

2009

# PHARMACOVIGILANCE POLICY

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BIOCON LIMITED



**EXECUTIVE SUMMARY**

Biocon is aware that once a product is marketed, new information is generated, which can have an impact on the benefits or risks of the product. Detailed evaluation of the information generated through pharmacovigilance activities is important for all products to ensure their safe use. The benefit-risk balance can be improved by reducing risks to patients through effective pharmacovigilance activities that can enable information feedback to the users of medicines in a timely manner.

Biocon has set up the pharmacovigilance system to ensure that any untoward effect occurring in connection with the administration of any of the Biocon products is identified, promptly collected and the analysed by experts and appropriately disseminated to contribute to making drug administration even more safe and to prevent occurrence of adverse reactions. There is an ongoing dialogue with expert consultants and with regulatory authorities for safety of Biocon products. Evaluation of the safety information of all the products is a continuous process here in Biocon.

Biocon is committed to inculcate good Pharmacovigilance practices and thus is committed to improve patient care and safety by:

- ✓ Contributing to the assessment of benefit, harm, effectiveness and risk of all its products
- ✓ Promoting education and training in pharmacovigilance
- ✓ Promoting effective communication of safety information to the medical fraternity and public
- ✓ Promoting rational and safe use of medicines and thus improve public health and safety

## **INTRODUCTION:**

### **Pharmacovigilance:**

The World Health Organization defines pharmacovigilance as 'the pharmacological science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem'. The goal of pharmacovigilance is the safer use of medicines and this is usually achieved by dissemination of accurate, timely and clinically relevant information.

Communicating the potential harm of drug-use to physicians and patients is a matter of high priority and every manufacturer should carry out the responsibility or actively participate in the process.

Early detection of safety signals from clinical trials and proactive postmarketing surveillance is necessary to identify the risks associated with the products. Number of recent high profile drug withdrawals point towards this fact. Information collected during the pre-marketing phase of drug development may not detect rare ADRs. The use of a drug during a clinical trial is under controlled conditions, also, limited and selected numbers of patients are enrolled in the clinical trials. Drug use in special situations and population or drug interactions may not be studied. Therefore, the post-marketing surveillance of drugs is important.

Spontaneous ADR reporting, during post-marketing surveillance, has shown to detect adverse event signals resulting from drug use in the population.

With this awareness, Biocon is instrumental in continuously monitoring unwanted effects and other safety aspects of drugs that are already in the market apart from being vigilant in pre marketing monitoring. Biocon believes that proactive monitoring of the risks helps to place robust risk management plans throughout the life cycle of the product.

### **Biocon`s Position:**

Biocon considers Pharmacovigilance as an important and integral part of clinical research and considers clinical trials safety and post-marketing pharmacovigilance as critical activities throughout the product life cycle. Biocon has taken initiative to have its own pharmacovigilance program to take care of it`s product range and the worldwide regulatory requirement.

Biocon caters to ensure safe administration of its drugs to patients. For this there is a constant effort to proactively collect the safety information of all investigational and marketed products, analyze it, collate and convey it to the health care professionals, nurses, pharmacists, patients and regulatory authorities.

If change in safety profile is indicated it is done promptly by updating the prescribing information of the product.

All the queries and product related complaints are addressed on priority basis. For this purpose various channels of communication are available to collect safety information round the clock. All employees of the company participating in the pharmacovigilance activities are trained, know their responsibility and are capable to perform their duties.

Biocon is striving hard to develop robust ways to tackle under reporting, improve quality of generated reports and establish and maintain effective collaboration with the regulators. Biocon believes this can be achieved with good pharmacovigilance practices and has strived to inculcate them.

Biocon has a vision to strengthen the Pharmacovigilance setup such that it will be compliant to the pharmacovigilance obligations imposed by worldwide Regulatory Authorities.

#### **Proposal for Pharmacovigilance:**

##### ***Safety Committee:***

Representatives of Biocon from core areas like regulatory, clinical and product quality have come together to form a **Pharmacovigilance Core Committee** responsible for drafting pharmacovigilance policy, setting up the Pharmacovigilance systems and carrying out day today Pharmacovigilance activities.

##### ***Purpose of establishing Pharmacovigilance Core committee:***

To have a pharmacovigilance policy and pharmacovigilance set-up in place as a step towards science-based approach in safety monitoring by safety information collection, analysis, reporting, risk documentation and risk management.

##### ***Scope:***

This policy applies to all marketed products for which Biocon is a marketing authorization holder or Biocon formulated products being marketed by Partners.

This policy also applies to all investigational products in clinical trials conducted by Biocon or Biocon formulated products for which partner is conducting clinical trials.

##### ***Goals:***

- ✓ Continuous monitoring of the safety of Biocon products (both marketed and investigational)

- ✓ Assessing the risks and benefits of all products and also to ensure that their risks and benefits remain acceptable
- ✓ Providing information to users on safe and effective use of products. To promote rational use of these products by providing information about ADRs.
- ✓ Identification, quantification and improving understanding of previously unknown adverse drug reactions.
- ✓ Identification of patients at particular risk of having an ADR (For e.g. the elderly, children, hepatic and renal compromised patients and terminally ill patients).
- ✓ Monitoring the impact of any action taken.

### ***The Pharmacovigilance Monitoring System:***

Biocon has built and maintained a robust pharmacovigilance system which is based on following elements:-

### **Collection of Adverse Event Information:**

All spontaneous adverse events (marketed products) are collected via phone, email, fax, postal and Biocon official website. All adverse events (investigational products) are collected as per the Clinical Trial Protocol or Safety Management Plan via above mentioned modes.

### **Adverse Event Reporting Form:**

There is a ready availability of standardized single adverse event reporting/product complaint form compatible to be used for all of the following:-

- Reporting product complaints and adverse event with Biocon Products.
- Reporting via all modes of collection (email, phone, fax, postal, web-online)
- For reporting of events Whole range of products of Biocon
- To be reported by Health Care Professional , Patient or others (e.g. relatives of patient).

### **Safety Database:**

The collected adverse events are recorded in global safety databases. Biocon has created a separate database for collection and archival of adverse events and products complaints reported from post-marketing. Safety data reported from the clinical trials are archived separately in the respective study databases.

These collected events are investigated by our core clinical and pharmacovigilance teams. These teams consist of dedicated scientists who monitor, review, evaluate and communicate safety issues.

**On going safety review:**

Ongoing safety review helps us continuously assess the balance of risks and benefits associated with a particular product. As appropriate, on case to case basis we respond to safety issues/product complaints via phone or written responses. Each enquiry or adverse event is promptly dealt and closed only after adequate response or processing is done. If needed we update product labels and communicate to doctors. In most cases these actions are sufficient; in a small number of cases we can propose and conduct risk minimisation activities, like further clinical trials, physician or pharmacy education. In certain extreme cases it is our duty to take decision to stop clinical trials or to withdraw the medicine from the market.

**Reporting to Regulatory Authorities:**

Biocon proposes to strengthen the Pharmacovigilance setup such that it will be compliant to the pharmacovigilance obligations imposed by worldwide Regulatory Authorities. The compliance will be w.r.t. timelines of reporting, form and format of reporting, necessary risk management planning and implementation.

**Marketed drugs:**

For drugs already in the market, type and frequency of all adverse events (serious and non-serious) is submitted in periodic safety update reports (PSURs) also added to the summary of product characteristics (SPCs) or prescribing information (PI) (if necessary). Individual spontaneous serious adverse events are also reported as ICSR to the Regulatory Authorities whenever required.

**Investigational drugs:**

For investigational drugs the serious adverse events are reported to the worldwide Regulatory Authority as per the applicable guidelines and also periodically updated in the Information Brochure.

**Education and training:**

Education and training of field force to in turn educate and spread awareness and alertness in physicians, pharmacists and nurses in the area of pharmacovigilance is also amongst our priorities. Various training programs, assessment at trainings and evaluation are routinely practiced in Biocon.