

L.N. 374 of 2012

**MEDICINES ACT
(CAP. 458)**

Pharmacovigilance Inspections Regulations, 2012

IN exercise of the powers conferred by article 106 of the Medicines Act, the Minister of Health, the Elderly and Community Care, after consultation with the Licensing Authority, has made the following regulations:-

1. (1) The title of these regulations is the Pharmacovigilance Inspections Regulations, 2012. Citation and scope.

(2) These regulations shall apply to authorised medicinal products for human use, their marketing authorisation holder and any pharmacovigilance activity connected therewith.

(3) These regulations implement the provisions of Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance inspections, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

2. For the purpose of these regulations: Interpretation.

"the Authority" means the Medicines Authority set up in terms of article 4 of the Medicines Act; Cap. 458.

"Pharmacovigilance system" means a system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities listed in these regulations and designed to monitor the safety of authorised medicinal products and detect any change to their risk-benefit balance;

"Pharmacovigilance system master file" means a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products.

3. (1) The Authority shall have a right to inspect the premises, records, documents and pharmacovigilance system master files of the marketing authorisation holder or any firms employed by the marketing authorisation holder to perform the activities described in Title IX of Directive 2001/83/EC. Inspection.

(2) After every inspection, the Authority shall report on whether the inspected entity complies with the requirements laid down in Title IX of Directive 2001/83/EC. The Authority shall communicate the content of the report to the inspected entity. Before adopting the report, the Authority shall give the inspected entity concerned the opportunity to submit comments.

(3) If the outcome of the inspection is that the marketing authorisation holder does not comply with the pharmacovigilance system as described in the pharmacovigilance system master file and with Title IX of Directive 2001/83/EC, then the Authority shall also inform other EU Member States, the European Medicines Agency and the European Commission with that outcome.

