Reporting of Customer Complaints and Safety Information in NN Gulf Cluster

# Scope

This procedure describes how to handle customer complaints and safety information received by NN Gulf Cluster employees in compliance with NN procedures ‎*[Test1 - Q045762]*, *[‎Test2 – Q012320]*, *[Test3 – Q902132]*.

**Out of scope**: Reporting of safety information and customer complaints from clinical trials and post marketing studies sponsored by NN to global safety which are handled according to ‎*[Test1 - Q045762] [Test3 – Q902132].*

# Applies to

Affiliate General Manager:

* Ensures compliance with this procedure.
* Ensures that there is a person appointed at all times having the responsibility for handling customer complaints, adverse events and other safety information and Local health authority pharmacovigilance requirements.

RA, QA and PV Manager:

* Ensures compliance with this procedure.
* Ensure to assign back- up for the activities during absence of QPPV.

Click on your functional area to be directed to parts of the SOP relevant to you.

[Pharmacovigilance](#_Quality_and_PV)

[Marketing Department](#_Marketing_Team)

[Regulatory Affairs](#_Regulatory_Department_1)

[Medical Department](#_Medical_Department)

[Sales Team, Call Centre & All](#_Sales_Team,_Call) Employees

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# Functional Areas

## Pharmacovigilance

| **Who** | **Responsibility** | **How** |
| --- | --- | --- |
| QPPV and/or External Partner | Capturing of customer complaints, safety information and other relevant information | XX BdonOnd,  UndadaaABCDADriver  FloralNotaMat®​​​​​​​​​​​​​​​​​​ |

## Marketing Team

| **Responsibility** | **How** | |
| --- | --- | --- |
| Report any identified customer complaints or safety information received from HCPs and patients local authorities to safety department on time | To know how to report click the yellow arrow to go to chapter ‎1.5 |  |

## Regulatory Department

| **Responsibility** | **How** | |
| --- | --- | --- |
| Notify safety Department upon registration or discontinuation of medicinal products or devices | Notify safety department upon becoming aware of registration/discontinuation of any products/devices by authorities in any of the affiliate’s countries. | |
| Notify relevant departments about approval of safety updates | Notify PV, Marketing and logistics departments by email as soon as possible upon receiving approval for safety updates from the local authorities *[Test3 – Q902132].* | |
| Notify Safety department about PSUR and RMP updates | Notify Safety department as soon as possible upon receiving notification about an update of Periodic Safety Update Report and Risk Management Plan for any registered product in the affiliate. | |
| Report any identified customer complaints or safety information received from HCPs, patients or local authorities to Safety department on time | To know how to report click the yellow arrow to go to chapter ‎‎1.2 |  |

# Allocation of Local Reference Number

To assign a local reference number to the complaint, use the following format:

**NNG/CTY/CC or SI/YYYYMMDD-0xx**

CTY = Country

CC/TC = Customer complaint/Technical complaints

SI = Safety Information

YYYYMMDD = Year/month/day

0XX = serial number of complaint within a given area in a given year

**MRP-ASS/YYYY-0XX**

YYYY = Year

0XX = serial number of PV assessment in a given year.

# Reporting of ICSRs to LHAs

## Reporting to Oman Authorities

The submission of any PV document for Omani MOH must be through MOH online portal: <https://www.moh.gov.om/en_US/-32>

**Required ICSRs for registered medicines:**

* Only Adverse Reactions occurring within Oman and their follow-up info regardless of source, seriousness and expectedness are reportable.
* Timelines:
* Serious cases: within maximum 15 days of knowledge.
* Non-serious cases: within maximum 90 days of knowledge.

## Reporting to Kuwait Authorities

* The submission of any documents to Kuwait authorities will be through NN distributor in Kuwait.
* All serious Adverse Reactions occurring within Kuwait should be reported within 15 days.
* All non-serious Adverse Reactions occurring within Kuwait should be reported within 90 days.

## Reporting to Yemen Authorities

* The submission of any documents to Yemen authorities will be through NN distributor in Yemen.
* All serious Adverse Reactions occurring within Yemen should be reported within 15 days.
* All non-serious Adverse Reactions occurring within Yemen should be reported within 90 days.

# Aggregated Reporting to LHAs

**Oman:**

PSURs submissions shall be based on EURD reference list

**Kuwait:**

PSURs submissions shall be based on EURD reference list

**Yemen:**

PSURs submissions shall be based on EURD reference list

# Reporting of Risk Management Plans

Upon receiving notification from RA department about an update of RMP, the updated RMP should be submitted to LHAs in Kuwait and Oman.

# Abbreviations

| Abbreviation | Term |
| --- | --- |
| CC | Customer complaint |
| CEP | Customer Engagement Program |
| DSURs | Development Safety Update Reports |
| EDC | Electronic Data Capture system for clinical trials |
| GRMs | Global Rules Management system |
| GS | Global Safety |
| HCP | Health Care Professional |
| IBD | International Birth Date |
| ICSR | Individual case safety reports |
| LHA | Local Health Authority |
| NCMDR | National Centre of Medical Devices Reporting |
| NN | Novo Nordisk |
| PASS | Post Authorization Safety Study |
| PSP | Patient Support Program |
| PSURs | Periodic Safety Updates Reports |
| PV | Pharmacovigilance |
| QPPV | Qualified Person for Pharmacovigilance |
| RMP | Risk Management Plan |
| SUSARs | Suspected Unexpected Serious Adverse Reactions |

# Definitions

This list contains definitions of abbreviations and terms used in this document.

| **Term** | **Definition** |
| --- | --- |
| Adverse Event (AE) | Any untoward medical occurrence in a patient or clinical investigation subject administered/using a Product and which does not necessarily have to have a causal relationship with this treatment.  An Adverse Event can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a Product, whether or not considered related to the Product.  **Note:** An Adverse Event may be associated with the use of a drug, a Medical Device or both. |
| Adverse Reaction (AR) | An Adverse Reaction is a response to a medicinal product which is noxious and unintended. This includes Adverse Reactions which arise from:   * The use of the NN product within the terms of the marketing authorisation. * The use of the NN product outside the terms of the marketing authorisation, including overdose, off-label use, misuse, abuse and medication errors. * Occupational exposure.   **Note:** An Adverse Reaction may be associated with the use of a drug or a Medical Device or both.  **For solicited cases:** An Adverse Reaction is an Adverse Event for which the causal relationship between the Product and the Adverse Event is suspected, i.e. judged possible or probable by either NN or the reporter.  **For unsolicited directly received cases:** Even if the relationship is unknown or unstated by reporter, it meets the definition of an adverse reaction. Therefore all spontaneous reports notified by Health Care Professionals, patients or Consumers are considered Adverse Reactions, since they convey the suspicions of the primary sources, unless the reporters specifically state that they believe the events to be unrelated or that a causal relationship can be excluded. |
| Customer | An organization or person received products provided by Novo Nordisk. Includes direct customers, importing distributors, wholesalers, hospitals, pharmacies and end users. |
| Customer Complaint | Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, labelling, actions, safety, effectiveness, or performance of a Product (medicine or device) after it is released for distribution (placed on a market or used in a Clinical Trial).  Complaints include report of suspected Adverse Reactions, alleged product defects and combinations thereof. Product inquiries are not Complaints". |
| Healthcare professional (HCP) | Medically qualified persons, such as physicians, dentists, pharmacists, nurses and coroners.  **Note:** A pharmacist technician/assistant is not a Health Care Professional, however the technician may call on behalf of a pharmacist. |
| Medication Error | A medication error is an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient.  **Note:** A failure in the drug treatment process does not refer to lack of efficacy of the drug, rather to human or process mediated failures.  Details of types of medication error and examples are given below:   * Medication errors associated with an adverse drug reaction(s). * Medication errors without an adverse drug reaction(s). * Intercepted medication errors (‘near miss’): this scenario applies when an intervention caused a break in the chain of events in the treatment process before reaching the patient which would have resulted in a ‘potential’ ADR. This intervention has prevented actual harm being caused to the patient, e.g., a wrongly prepared medicine was actually not administered to the patient because the error was noticed by the nurse.   Potential medication errors: this is the recognition of circumstances that could lead to a medication error and may or may not involve a patient. The term potential medication error refers to all possible mistakes in the prescribing, storing, dispensing, preparation for administration or administration of a medicinal product by all persons who are involved in the medication process. An example is a pharmacist who noticed that the names of two medicines are similar and could clearly lead to product name confusion, but no patient was actually involved or has taken the medicine. |
| Occupational Exposure | An exposure to a medicinal product, as a result of one’s professional or non-professional occupation. It does not include the exposure to one of the ingredients during the manufacturing process before the release as finished product. |
| Off-Label Use | A use that fails to comply with the currently approved Labelling of products. This relates to situations where the medicinal product is intentionally used for a medical purpose. |
| Post Authorization Safety Study | A Non-Interventional Study or a Clinical Trial relating to an authorised medicinal Product conducted with the aim of identifying characterising or quantifying a safety hazard, confirming the safety profile of the medicinal Product or measuring the effectiveness of a risk management measure. |
| Product Defect | Non-fulfilment of a requirement related to an intended or specified use of a product. |
| Safety information | All reports of Adverse Events occurring during the use of a Novo Nordisk product.  In addition, Safety Information includes any of the following information relevant to the safety of the Novo Nordisk product:   * Serious outcomes, e.g., sudden death * All reports relating to pregnancies, including outcome of a pregnancy, where the foetus may have been exposed to a drug product through parental exposure * Any adverse event occurring in infants following exposure to a drug product from breastfeeding * Reports of lack of efficacy * Any suspected transmission of an infectious agent via drug product * All reports of overdose, drug abuse, drug misuse and occupational exposure * All reports of medication errors * All device failures with Novo Nordisk devices or the device part of marketed drug-device combination products, which could have led to death or serious deterioration in the state of health, even if in the actual situation nothing happened |
| Serious Adverse Event (SAE) | A Serious Adverse event is an experience that at any dose results in any of the following:   * Death * Life-threatening experience * Inpatient Hospitalisation or prolongation of existing Hospitalisation * A persistent or significant disability/incapacity or is a congenital anomaly/birth defect * Important medical events that may not result in death, be life-threatening, or require Hospitalisation may be considered a Serious Adverse event when, based upon appropriate medical judgement, they may jeopardise the patient or subject or require medical or surgical intervention to prevent one of the outcomes listed in this definition. Suspicion of transmission of infectious agents must always be considered an SAE.   **Note:** The term life-threatening in the definition of serious refers to an event in which the patient was at risk of death at the time of the event. It does not refer to an event, which hypothetically might have caused death if it was more severe. |
| Solicited adverse event report | Reports derived from organized data collection systems, which include, e.g., clinical trials, Non-Interventional Studies, Registries, and surveys of patients or healthcare providers. For the purposes of safety reporting, solicited reports should be handled as Non-Interventional Study reports, and therefore should have an appropriate causality assessment by NN and if possible by the reporter. |
| Sources of Safety Information | The information may be obtained or otherwise received by Novo Nordisk from any source, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from regulatory authorities and the internet. |
| Sponsor | An individual, a company including local affiliate, an institution, or an organization which takes responsibility for the initiation, management and/or financing of a clinical trial. |
| Spontaneous AE report | See Unsolicited adverse event report. |
| 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. |
| Unsolicited adverse event report | Any spontaneous communication to a company, Regulatory Authority or other organization that describes one or more adverse events in a patient given one or more products which does not derive from a study or any organized data collection scheme. Cases of adverse events from the medical and scientific literature, including relevant published abstracts from meetings might qualify for reporting. Unsolicited reports from the internet shall also qualify for reporting. For the purpose of reporting the criteria for a valid report apply. |
| Valid report | A case which contains information on an identifiable reporter, suspected product, adverse event, and identifiable patient (as recognized by, e.g., sex, age group, date of birth or initials). |