Ministry of Health Decree No. (368) of 2012 Regarding Egyptian Pharmacovigilance Center Promulgated to Amend Ministerial Decrees Nos. (397) and (398) of 1995

The Minister of Health
After perusal of the following:

- Law No. 127 of 1955 regarding Pharmacy Profession Practice
- Presidential Decree No. 242 of 1996 regulating the Ministry of Health amended by Decree No. 74 of 2009.
- Ministerial Resolution No. 2494 of 2008 appointing Prof. Dr. Kamal Sabra, Assistant to the Minister of Health for Pharmacy Affairs.
- Ministerial Decree No. 208 of 1992 for the establishment of Drug Services Committee.
- Ministerial Decree No. 37 of 1993 regarding the competences of Drug Services Committee.
- Ministerial Decree No. 149 of 1995 amending the name of Drug Services Committee to Drug Planning & Policies Center
- 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.
- Minister of Health Resolution No. 398 of 1995 regarding the formation of the Supreme Council for Detecting Side Effects & Disadvantage of Drugs.
- Minister of Health Resolution No. 632 of 2010 regarding the reformation of some specialized scientific committees.
- Resolution of the Assistant to the Minister of Health No. 2 of 2010 regarding the Rules Regulating Pharmacovigilance and Pharmaceutical Products Safety.

Decided

Article (1): Amending the name of the National Center for Detecting Drug Side Effects & adverse events to become the "Egyptian Pharmacovigilance Center".

Article (2): The center shall be managed by the General Manager of the Egyptian Pharmacovigilance Center who shall be directly reporting to the Head of Central Administration for Pharmaceutical Affairs.

Article (3): The center comprises several sub-departments specialized in monitoring the safety of pharmaceutical products that include human drugs, biological products, food supplements, cosmetics, veterinary medicines, medical devices, antiseptics, and pesticides.

Article (4): Establishment of Regional Pharmacovigilance centers in each governorate of the Republic that report to the Egyptian Pharmacovigilance Center, operate under its technical supervision and whose members shall be selected by the Center.

Article (5): The Supreme Council for Detecting Drug Side Effects & adverse events shall be cancelled, and one or more scientific committee shall be formed to provide technical support to the center in accordance with its jurisdictions of which is the Pharmacovigilance Committee. The Center shall have the right to refer to relevant committees in the Central Administration for Pharmaceutical Affairs

Article (6): The Egyptian Pharmacovigilance Center shall be the national center in the Arab Republic of Egypt in charge of monitoring the safety of pharmaceutical products along their life cycle

and shall represent the regulatory authority for everything related to the field of pharmaceutical vigilance and its applications through the following specializations:

1. Developing the bases and regulations of pharmacovigilance and the continuous safety monitoring of pharmaceutical products shown in Article (3) of this decision.
2. Detecting the adverse events of pharmaceutical products at all health service centers in the Republic, receiving Individual Case Safety Reports (ICSRs) from health care team members, patients / their relatives, Marketing Authorization Holders (MAHs) or any other body.
3. Evaluation and classification of case safety reports, analysing their data and listing them in the national database.
4. Sending Individual Case Safety Reports that are detected in the Arab Republic of Egypt to the headquarter of Uppsala Monitoring Center in Sweden (as needed) as per the membership of the Egyptian Pharmacovigilance Center in the WHO Program for International Drug Monitoring.
5. Detection and characterization and following up of pharmaceutical products safety signals (in other words; adverse events with no previous known association with the use of pharmaceutical product).
6. Continuous monitoring and detecting the safety profile, assessing the benefit risk balance of registered / under registration pharmaceuticals in Egypt as well as the information that has been globally published in relation to the safety of these pharmaceutical products.
7. Periodically publishing a newsletter about pharmaceutical products safety updates in Egypt and / or other countries of the world.
8. Taking all appropriate regulatory procedures against pharmaceutical products -with regard pharmacovigilance and its applications- in order to preserve the positive benefit risk balance of the pharmaceutical product in addition to providing recommendations to relevant committees at the Central Administration of Pharmaceutical Affairs with regards other regulatory procedures.
9. Exchanging information related to pharmaceutical product safety and the related regulatory procedures with the National Pharmacovigilance Centers and the regulatory authorities over pharmaceutical products in other countries, World Health Organization and organizations working in the field of pharmacovigilance.
10. Performing the regulatory role of the center over Marketing Authorization Holders (MAHs) to assure the fulfilment of pharmacovigilance and safety requirements in accordance with the global and Egyptian guidelines in this field.
11. Evaluating pharmacovigilance documents which Marketing Authorization Holders are committed to submit to the center on regular basis upon registration / re-registration or in accordance with the request of the center.
12. Executing pharmacovigilance inspection inside or outside Egypt.
13. Monitoring the safety of pharmaceutical products during clinical trials and Post Authorization Safety Studies (PASS) that are conducted in the Arab Republic of Egypt in cooperation with relevant bodies.
14. Participating – as needed – in activities, meeting, local and/or international projects related to pharmacovigilance in cooperation with World Health Organization, Uppsala Monitoring Centre (UMC) and other international bodies working in the field of pharmacovigilance.
15. Detecting, following up, analysing and consequently attempting to prevent the effects resulting from medication errors and counterfeit/substandard pharmaceutical products and other activities that target raising the safety of pharmaceutical products marketed in the Arab Republic of Egypt.

11 NOV 2021

Name of the Certified Office
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Certification # 12001
Expiry date 1-1-2022
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16. The Center shall form work groups from among its members or who shall be nominated to assume the responsibilities or tasks determined by the center.
17. The Center shall perform training tasks through:
    1) Holding training courses for medical profession members to keep them acquainted with pharmaceutical vigilance and train them on detecting / following up adverse events cases
    2) Holding training courses to pharmacovigilance focal points in regional centres and hospitals
    3) Holding and / or participating in scientific seminars and conferences in various governorates.
    4) Awareness campaigns in the field of pharmacovigilance for specialists and the society as whole to disseminate awareness and introducing the importance and the means of reporting adverse effects of drugs.
    5) Holding training courses for Marketing Authorization Holders (MAHs) on the regulations and rules governing pharmacovigilance in Egypt and the means of their application provided that the so required participation fees shall be collected from the trained companies.
18. Performing the tasks that might come up in accordance with the continuous global development in the field of pharmacovigilance.

Article (7): Pharmacovigilance Guidelines and regulations issued by the Center for pharmaceutical products marketing authorization Holders are the detailed regulation of this decision from which its legality is derived.

Article (8): The following bodies shall finance the Center:
1. Service Improvement Fund at the Ministry of Health from the account of Drug Planning and Policies Center.
2. Contributions presented from international organizations such as World Health Organization and others.
3. International projects
4. Donations from local or international bodies.

Article (9): A percentage of the Center's finance shall be allocated to raise the scientific performance level of its members such as sending its members to attend training course in the field of specialization inside or outside the Arab Republic of Egypt, purchasing scientific books, subscribing in scientific websites and journals as well as pharmacovigilance related associations, attending the annual meeting of the National Pharmacovigilance Centers organized by World Health Organization, attending scientific conferences, establishing and managing electronic site for the Center and purchasing the required electronic programs.

Article (10): This resolution shall be published in the Egyptian Gazette (Al-Waqa'i al-Misriyya) and shall be in force as of the date of its publication.

Article (11): All resolutions that are in conflict or contradict this resolution shall be cancelled.

Minister of Health and Population
(signature)
Prof. Dr. Fouad El Nawawy

Issued on: 23.05.2012

11 NOV 2021

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CR: 353570
Tax ID: 200-328-697
ISO 9001-2015 Certified

EGYPTA - https://arabic.com - Name of the Certified Office: EGY MARK for certified translation - Certification # 12001 - Expiry date 1-1-2022 - Date & Signature - Translators Association Accredit by Arab Federation for Translators

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