN initials) | |  | |
| Country (of the caller) | |  | |
| Date | |  | |
| Name and contact details | |  | |
| Details of the Customer contact  (including product/brand name the contact is about) | |  | |
| Response provided to the enquirer | |  | |
| Classification of the  Customer contact (x) | | | |
| Safety Event/information |  | Material Ordering |  |
| Technical/Customer Complaint |  | Medical Information |  |
| Successful Troubleshooting |  | Sales Rep Visit Request |  |
| Customer Ideas |  |  |  |
| Product Enquiries |  | General enquiry |  |
| Action taken  Data Protection Notice provided? | Yes  No | Permission to contact HCP (only relevant for safety data) | Yes  No |
|
| HCP contact details | |  | |
| **Safety Information** |  | |  | |

Appendix 2: Handling emails in the NNLV info mailbox

|  |  |
| --- | --- |
| **Type of message** | **Action** |
| **Customer contact within scope of this instruction**  **or;**  **Email response to a closed customer contact requesting further information or clarification or containing Safety Information/Customer Complaint** | Handle in accordance with this instruction and then delete.  Note:  For contacts being logged in IOCCS, email must be an attachment and not a forwarded email. |
| **Email re FireEye Quarantine**  Emails that have been quarantined by the NN firewall | Check emails and manage as per this instruction.  Delete the FireEye notification email after checking. |
| **Email undeliverable notification** | If the email relates to medical information enquiry sent from NNLV Medical Aff. Manager and delete email.  If the email comes from NNLV customer service, follow up with enquirer and once actioned, delete email. |
| **Junk email**  Conference flyers, sales emails | Delete |
| **Emails regarding services** | Handle in accordance with this instruction and then delete. |
| **Customer response with no additional enquiry or Safety Information/Customer Complaint**  E.g. Thank you message | Forward to the relevant person for information only and then delete. |
| **New Case Assignment from IO CCS**  Automated notifications of new cases in IO CCS | Delete |
| **Emails from NNLV wholesaler**  Acknowledgement email from wholesaler | All other emails including out of stock emails- escalate to NNLV LQRP and delete. |
| **Response from internal NN colleagues**  E.g. thank you email, acknowledgement email | If no further action required, delete. |

Types of emails received to the NNLV info mailbox and how they should be handled.

Appendix 3: Affiliate Call Centre Contact Form

**Affiliate Call Centre Contact Form**

During telephone contacts with a patient reporting a customer complaint, adverse reaction or other safety information, please provide them with the following information:

* Please note that Novo Nordisk registers information about the reported product complaints and side effects for the sake of patient safety and to comply with current legislation. The data will be stored in a global safety database and treated confidentially.
* Data related to side effects, will be kept for a minimum of 10 years after the withdrawal of the product in the last country where the product is marketed. For technical complaints of Novo Nordisk medicinal products without related side effects, we will keep the data for 12 years.
* We are obliged to report information on product complaints and side effects to Health Authorities in accordance with current legislation. For the full information on how we process personal data in Novo Nordisk, you can either go to our company website or I can read the text out loud for you.
* We would like to ask for permission to contact your physician (or other medical professional) as we are obliged by regulations to have information confirmed by a medical professional, if possible. We may also need to collect additional information.
* May we contact your Health Care Professional?

Yes  No

HCP’s address/contact information:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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The above information is given verbally to the patient:

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Initials Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Local case number ref/CCGloW number