# VIGILANCE

1. All Product Complaints (Adverse Events and Medical Device Malfunctions) and Events of Special Interest (as defined below) received for the Product by Distributor will be forwarded to Alcon immediately upon receipt, which shall be no later than 1 calendar day following receipt.

**Alcon representative:** Full-time and part-time Alcon associates as well as individuals working on behalf of or contracted to represent Alcon (e.g.: an agent, Contract Research Organization, contractor, distributor, etc.). In the context of this contract the Distributor is considered an Alcon representative.

**Date of first receipt (DFR):** The date the initial reporter provided the first information about the event to an Alcon representative. (Day 0). The Date of First Receipt is the date Alcon, or any person acting on their behalf receives the first communication on a possible safety related event regardless of its validity.

**Event of Special Interest:** An event that is of special interest to healthcare authorities, and therefore required to be recorded by Alcon, including:

* + *For medical device products (device and OTC)*
    - Use error
    - Abnormal Use
    - Product tampering
    - Product counterfeiting
    - Product Theft
  + *For medicinal products (drugs, cosmetics and dietary supplements)*
    - Medication error. Any unintentional error in the prescribing, dispensing, or administration of a medicinal product while in the control of the healthcare professional, patient or consumer.
    - Misuse. This refers to situations where the medicinal product is intentionally and inappropriately used not in accordance with the authorized product information.
    - Overdose. This refers to the administration of a quantity of a medicinal product given per administration or cumulatively, which is above the maximum recommended dose according to the.
    - Abuse. This corresponds to the persistent or sporadic, intentional excessive use of a medicinal product, which is accompanied by harmful physical or psychological effects.
    - Off-label use. This relates to situations where the medicinal product is intentionally used for a medical purpose not in accordance with the authorized product information.
    - Lack of expected pharmacological action/efficacy
    - Use during conception, pregnancy, or lactation
    - Use in children
    - Occupational exposure to product. This refers to the exposure to a medicinal product, as a result of one’s professional or non-professional occupation.
    - Suspected transmission of infectious agents
    - Product tampering
    - Product counterfeiting
    - Product theft

**Product Complaint:** Any oral, electronic, or written communication that alleges deficiencies related to the identity (labeling), quality, durability, reliability, safety, effectiveness, or performance of a marketed product, including failure of the product, labeling or packaging to meet specifications, whether or not the product is related to, or caused the alleged deficiency. A complaint may allege that an adverse event or medical device malfunction has occurred (see related definitions).

* **Adverse Event (Device)**: Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the medical device.
* **Medical Device Malfunction:** The failure of a device to meet its performance specifications or otherwise perform as intended. If a medical device detects an operating problem during use, and per its design defaults to a “safe” mode, the event that triggered the default may be a medical device malfunction and must therefore be submitted to Alcon for evaluation.

# Adverse Event/Undesirable Effect (Cosmetics): Adverse reactions for human health attributable to the normal or reasonably foreseeable use of a cosmetic product.

* **Adverse Event (Drugs):** Any untoward medical occurrence in a patient or clinical- trial subject administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Distributor shall forward a copy of the source document along with all available information to Alcon concerning any Product Complaint (Adverse Events and Medical Device Malfunctions) and Event of Special Interest associated with the Product(s) upon learning of any such occurrences to the address specified in the Agreement.

1. Product Complaints (Adverse Events and Medical Device Malfunctions) and Events of Special Interest exchanged between the Parties shall be reconciled on a quarterly basis.
2. Alcon as manufacturer will be responsible for notifying the relevant regulatory authorities about any reportable Product Complaint (Adverse Events and Medical Device Malfunctions) and Event of Special Interest. Any communication on quality or safety information or issues that the Distributor receives from the authorities will be forwarded immediately to Alcon, which shall be no later than 1 (one) calendar day following receipt.
3. Distributor shall fully cooperate, as requested by Alcon, in responding to and/or gathering any additional information, including samples when available, for any Product Complaint (Adverse Events) and Event of Special Interest, Distributor receives relative to the Product.
4. Distributor shall return complaint samples to Alcon for investigation as soon as possible.
5. Distributor shall maintain an effective recall system and records so that Distributor can recover any of the Product from the channels of distribution if necessary. At any time, should information come into the possession of either Party that would indicate the need or the

necessity for a review for a possible post-market action (including recall) of the Product, such Party will notify the other Party immediately and the Parties will assist each other as required in the course of the action. In the event Alcon shall be required or shall voluntarily decide to effect a post-market action related to any of the Product, then Distributor shall cooperate with Alcon in implementing such post-market action.

1. Distributor shall maintain all safety (including Product Complaints and Events of Special Interest) and other applicable records per the relevant laws and regulations for the amount of time required by such laws and regulations.
2. Distributor shall ensure that its personnel have adequate training regarding their safety and other relevant obligations per the applicable laws and regulations.
3. For agreements covering promotional activities, Distributor shall make every effort to collect the following data to facilitate the company’s ability to contact the reporter:
   * The reporter’s contact information including name, occupation (only when the reporter is a healthcare provider), telephone number, and address
   * Description of the complaint and complaint/procedure details\*
   * Product(s) associated with the complaint
   * Product identifiers as applicable, i.e. name of the product, lot number, serial number, catalog number, software version
   * The contact information of any healthcare provider consulted for the complaint
   * Patient identifiers, when there is a patient (any information that indicates discrete individuals may be associated with the complaint. Such information include: age, age group, gender, weight, date of birth, date of surgery, time of surgery, other medical characteristics, etc.)
   * Outcome (For adverse events only; did the event resolve, improve, or continue with or without treatment?)
   * Action or medical intervention taken
   * Sample availability

\* For surgical devices, appropriate details of the complaint includes:

1. patient impact
2. what procedure was being performed
3. how the product was used
4. the length of delay, and the reason for the delay, only if it is reported that a delay occurred during the procedure
5. the likelihood that the reported deficiency would have been detected/noted prior to use of the device.

MAH for the Territory shall inform the other Party on an annual basis (by October of every year) of any requests for periodic/aggregate safety reports and provide any information required for the preparation of such reports. MAH of the Territory will be responsible for submitting periodic/aggregate safety reports to the relevant regulatory authorities in accordance to local pharmacovigilance regulations.