

NATIONAL PHARMACOVIGILANCE PROGRAMME

Before a product is marketed, experience of its safety and efficacy is limited to its use in clinical trials, which are not reflective of practice conditions as they are limited by the patient numbers and duration of trial as well as by the highly controlled conditions in which Clinical Trials are conducted.

The conditions under which patients are studied during the pre-marketing phase do not necessarily reflect the way the medicine will be used in the hospital or in general practice once it is marketed. Information about rare but serious adverse drug reactions, chronic toxicity, use in special groups (e.g. pregnant women, children, elderly) and drug interactions are often incomplete or not available. Certain adverse drug reactions may not be detected until a very large number of people have received the medicine.

Pharmacovigilance is therefore one of the important post-marketing tools in ensuring the safety of pharmaceutical and related health products.

Pharmacovigilance is defined as the detection, assessment and prevention of adverse drug reactions in humans. It is the process of:

- Monitoring medicines as used in everyday practice to identify previously unrecognized adverse effects or changes in the patterns of their adverse effects.
- Assessing the risks and benefits of medicines in order to determine what action, if any, is necessary to improve their safe use.
- Providing information to users to optimize safe and effective use of medicines
- Monitoring the impact of any action taken.