

Egyptian Drug Authority Decree No. 590 of 2021 On the Guidelines for the Promotional, Educational, and Awareness Materials through Websites and Electronic Platforms

President of the Egyptian Drug Authority,

After perusing:

- Law No. 127 of 1955, on the Pharmacy Profession Practice and its amendments;
- Law on The establishing Egyptian Drug Authority by Law (No. 151/2019), and its executive regulation; and
- The Meeting Minutes of the Egyptian Drug Authority Board of Directors Held in its Session on 20/7/2020; and
- What was presented by the Head of the Central Administration for Pharmaceutical Care; and
- Having considered the interest of work;

has decided:

(Article One)

This decree applies to the dissemination of promotional, educational and awareness materials through websites and electronic platforms.

(Article Two)

The responsibility of each of the concerned parties, whether before or after publication, is determined as follows:

1)The responsibility for the submission of all types of promotional, educational, and awareness materials published through websites and electronic platforms on companies and scientific offices for obtaining prior approval from the General Administration for Regulation of Marketing and Advertising Materials including its responsibilities to control the published content and take all measures to correct and remove any misinformation according to the rules specified in the guidelines within the specified time frames.

2)The following are excluded from obtaining prior approval mentioned in the previous clause:

- Disease awareness materials published by companies and scientific offices (provided that they do not contain any trade or scientific names for pharmaceutical preparations), but required to notify the General Administration for Regulation of Marketing and Advertising Materials with every material, at least three days prior to publication.
- Educational materials presented by healthcare professionals selected by the company and unaffiliated with it but under the company sponsorship and published through only healthcare professionals specific websites and electronic platforms (provided that they do not contain any trade or scientific names for pharmaceutical preparations or any indications unregistered in

the Egyptian Drug Authority), but required to notify the General Administration for Regulation of Marketing and Advertising Materials with every material, at least three days prior to publication

- Unconditioned educational grants provided by companies to a medical or pharmaceutical community, provided that it is specialized only in providing campaigns to raise awareness of diseases (provided that the awareness materials do not contain any trade or scientific names for pharmaceutical preparations) in which the company's role is limited to providing educational sponsorship or grant without any other role, but required to notify the General Administration for Regulation of Marketing and Advertising Materials with every material, at least three days prior to publication.

(Article Three)

- All types of promotional, educational, or awareness materials published through websites and electronic platforms, should include the approval code and invalidation date as an integral part of the material in an apparent and readable place with the obligation to all the conditions for each type of material as detailed in the guidelines.

(Article Four)

- The different file types and the submission requirements for each type of materials published through the websites and electronic platforms are specified as detailed in the guidelines.

(Article Five)

- The content owner company is obligated to monitor the user-generated content to remove or correct any misinformation using responses from the previously approved user-generated-content responses list or new responses outside the previously approved list, with the obligation to submit them later as a notification. The company is also obligated to take the required action within the specified duration, provided that it does not exceed five days, and in the case that a violated material is discovered by the company on one of the websites or electronic platforms (which is unaffiliated with the company), The company shall notify the General Administration for Regulation of Marketing and Advertising Materials to take the necessary measures in addition to any other measures that can be taken directly from the company, the company shall also send an official warning stamped with the company's stamp to the violated party to remove the violated content.

(Article Six)

- The General Administration for Regulation of Marketing and Advertising Materials is responsible for the follow-up and monitoring of all websites and electronic platforms and when monitored any violation of promotional materials for preparations registered in the Egyptian Drug Authority or educational materials or awareness materials are verified and sending attention letter, type one warning letter or type two warning letter (according to the situation) to the company, including the corrective measures that must be taken based on the type of violation, within the duration specified by the administration, with the company's obligation to pay for the service of submission continuing after the warning letter issuing.

(Article Seven)

- The head of the Central Administration for Pharmaceutical Care will issue the guidelines (for promotional, educational and awareness materials through websites and electronic platforms) within fifteen days from the date of adopting this decree.

(Article Eight)

- The services considerations attached to this decree shall be paid for the services provided by the General Administration for Regulation of Marketing and Advertising Materials affiliated with the Central Administration for Pharmaceutical Care, regarding promotional, educational, and awareness materials published through websites and electronic platforms.

(Article Nine)

- The specified services considerations for the provided services shall be deposited in the account of the Egyptian Drug Authority accounting unit.

(Article Ten)

- This decree shall be effective from 01/01/2022, and the competent administrations shall implement it, each in its own jurisdiction.

President of the Egyptian Drug Authority
Prof. Tamer Mohamed Essam

Issued on: 2/12/2021