Pharmacovigilance Policy

1. Background:

As a pharmaceutical company, Alkem has a mandatory responsibility to monitor the safety of Alkem's Products worldwide that we have in development or are marketing in any country.

Pharmacovigilance is defined as the science and activities relating to the detection, monitoring, assessment, understanding and prevention of adverse effects or any other drug related problems.

Major aims of pharmacovigilance are:

1. Early detection of unknown adverse reactions and interactions

2. Detection of increases in frequency of (known) adverse reactions

3. Identification of risk factors and possible mechanisms underlying adverse reactions

4. Estimation of quantitative aspects of benefit/risk analysis and dissemination of information needed to improve drug prescribing and regulation.

The ultimate goals of pharmacovigilance are:

• the rational and safe use of medical drugs

• the assessment and communication of the risks and benefits of drugs on the market

• educating and informing of patients.

This policy summarizes the well-established pharmacovigilance system that Alkem has in place to monitor and review the safety of our medicines throughout clinical development and following their approval by Regulatory Authorities.

We comply with international regulations governing the reporting, analysis and communication of side effects. We have a governance framework and policies in place to help us detect and act on any side effects and other human safety information that may be associated with our products.

Alkem continuously monitors and evaluates the benefit/risk profile of our marketed products. We are committed to transparency in our evaluation and communication of these benefits and risks with patients, healthcare professionals and regulators.

2. Alkem's Safety Governance System

The benefit/risk profile of Alkem's product is assessed throughout its lifecycle using a benefit/risk analysis. When negative benefit/risk ratio is identified, then action is taken to characterise, communicate and minimise the risk.

Alkem collects safety information of its products from multiple sources including:

- Clinical trials
- Spontaneous reports from HCPs and patients/consumers
- Regulatory authorities
- Medical and scientific literature

- Social media

Alkem employees and affiliate workers are trained on their responsibilities to report human safety information. It is Alkem's policy that employees are required to immediately report any issues relating to the safety or quality of our products at pvglobal@alkem.com.

The pharmacovigilance department is accountable for establishing a Pharmacovigilance System to ensure collection and reporting of safety information to the relevant regulatory authorities in accordance with their respective requirements.

The data is recorded on a centralised computerised database for ease of retrieval and analysis. Our Pharmacovigilance database is hosted in India.

3. Governance Committees:

The Governance Committees provides organization-wide oversight of the system of principles, policies and responsibilities that ensure the safety evaluation of our products is operating effectively.

At designated milestones during the clinical development stage, the Alkem's Drug Safety Monitoring Board (DSMB) reviews the benefit/risk balance of medicines, and the protection of patient welfare.

Similarly for marketed products, Alkem's Drug Safety Review Committee (DSRC) monitors the benefit/risk balance.

4. Data Privacy:

We are required to process certain personally-identifiable information and sensitive personal data ("Personal Data") of a patient/ consumer and/ or the reporter of an adverse event that we receive, in order to comply with strict obligations to perform benefit/ risk assessments of Alkem's Products and to report suspected Adverse Drug Reactions (ADR) or Adverse Events (AE) to relevant regulatory authorities (for the "Pharmacovigilance Purposes").

All Personal Data received by Alkem's Pharmacovigilance Team is processed exclusively for Pharmacovigilance Purposes.

4.1 Personal Data we process for the Pharmacovigilance Purposes:

We may collect personal data directly from patient/consumer, or from anyone reporting patient's/consumer's symptoms on their behalf. We may collect personal data including but not limited to:

- Patient's name, contact details, email, telephone number, address, date of birth, gender, weight, height and related demographic data;
- Medicines and products taken including dosages, medical history, adverse events/reactions and laboratory reports;
- Reporter's name, contact details, including email, telephone number, address, professional role and patient relationship.

- Special Category Data: Some of the Personal Data we collect is considered by law to be particular sensitive and constitutes a special category of personal data. This includes any information that tells us about a patient's – health, racial/ethnic origin, genetic data and sexual life.

4.2 Use of Personal Data for Pharmacovigilance Purposes:

As part of meeting our pharmacovigilance obligations, we may use and share Personal Data to:

- investigate the adverse event;
- contact patient/consumer/reporter for further information about the adverse event reported;
- collate the information about the adverse event with information about other adverse events received by Alkem to analyse the safety of a batch, Alkem's product or active ingredient as a whole; and

provide mandatory reports to national and/or regional authorities so that they can analyse the safety of a batch, Alkem product, generic or active ingredient as a whole alongside reports from other sources.

4.3 Sharing/disclosure of Personal Data for Pharmacovigilance Purposes:

Personal Data collected from patient/consumer/reporter in accordance with this Policy may also be transferred to a third party in the event of a sale, assignment, transfer, or acquisition of the company or a specific product or therapeutic area, in which case we would require the buyer, assignee or transferee to treat that personal data in accordance with applicable data protection laws. Additionally, personal data may be shared with our vendor partners who are responsible for ADR processing.

We may also share Personal Data with affiliates and other pharmaceutical companies who are our co-marketing, co-distribution, or other license partners, where pharmacovigilance obligations for a product require such exchange of safety information.

We share information with international, national and/or regional regulatory authorities as required by pharmacovigilance laws. We are not responsible for further processing of Alkem provided Personal Data by regulatory authorities.

We may publish information about adverse events (such as case studies and summaries).We will remove personally identifiable data from any publications so that no individual can be uniquely identified.

4.4 Security of Personal Data

Alkem takes strict measures to secure Personal Data from accidental loss and from unauthorised access, use, alteration or disclosure. Additionally, we take further information security measures including access controls, stringent physical security and robust information collection, storage & processing practices for ensuring security of personal data.

4.5 Retention periods for use of Personal Data

We will use and store Personal Data in accordance with mandatory requirements governing storage and reporting of Pharmacovigilance related information. These requirements oblige us to archive

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Pharmacovigilance information which may include Personal Data, at least for the duration of the product life-cycle and for an additional ten years after the respective medicinal products and medical devices have been withdrawn from the market.