

11 NOV 2021



Decree
Assistant to the Minister No. (2) of 2010
Regarding the Rules Governing Pharmacovigilance the
Safety of Pharmaceutical Products

The Assistant Minister of Health

After perusal of the following:

- Law No. 127 of 1955 regarding Pharmacy Profession Practice
- Minister of Health Resolution No. 397 of 1995 for the establishment of the National Center for Detecting Drug Side Effects & adverse events in the Arab Republic of Egypt.
- Presidential Decree No. 242 of 1996 regulating the Ministry of Health amended by Decree No. 74 of 2009.
- Presidential Decree No. 398 of 1995 regarding the establishment of the National Organization for Research and Control of Biological Products.
- Ministerial Resolution No. 2494 of 2008 appointing Prof. Dr. Kamal Sabra, Assistant to the Minister of Health for Pharmacy Affairs.
- The Minister of Health decision No. 460 of 2008 appointing Prof. Dr. Assistant Minister for Pharmaceutical Affairs to supervise both the Central Administration for Pharmaceutical Affairs, the National Organization for Drug Control and Research and the National Organization for Research and Control of Biological Products
- Minister of Health Resolution No. 296 of 2009 regarding the re-organization of human pharmaceutical product registration procedures.
- Minister of Health Resolution No. 297 of 2009 regarding the rules of biological products, antisera, vaccines and blood products registration procedures.
- Minister of Health Resolution No. 221 of 2008 regarding the establishment of the Scientific Committee on Causality Assessment.

Preamble

This resolution shall apply on all pharmaceutical products and biological products.

Decide

Article (1): The Marketing Authorization Holders of pharmaceutical product shall be committed to have a pharmacovigilance system with the aim of monitoring the safety of its products in the Post marketing stage by collecting analysing and evaluating adverse events of pharmaceutical products and problems related to their usage to ensure the continuous safety of such products.

Article (2): The Marketing Authorization Holders of pharmaceutical products shall be committed to report serious and unexpected adverse events resulting from the use of the product within a period of no more than 15 days as of the date of first knowledge of these events.

Article (3): The Egyptian Pharmacovigilance Center shall receive individual case safety reports of pharmaceutical products that occurs inside the Arab Republic of Egypt from healthcare professionals and patients, their relative or any other body and work on their evaluation, analysis and listing them in the national database.

Article (4): The expanded program on immunization related to the Ministry of Health shall collect adverse events following immunization that occur inside the Arab Republic of Egypt which are investigated by the expanded program on immunization and the National Organization for Research and Control of Pharmaceutical Products and sent the investigation results of Serious Adverse Events Following Immunization (AEFI) for evaluation by the Scientific Committee for Causality Assessment and list them in the Egyptian Pharmacovigilance Center (National) Database.

Article (5): The Marketing Authorization Holders of pharmaceutical product shall submit Periodic Safety Update Report for the pharmaceutical product as well as the clinical trials phase four to Central Administration for Pharmaceutical Affairs to ensure the safety of the product in the following cases:

1. When registering or re-registering the new pharmaceutical product (Innovator)
2. When re-registering generic or biosimilar products.

Article (6): The Marketing authorization Holders of the pharmaceutical product shall be committed to submit all updates related to information, studies or regulatory decision taken in any of the other countries in which the product is marketed regarding the safety of the product to the Central Administration for Pharmaceutical Affairs.

Article (7): The principle investigator of clinical tests and the company responsible for the clinical studies of the pharmaceutical products inside the Arab Republic of Egypt shall immediately report Suspected Unexpected Serious Adverse Reactions (SUSARs) which resulted in the death or threatening the life of the volunteer or patient within one day as of the time being knowledgeable of the adverse reaction. As for other adverse reactions that occurred during the conduct of the study, they shall be reported within seven days as of the date of being knowledgeable of the adverse reaction.

Article (8): The Pharmacovigilance Center shall send recommendations to the technical committee for drug monitoring at the Central Administration for Pharmaceutical Affairs in order to take any of the following decision with regards the pharmaceutical product after verifying and evaluating product related reports or the information:

- Import Banning
- Prevent marketing
- Suspending authorization and manufacturing for a certain time.
- Withdrawal of authorization

Article (9): This regulation shall be in force as of the date of its issuance and competent bodies shall

Assistant tot
for Pharmaco
(signature)

Prof. Dr. Kamal Sabra

Issued on: 07.09.2010



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