Central Administration for Pharmaceutical Care
General Administration for Regulation of Marketing and Advertising Materials

Guidelines for Online Promotional, Educational and Awareness Materials Activities 2021

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I. INTRODUCTION AND GUIDELINES CONTEXT:

Scope: This document provides guidance to Applicant of Materials (Marketing Authorization Holders/Scientific offices) aiming to publish over online websites and/or social platforms i.e. Digital marketing the following types of materials:

1. Promotional prescription and non-prescription medicine materials.
2. Educational materials about pharmaceutical products either with trade names or scientific names.
3. Awareness materials about a particular condition or disease.

These guidelines covers the contents targeted to healthcare professionals (HCPs), patients and public audience.

Classification of online material according to targeted audience:

Possible Type of Online Materials	If the Targeted Audience is:		
	Healthcare Professionals	Patients	Public
Promotional materials for prescription pharmaceutical products	Permitted with securing		
Promotional materials for non-prescription pharmaceutical products	Permitted with securing	Permitted	Permitted
Educational Materials for prescription pharmaceutical products	Permitted with securing	Permitted with securing	
Educational Materials for non-prescription pharmaceutical products	Permitted with securing	Permitted	Permitted
Educational Materials about drugs by scientific name	Permitted with securing		
Awareness materials about health or disease directed to HCPs	Permitted with gating		
Awareness materials about health or disease directed to patients or public	Permitted	Permitted	Permitted

II. DEFINITIONS AND LIST OF ABBREVIATIONS:

Definitions:

1. **Applicant of Material:**
The Marketing authorization holder (MAH) or the scientific office or their authorized delegates, which are responsible for advertising, promotional, educational or awareness activities and submitting the material to Egyptian Drug Authority (EDA).

2. **Medical/Pharmaceutical Communities:**
Entities that function independently, their practice is under the supervision of specialized Healthcare professionals, they may also be sponsored and receive grants (disease awareness grant) by an Applicant of Material, in this case they may be referred as "grantee".

3. **Social media:**
Social media is a broad term for internet activities that engage or encourage engagement through online discussions or interactions. e.g.: blogs, microblogs (Twitter), chat rooms, forums, video/photo sharing (YouTube, Flickr), or social networking (Facebook, Instagram), podcasts, user forums/discussion groups, wikis, news aggregation, apps etc.

4. **Uniform Resource Locator (URL):**
A "human-friendly" address of resource on the Internet. www.product.com/risk is a URL.

5. **Hyperlink**
A place in an electronic document on a computer that is linked to another electronic document, it may also link to websites or apps.

6. **Landing page:**
The page a visitor arrives at after clicking on the URL or hyperlink
A standalone web page, It's where a visitor "lands" after they click on a link in an email, or ads from Google, Bing, YouTube, Facebook, Instagram, Twitter, or similar places on the web.

7. **Hashtag:**
A word or phrase preceded by a hash symbol (#) used on social media sites to identify digital content or group messages on a specific topic.

8. Community management rules:
Protocols that control a specific online community.

9. Content Securing:
The appropriate measures taken by the Applicant of Material, Medical/Pharmaceutical Communities to ensure that the online-published material will be accessible to the target audience only excluding all others.

10. Content Gating:
The appropriate measures taken to ensure that the online-published content will be accessible only to the target audience (e.g. healthcare professionals and patients). This content is referred to as "Gated content". The target audiences can access this content only after providing their information typically an email address, phone number, or answer to a question.

11. Public:
A member of the general community who is neither a patient nor a healthcare professional including potential patients.

12. Quick Response code:
A type of barcode that stores information and can be read by a digital device, such as a cell phone.

ABBREVIATIONS:

Abbrev.	Meaning
EDA	Egyptian Drug Authority
EPVC	The Egyptian Pharmacovigilance Center
HCPs	Health Care Professionals
MAH	Marketing Authorization Holder
PIL	Patient Information Leaflet
QR Code	Quick Response Code
RMA	General Administration for Regulation of Marketing & Advertising Materials
SGC	Site Generated Content
UGC	User Generated Content
URL	Uniform Resource Locator

III. CLASSIFICATION OF ONLINE CONTENT:

Online content is content on websites and/or webpages that are owned, controlled, influenced, created, sponsored, operated by, or on behalf of the Applicant of Material, even if that influence is limited in scope.

1. Static online content:

Does not allow real-time communications, where no further modification on the content or interaction (commenting or sharing/retweeting) can be made by HCPs, patients or the public (any potential interactions tools properly deactivated).

a. Static websites.

Example: The website of the applicant of Material.

b. Static materials without interaction tools or whose interaction tools are disabled

Examples:

- Online paid search: which is a form of digital marketing where search engines such as Google and Yahoo allow advertisers to show ads on their search engine results pages. Paid search works on a pay-per-click model, or less commonly, when the ad is displayed.
- Banner ads; which allow embedding an advertisement into a web page in a form of a graphic display that stretches across the top, bottom, or sides of a website or online media property.
- Pop-ups ads; online advertising in the form of a graphical user interface display area, usually a small window, that suddenly emerges in the foreground of the visual interface.

2. Dynamic online content (interactive):

- That allows real-time communications, where reactions on the content can be made either by the content generator or by HCPs, patients or the public (commenting, or sharing/retweeting). Potential interactions tools activated.

ONLINE CONTENT CAN BE FURTHER CLASSIFIED:

a. According to character/space limitations:

i. Dynamic online content with **no character/space limitations**.
Example: Social networks i.e. Facebook, YouTube.

ii. Dynamic online content with **character/space limitations**:
Example: Online microblog messaging: (e.g., messages on Twitter or "tweets," which are currently limited to certain number of character spaces per tweet).

b. According to the content generator:

i. Site-generated content (SGC).
The content initiated by the Applicant of Material but may also be presented to the audience by the Medical/Pharmaceutical Communities.
Examples: blogs, webisodes, videos and articles.

ii. User-generated content (UGC).
Any material that is created by and posted by a user (audience such as healthcare professionals, patients, or public)

The content/dialogue created by HCPs, patients or the public in response to site-generated content.

Examples:
UGC found on the site of the Applicant of Material or other social media platforms such as Facebook, Twitter and YouTube.
- A Link rated and forwarded
- A comment added into an open text field
- A descriptor selected from a list of choices
- A photo or other media uploaded

IV. ONLINE CONTENT REQUIREMENTS

1. General requirements

Online content; shall adhere to the same regulations & guidelines issued by RMA, this document regulates specific particulars related to online materials but shall not repeal, amend or replace previous RMA guidelines, specially, but not limited to:

a. RMA prior approval shall be required for Site Generated Content (SGC) and community management rules (except in the cases mentioned in Section-V Responsibilities, points 2 b-c & 3).

b. Applicant of the material may initially get RMA prior approval for a list of possible responses to different scenarios of User Generated Content (UGC).
In the cases mentioned in Section-V Responsibilities, points 2 b-c & 3, the Applicant of the material may initially notify RMA with a list of possible responses to different scenarios of User Generated Content (UGC).

c. **New User Generated Content and responses shall be submitted monthly, by means of notification,** to monitor compliance of Applicant of Material to effective and proper control of UGC.

d. Hashtags are permitted, provided the prior approval of their content, according to the following conditions:

i. Regarding awareness material:
Hashtags theme shall be followed by the **company name**

Example: #Theme _Company name

 # احمي طفلك_شلل_الأطفال_اسم-الشركة
 # احمي طفلك_ اسم-الشركة

ii. Regarding promotional material to a non-prescription medication: Hashtags theme shall be followed by the **product name**;
Example: #Theme_ product name

 # صحتك_تهمنا_ اسم-المستحضر

iii. Whenever a claim is included within a Hashtag, it shall be evaluated if the claim is included in the master file list of claims, it may be used without further evaluation.

e. **All types of online materials content shall include the following:**

i. **Target audience determination** as an integral part of the material in an apparent and readable place compared to other claims.

ii. **Name of the Applicant of Material** as an integral part of the material, in an apparent and readable place compared to other claims (except for official social platforms accounts having the Applicant of Material's name as the account's picture).

iii. **Electronic means of communication** shall include, but not limited to:
Applicant of Material's e-mail.

iv. References.

v. RMA approval details (may be added as a first pinned comment in case of social platforms). All RMA approved online material shall visibly display its approval number, invalidation date, approval QR code in the following way:

"Approved by Egyptian Drug Authority: XXXXXX. Invalidation date: XX/XX/XXXX.
Kindly report any violated online promotional, educational and awareness material not having this message to The General administration for Regulation of Marketing & Advertising Materials at: www.edaegypt.gov.eg"

"هذه المادة حاصلة على موافقة هيئة الدواء المصرية برقم XXXXXX تاريخ الانتهاء XXXX/XX/XX
برجاء إبلاغ الإدارة العامة لتنظيم مواد التسويق والإعلان عن أي مواد دعائية أو تعليمية أو توعوية مخالفة لا تحتوي على هذه البيانات من خلال خدمة الإبلاغ عن مواد دعائية دوائية غير ملائمة www.edaegypt.gov.eg"

2. Special Requirements for online promotional materials (for prescription-only pharmaceutical products)

All online promotional materials shall fulfil all the general considerations (refer to section IV point 1). In addition to the above-mentioned general considerations, online promotional materials shall include:

A. Trade name(s) and generic name(s) (shall be listed directly next to the trade name).
B. The promoted dosage form(s) and quantitative ingredient(s).
C. The promoted approved indication(s) and dosage regimen.
D. Method of use.
E. "Brief Risk Information" shall include the following:
- **i.** Contra-indications.
- **ii.** In case of Boxed warnings, briefly defined.
- **iii.** In case of Fatal or Life-threatening Risks and interactions, briefly defined.
- **iv.** Full Warnings & Precautions (including those related to the excipients) in details.
- **v.** Pregnancy, lactation & fertility information.
- **vi.** Adverse drug reactions.
- **vii.** Driving & using machines warnings (if affected).

In font size not less than half the traditional size of other claims in a prominent area

In case of **online content with character space limitations** "Brief Risk Information" could be presented by either using uniform resource locator (URL) shortening services or hyperlinking that leads to a landing page as "browser viewed pdf file" . (Refer to section IV point 7)

F. The following statement:
"Always read the full prescribing information". Leaflet approval date

G. A statement for Healthcare professionals shall be included:
"Healthcare professionals should report any suspected adverse reactions to the Egyptian Pharmacovigilance Center (EPVC) & Pharmacovigilance department of the product Applicant of Material". With a hyperlink or contacts of the reporting channel.

3. Special Requirements for online promotional materials (for Non-prescription pharmaceutical products)

All online promotional materials shall fulfil all the general considerations (refer to section IV point 1). In addition to the above-mentioned general considerations, online promotional materials shall include:

A. Trade name(s).
B. The promoted approved indication(s) according to the PIL (at least one indication).
C. Method of use.
D. "Brief Risk Information".

- Information that shall be visible in the material itself (in font size not less than half the traditional size of other claims in a prominent area) If the drug is approved in Egyptian Non-prescription pharmaceutical products list with certain restriction (e.g. age, special population), this restriction should be clearly stated

"لا يجب استخدامه للأطفال أقل من ١٢ سنة إلا بوصفة طبية"

- Information that could be presented by either using uniform resource locator (URL) shortening services or hyperlinking that leads to a landing page as "browser viewed pdf file".
  - **i.** Contra-indications.
  - **ii.** Warnings & Precautions.
  - **iii.** Pregnancy, lactation & fertility information. (if affected)
  - **iv.** Adverse drug reactions (also rare adverse drug reactions but may be serious).
  - **v.** Driving & using machines warnings (if affected).
  - **vi.** Also generic name(s), the promoted dosage form(s) and quantitative ingredient(s).

E. A statement directing the patient or the public:
"Ask your physician or pharmacist about the proper dose, use and precautions of this medication"

"اسأل الطبيب أو الصيدلي عن الجرعة والاستخدام الأمثل للدواء والاحتياطات الواجب اتباعها"

In font size not less than half the traditional size of other claims in a prominent area

F. The following statement:
“Always read leaflet information before using the medication”. Leaflet approval date

"يجب دائما قراءة النشرة الداخلية قبل استخدام الدواء"

In font size not less than half the traditional size of other claims in a prominent area

G. A statement for consumers shall be included:
“Consumers should report any suspected adverse reactions to the Egyptian Pharmacovigilance Center (EPVC) & Pharmacovigilance department of the product Applicant of Material”. With a hyperlink or contacts of the reporting channel

" يتعين على المستهلكين إبلاغ مركز اليقظة الصيدلية المصري وكذلك قسم اليقظة بالشركة حال حدوث أي آثار عكسية من الدواء"

4. Special Requirements for online disease awareness materials

All online awareness materials shall fulfil all general considerations (refer to section IV point 1). In addition to the above-mentioned general considerations, online disease awareness materials directed to the patients/public shall include a statement directing the patient or the public to seek further information about the condition or treatment options from his/her doctor.
“Seek further information about the condition or treatment options from your doctor”

"استشر طبيبك لمزيد من المعلومات عن الحالة وطرق العلاج"

5. Special Requirements for online educational materials

All online educational materials shall fulfil all the general considerations (refer to section IV point 1). In addition to the above-mentioned general considerations, online educational materials shall include:

A. Trade name(s) Trademark(s) whenever applicable and generic name(s)/or generic name (s) only.
B. At least, the relevant dosage form(s) and quantitative ingredient(s).

C. In case of educational materials directed to patients or public: A statement directing the patient or the public to seek further information about the medication from doctor or pharmacist.
“Seek further information about the medication from your doctor or pharmacist”

"اسأل الطبيب أو الصيدلي لمزيد من المعلومات عن الدواء"

D. A statement for consumers or Healthcare professionals shall be included to encourage **reporting any suspected adverse reaction.**

For Healthcare professionals:
“Healthcare professionals should report any suspected adverse reactions to the Egyptian Pharmacovigilance Center (EPVC) & Pharmacovigilance department of the product Applicant of Material”. With a hyperlink or contacts of the reporting channel

"يتعين على مقدمي الرعاية الصحية إبلاغ مركز اليقظة الصيدلية المصري وكذلك قسم اليقظة بالشركة حال حدوث أي آثار عكسية من الدواء"

For consumers:
“Consumers should report any suspected adverse reactions to the Egyptian Pharmacovigilance Center (EPVC) & Pharmacovigilance department of the product Applicant of Material”. With a hyperlink or contacts of the reporting channel

" يتعين على المستهلكين إبلاغ مركز اليقظة الصيدلية المصري حال حدوث أي آثار عكسية من الدواء"

6. Methods of effective representation of online content within different sites and social platforms:

All the required contents and company claims should be fully stated except for:

- **Applicant of Material's contacts (e-mail, office address, telephone numbers, etc.).**
- **References.**
- **Brief risk information (in case of promotional materials).**

These contents could be presented by either using uniform resource locator (URL) shortening services or hyperlinking that transfers to a landing page as "browser viewed pdf file"

For example, the Applicant of Material could add the **e-mail of the company** or the title **"Contact"** in the form of hyperlink or add a URL adjacent to it.
The same applies to other contents as **"References"** and **"Brief Risk information"**.

THE FOLLOWING POINTS SHOULD BE CONSIDERED WHEN USING ANY OF THESE METHODS:

Method	Uniform Resource Locator (URL)	Hyperlinking
Consideration	• When using uniform resource locator (URL) shortening services, the URL or web address itself should denote to the user what the landing page consists of (e.g., www.ABCDX.com/risk). • The URL or web address itself shall **NOT** be promotional in content or style (e.g., a URL such as www.bestcancercuredrug.com will not be accepted) it should be a "browser viewed pdf file" that contains the content.	• The hyperlink should be obvious. • The hyperlink should be labeled appropriately to convey the importance, nature, and relevance of the information it leads to. • The hyperlink styles should be used consistently, so consumers know a hyperlink is available. • The hyperlink should be placed as close as possible to the relevant information it qualifies and should be noticeable. • The hyperlink should transfer directly to the landing page as "browser viewed pdf file".

7. Methods of effective representation for online content with character space limitations

- Applicant of Materials shall carefully consider the mandatory requirements mentioned in the above sections along with the importance to represent a fair balance of benefits vs. warnings/contraindications for each material type to determine whether a character-space-limited material is a viable communication tool for a particular message.
- Whenever the content exceeds the limitations of the online site, a picture may be combined and uploaded; that includes any part of the content mentioned in the above subsections of Requirements For Online Content.
  For example the Applicant of Material may add the online material's approval number, invalidation date, approval QR code and the requested disclaimers within the uploaded picture.

Examples for online promotional materials on sites with 250 character space limitations:

Directed to patients Product X (500 mg Paracetamol tablets) Relieves headache & fever in 20 minutes Gentle on stomach **Brief risk info** (clickable hyperlink) **References & Contact** (clickable hyperlink) **"Ask your physician or pharmacist about the proper dose, use and precautions of this medication"** **"Always read leaflet information before using the medication". Leaflet approval date 1/10/2020** **"Consumers are encouraged to report any suspected adverse reactions to the Egyptian Pharmacovigilance Center (EPVC) & Pharmacovigilance department of company X"** **"This material is approved by EDA. Approval number: 123456. Invalidation date: 01/10/2022. Kindly report any online promotional, educational and awareness material not having this message to The General administration for regulation of marketing & advertising materials at: www.edaegypt.gov.eg"**	Directed to patients Product X (500 mg Paracetamol tablets) Relieves headache & fever in 20 minutes Gentle on stomach **Brief risk info** http://www.productxxxxx.com/Risk **References & Contact** http://www.productxxxxx.com/References&Contact **"Ask your physician or pharmacist about the proper dose, use and precautions of this medication"** **"Always read leaflet information before using the medication". Leaflet approval date 1/10/2020** **"Consumers are encouraged to report any suspected adverse reactions to the Egyptian Pharmacovigilance Center (EPVC) & Pharmacovigilance department of company X"** **"This material is approved by EDA. Approval number: 123456. Invalidation date: 01/10/2022. Kindly report any online promotional, educational and awareness material not having this message to The General administration for regulation of marketing & advertising materials at: www.edaegypt.gov.eg"**

IMAGE

IMAGE

V. RESPONSIBILITIES

1. **General rule:**
   - **a.** When the content is developed by the material Applicant of Material (the company), the company will be responsible for submitting the material to RMA via the applicable submission pathway. The responsibility includes also the controlling of this content and taking action towards correction or removal of misinformation.
     An Applicant of Material is responsible for materials on websites/social media channels and pages/mobile apps owned, controlled or influenced by the company.
   - **b.** Whenever an Applicant of Material is providing or sponsoring online content, by means of a grant proven through legalized documentation, to a Medical/Pharmaceutical Communities site and has no control or influence on other content on that site, the Applicant of Material is not responsible for the **other content** on that site provided that the Applicant of Material

trademarks(s), trade name(s), product(s) and all other means of identification, whether expressed or implied, is/are not included within the **other content.**

2. **Special considerations for awareness materials:**

Responsibility of awareness materials is determined according to creator and venue:

a. **Online disease awareness materials developed by the Applicant of Material (the company) that include drug therapy area (contains scientific names):** the Applicant of Material will be responsible for submitting the material to RMA for prior approval.
b. **Online disease awareness materials developed by the Applicant of Material that do NOT include drug therapy area (and not containing trade names or scientific names):** The material shall only be submitted to RMA by notification at least 3 days prior to dissemination without prejudice to RMA rights of supervision and taking all required procedures for applying corrective measures.
c. **Online disease awareness materials created and presented by sponsored entities (Medical/Pharmaceutical Communities, all of which hereunder referred to as "grantee") which contain the logo/name of the sponsor pharmaceutical company. This is usually considered as grant from the company for disease awareness materials NOT including drug therapy area (and not containing any trade names or scientific names):**

The company shall **NOT** be responsible for submitting the material itself to RMA, provided that the company has no actual or assumed control over such material, but shall do the following:

i. Legally oblige the grantee to add a disclaimer within the material that reads as follows: **"This material is offered as an unrestricted grant by Company (X). This material is not owned or developed by the company and does not promote the use of any of its products. The material is not monitored by the company and the company is not responsible for it".**

"هذه المادة مقدمة كمنحة غير مشروطة بواسطة شركة (س). هذه المادة غير مملوكة ولم يتم تطويرها بواسطة الشركة ولا توجه لاستخدام أي من منتجات الشركة. هذه المادة غير مراقبة بواسطة الشركة والشركة غير مسئولة عن محتواها"

ii. **Notify RMA with the sponsorship grant** to these entities, for each sponsored campaign, **at least 3 days prior** to dissemination, the notification shall include:

- Sponsorship (grant) duration.
- Aims.
- Venue where the material will be published (to facilitate monitoring by RMA).
- The online site address (a link to the page where the material exists).
- Date of publishing.
- Other relevant information (official contacts).
- Cases of immature cancelation.

iii. Payment of the service considerations according to the sponsorship (grant) duration.

Failing to abide by the procedures and norms; aforementioned, shall constitute a breach to this guidelines, Law No. 127 for Year 1955 regarding the pharmacy profession practice, Law establishing the Egyptian Authority for Unified Procurement, Medical Supply and Management of Medical Technology (UPA) and Egyptian Drug Authority (EDA) as promulgated by Law No. 151 for Year 2019, and its executive regulation, and other related laws and executive regulations, and decrees, norms, regulating the same. RMA shall take all appropriate actions against violators.

3. Special considerations for educational materials:

Online educational materials (with scientific name NOT trade name) with ALL the following conditions:

- The material prepared and presented by external speakers (not a representative of the company) e.g. recorded webinar/conference sponsored by the company
- The material is directed to HCPs (not directed to patients or public)
- The material presented on a **platform or website which is specified for HCPs only**.
- The material shall not contain any scientific or trade names of products not registered in EDA.
- The material shall not contain any off-label uses according to EDA approved leaflets.
- The material contains a disclaimer that the scientific content is the responsibility of the external speakers.
- The material is in English.

The material shall only be submitted to RMA by notification **at least 3 days prior** to dissemination without prejudice to RMA rights of supervision and taking all required procedures for applying corrective measures.

4. **Responsibility of correcting and/or removing online misinformation:**
   - **a.** The Applicant of Material shall be responsible to ensure the information presented is accurate as per the RMA regulations.
   - **b.** Misinformation detected on a site that has a pre-approved material by RMA could result in the withdrawal of that approval and taking other corrective actions.
   - **c.** For online materials **produced by the Applicant of Material:**
     The Applicant of Materials shall be responsible for removing or correcting misinformation & reporting to RMA with the action taken within the interval specified within the notice sent by RMA, and in any case not later than **7 calendar days**.
   - **d.** For online disease awareness materials produced by Medical/Pharmaceutical Communities and sponsored by the Applicant of Material:
     The Medical/Pharmaceutical Communities are responsible for removing or correcting misinformation & reporting to RMA with the action taken within the interval specified within the notice sent to the sponsor/grantor company by RMA, and in any case not later than **7 calendar days**.

VI. CONTENT SECURING OR GATING:

1. Classification of online material according to securing/gating requirements:

Targeted Audience	Possible Types of Online Materials	Securing/Gating Measures Required
Healthcare Professionals Only	• Promotional materials of any pharmaceutical products. • Educational Materials (with trade names).	Require effective securing measures
	• Educational Materials (with no trade names nor advertising claims). • Awareness materials directed to HCPs	Require gating measures
Patients Only	• Educational Materials of prescription only pharmaceutical products (with trade names).	Require effective securing measures

	• Promotional materials of non-prescription pharmaceutical products. • Educational materials of non-prescription pharmaceutical products (with trade names). • Awareness materials directed to patients/public.	No required securing/gating measures
Public	• Promotional materials of non-prescription pharmaceutical products. • Educational materials of non-prescription pharmaceutical products (with trade names). • Awareness materials directed to patients/public.	No required securing/gating measures

2. **<u>Method of Effective securing authentication for promotional materials directed to HCPs and educational materials (with trade names) directed to HCPs or patients (not public):</u>**
   - **a.** To ensure effective securing; any established online gate should require user authentication that could be attained by the Applicant of Material through generating one or multiple password(s) to the online content and controlling its distribution to the healthcare professionals or to the patients through their healthcare professionals. Considering the inviolability of private data (email, name, medical condition …. etc.) which is forbidden to be collected according to the constitution and applicable laws.
   - **b.** The Applicant of Material shall submit the online site link and a username and password to RMA before dissemination of their material.

3. **<u>Gating method for awareness and educational materials (with no trade names nor advertising claims) directed to HCPs:</u>**
   - **a.** Site disclaimer should be added stating that the online content is designed only for use by licensed health care professionals and a self-declaration that the user is a healthcare professional
   - **b.** The Applicant of Material shall submit the online site link to RMA after approval of their material.

VII. SUBMITTING ONLINE CONTENT

1. **<u>Submitting New Material for Approval:</u>**

A. Single Material

The Applicant of Materials shall submit a file which includes:

- The online site or social platform name (A separate file should be submitted for each site/social platform).
- URL of the online site or social platform.
- The Applicant of Material first SGC at the time of initial display.
- Screenshots or other visual representations of the actual site.
- In case of secured online content, access means (site link, a user-name and password to RMA if ready, or a written attested pledge to submit not later than the issuing date of the approval).
- In case of Medical/Pharmaceutical communities, home page of each site.
- Disclaimers and community management rules that will be added on the online sites and social platforms.
- The landing page content (if included).
- For dynamic contents: the Applicant of Material may submit a proposed list of responses for UGCs.

N.B. Launching a website/social platform:

- In case of launching a website/social platform **(containing different materials at the first launch)**, the Applicant of Material shall submit all launching materials as separate files.
- Each material will have a separate approval number & can be extended or variated separately.

Services Considerations (Refer to section XII, part A, points 1:12 – part D, points 1:3 – part E, points 1:3)

B. Master file

The Applicant of Material may submit a "master file" for a certain campaign (promotional campaign for a certain product, educational campaign for certain topic or product or awareness campaign for a certain disease or topic) that includes:

- All medical claims that will be used across the campaign timelines provided that they are **not sequential & each claim is specific and complete** so that it can be used separately (after approving the campaign master file)
- The imagery guidance and consideration that matches the main theme.

- For dynamic contents: the Applicant of Material may submit a proposed list of responses for UGCs.

Services Considerations (Refer to section XII, part A, points 13&14 – part D, points 1:3 – part E, points 4:6)

2. Notification Files:

A. Notification file for material taken from an approved master file

The Applicant of Material shall submit a notification file to RMA whenever posting any material from the previously approved campaign master file before or at the time of publication, this notification file shall include:

- The online site or social platform name.
  (A separate **notification** file shall be submitted for each site/social platform)
- URL of the online site or social platform
- The Applicant of Material first SGC at the time of initial display.
- Screenshots or other visual representations of the actual site.
- In case of secured online content, access means (site link, user-name and password to RMA if ready, or a written attested pledge to submit not later than the dissemination date)
- In case of Medical/Pharmaceutical communities, home page of each site.
- Disclaimers and community management rules that will be added on the online sites and social platforms.
- The landing page content (if included).

N.B. For all materials at the time of initial display

When submitting the SGC, RMA recommends that an Applicant of Material takes formatting factors (e.g., appearance, layout, visual impression) into consideration to enable RMA to view the communications as a whole.

B. Notifying RMA for Online disease awareness materials developed by the Applicant of Material **NOT including drug therapy area** (and not containing trade names or scientific names)

The material shall be submitted to RMA by notification **at least 3 days prior to dissemination**.

The notification file shall include:

- The online site address (a link to the page where the material exists)
- The content included
- Date of posting
- For dynamic contents: the Applicant of Material may submit a proposed list of responses for UGCs by notification

C. **<u>Notifying RMA for</u>** Online educational materials prepared and presented by external speakers and directed to HCPs only with the conditions mentioned in section-V point 3

The material shall be submitted to RMA by notification **<u>at least 3 days prior to dissemination</u>**.

The notification file shall include:

- The online site address (a link to the page where the material exists)
- The external speaker name(s), agreement(s) and event title
- The content included
- Date of posting
- Access means (site link, a user-name and password to RMA)
- For dynamic contents: the Applicant of Material may submit a proposed list of responses for UGCs by notification

D. **<u>Notifying RMA for</u> Online disease awareness materials created and presented by grantee (Medical/Pharmaceutical Communities) with the conditions mentioned in section-V point 2-C**

The company shall notify RMA with the sponsorship (grant) to these entities, for each sponsored campaign, **<u>at least 3 days prior to dissemination</u>**.

The notification shall include:

- Sponsorship (grant) duration.
- Aims.
- Venue where the material will be published (to facilitate monitoring by RMA).
- The online site address (a link to the page where the material exists).
- Date of publishing.
- Other relevant information (official contacts).
- Cases of immature cancelation.

<u>Services Considerations (Refer to section XII, part F, points 1:8, part E, point 7)</u>

3. **<u>Variation</u>**

If subsequent changes occurred to a previously approved material, the Applicant of Material shall submit a variation file:

- If variation is due to the update of an official document without affecting the valid approval content, the Applicant of Material shall submit a variation type 1 file.
- If variation results in an online material derived from a previously approved valid online material, the Applicant of Material shall submit a variation type 2 file.
- If variation results in an online material derived from previously approved valid online material having different size and/or type with same content (i.e. to be displayed on different platforms), the Applicant of Material shall submit a variation type 3 file.
- If the subsequent any change is not included in the above-mentioned cases, the Applicant of Material shall submit a new file.

Services Considerations (Refer to section XII, part C, points 1:3 – part D, points 1:3 – part E, points 4:6)

4. **Extension**

The online material approval can be extended for an additional period as the following:

- Six months approval can be extended for an additional 1 year.
- One-year approval can be extended for an additional 1 year.

Services Considerations (Refer to section XII, part B, points 1:6 – part E, point 2)

5. **Notification file for responses to UGCs**

The Applicant of Material shall pay the required monitoring service consideration as determined by EDA Chairman decree (for RMA team to monitor the UGCs and responses) with the initial file submission. Accordingly, a monthly notification file with **only** the newly added responses shall be submitted.

On submitting the notification file for responses to UGCs; the Applicant of Materials shall submit a separate file for each site/platform which includes:

- The approval number/notification code of the original file.
- The site/platform name.
- URL.
- All content related to the discussions and interactions with users (e.g., all UGCs and the responses or actions taken).
- In case of secured online content, access means (site link, a username and password).

VIII. CONTROLLING DYNAMIC ONLINE CONTENT BY THE APPLICANT OF MATERIAL

1. **General Rule:**

When online information for contents of any social media page or website created or managed by Applicant of Material himself or through any of his affiliates, sister companies or other contractors or subcontractors, (including, but not limited to mobile applications, websites, social media channels, blog posts or discussion forums) is coupled with a user's ability to provide interactive content, the Applicant of Material shall respond quickly to individual user's issues to enhance the proper control over these sites in compliance to the RMA guidelines.

2. **Internal Management Policies**

Applicant of Materials shall develop internal management policies that address the following elements:

i. **Terms and Conditions:**

The Applicant of Material shall provide (in a clear and accessible manner) the community management rules, terms and conditions for users. For example, a site may forbid any pharmaceutical product and will remove any UGC that include them.

Main points to be included within the dynamic online sites and social media platforms disclaimers:

- **Introduction:** specific online site or social platform by name and encourage users to be involved and engaged, to ask questions and to comment.
- **Rules of conduct/Prohibited content:** site may forbid any discussion of drug therapy such as mentioning off-label uses, competitors and benefits not listed in the claim
- **Right to remove content:** the publisher has the right to remove any posts that violate the community management rules.
- **Content ownership:** the **content** including users' posts are regulated according to relevant intellectual property laws, and the company is entitled to share such content with the Egyptian Drug Authority for regulatory purposes.

ii. **Controlling the Conversations on sites owned, controlled, or influenced by the Applicant of Material:**

Applicant of Materials shall control the User-generated content (UGC) to ensure that compliance is maintained. To improve the controlling effectiveness, it is recommended that Applicant of Materials use a semantic, automatic filtering mechanism (e.g. trade name key words, side effects) if the social technology supports it. Controlling is a shall for the following:

A. Misinformation:

The Applicant of Materials shall control the UGC to:

- Correct any misinformation by using responses from the initially submitted list or new responses outside the initially submitted list. In case of using responses outside the initially submitted list, the Applicant of Material shall notify RMA with the UGCs and the new responses every month (as stated in section VII).

- Remove any UGC that deems in violation with the community management rules included within the site's disclaimer.

Actions shall be taken within the interval specified within the notice sent by RMA, and in any case **not later than 7 calendar days**.

B. Off-label Discussions:

Discussions of a pharmaceutical products and devices that fall outside of the approved leaflet/label can occur in UGC. As the Applicant of Material is fully responsible for the content of the site (including the content created by the community), failure to address off-label discussions will render the site non-compliant. Off-label discussions shall be removed completely and promptly.

Actions shall be taken within the interval specified within the notice sent by RMA, and in any case **not later than 7 calendar days**.

iii. **Controlling materials neither developed nor sponsored by the Applicant of Material, and put on a website other than contracted ones but the company was mentioned by the Medical/Pharmaceutical Communities without being notified**

If the material have been officially discovered by the company and has been deemed as (necessary to be reported), the company will notify RMA to take the necessary actions as well as any other actions that might be taken directly through the company legal team and IT team, The company shall send an official warning to the violating party to remove the content.

IX. MONITORING BY RMA

1. RMA will investigate the online sites and social platforms; presented by the Applicant of Material to publish including pre-approved online content; to ensure the whole content is in line with issued approval.
2. The RMA will also investigate the validity and truth of disclaimers attached to pre-approved published online content mentioned in section V:
   "This material is approved by EDA. Approval number: 12345. Invalidation date: 01/10/2021. Kindly report any online promotional, educational and awareness material not having this message to The General administration for Regulation of Marketing & Advertising Materials at: www.edaegypt.gov.eg"
3. **For online materials on social media platforms:**

- The Applicant of Materials shall mention/tag the official RMA profile/account on social media platforms (e.g. Facebook, Instagram and Twitter) in each approved/notified published online material to facilitate monitoring of compliance to RMA guidelines.
- The official RMA account shall be added to any private/closed group or within the customized privacy for any online activities covered within these guidelines.

4. **For online materials on secured or gated sites:**
   - The Applicant of Material shall submit the authentication password to RMA.
5. **For online disease awareness materials that do NOT include drug therapy area** (submitted to RMA by notification).
   - In case of violation to the requirements of this type of files, the material shall be removed and submitted to RMA as a new file for review.
6. **For online disease awareness materials created and presented by sponsored entities (Medical/Pharmaceutical Communities)** (Not submitted to RMA).
   - In case of violation to the requirements of this type of files, Attention letter will be sent to the sponsor/grantor company to stop the current and future sponsorship/grant in case of repeating this violation.
   - In case of noncompliance or recurrence, precautionary measures shall be taken/applied against/on all parties in question, according to applicable laws and EDA's chairman decrees.
7. **For online educational materials prepared and presented by external speakers with the conditions mentioned in section-V point 3** (submitted to RMA by notification).
   - The Applicant of Material shall submit the authentication password to RMA.
   - In case of violation to the requirements of this type of files, the material shall be removed and submitted to RMA as a new file for review.
8. RMA will perform random monitoring on all social platforms periodically to investigate any violations. RMA will also investigate complaint about violation.

   On detecting any violation, an attention letter, a warning letter or a red-flagged letter (according to the case) will be directly sent to the Applicant of Material with corrective actions needed to be taken based on the type of the detected violation.
   In case of noncompliance or recurrence, precautionary measures shall be taken/applied against/on all parties in question, according to applicable laws and EDA's chairman decrees

Services Considerations (Refer to section XII, part E, points 1:7)

9. **The types of letters issued by EDA in case of violations and the corrective actions needed:**

Letter	Attention Letter	Warning Letter	Red-Flagged Letter
Issued to	**Applicant of Material**	**Applicant of Material**	**Applicant of Material**
Reasons for Issuing the Letter	• **Case 1:** Detecting any violations/misinformation in approved/notified online materials (for the first time) • **Case 2:** Posting any content from a pre-approved campaign master file without notifying RMA (for the first time) • **Case 3:** Un-notified sponsorship to Medical/Pharmaceutical Communities, disease awareness without drug therapy, educational material prepared and presented by external speakers or newly added UGCs responses. **Note: Repetition of any case after issuing of attention letter will be raised to the next step (warning then red-flagged letter).**	• **Case 1:** Publishing an online content without getting prior RMA approval even if the content complies with regulations (for the first time) • **Case 2:** The content of the claim is outdated and the Applicant of Material did not apply to RMA for update. • **Case 3:** Failure to respond to RMA attention letters after 5 working days. • **Case 4:** Repetition of any case after issuing of attention letter.	• **Case 1:** Repetition of any case after issuing of warning letter. • **Case 2:** Failure to respond to RMA warning letters after 5 working days.

Corrective Action Needed	• **Case 1:** Correct or remove violation and Notify RMA that the corrective actions are taken completely and declaring no further violations will happen. • **Case 2:** Send the notification file to RMA and declaring no further violations will happen. • **Case 3:** Notify RMA of sponsorship and declaring no further violations will happen.	**Cases 1 to 4:** • Instant removal of the online activity upon receiving of the letter • Payment of the service consideration required to continue submitting files to the administration. (refer to section XI) • Notify RMA the corrective actions are done completely and declaring no further violations will happen. • Obligation to submit this violated material as a new file for review.	**Cases 1 & 2:** • Instant removal of the online activity upon receiving of the letter. • Payment of the service consideration required in order to continue submitting files to the administration. (refer to section XI) • Notify RMA the corrective actions are done completely and declaring no further violations will happen. • Obligation to submit the violated material as a new file for review.
Period to do Corrective Actions	Maximum **five** calendar days	Maximum **five** calendar days	Maximum **seven** calendar days
Letter Status	The Letter will be sent officially to the Applicant of Material	The Letter will be sent officially to the Applicant of Material and will be published on EDA website	
Content of Letters	**The Letter will include:** **1.** The name of the Applicant of Material. **2.** The content of the detected claim. **3.** The reason of issuing the letter. **4.** Explanation of the case. **5.** Corrective actions needed.		

X. CONTINUING SUBMISSION SERVICE CONSIDERATION

1. Whenever issuing a Warning Letter or a Red-Flagged Letter to an Applicant of Material upon detecting any violation by The General administration for Regulation of Marketing & Advertising Materials, the following service consideration will be due to continue submitting files to the administration.

2. A service consideration of 20,000 Egyptian pounds is due to be paid by the Applicant of Material with each issued Warning Letter to continue submitting files to the administration.
3. A service consideration of 50,000 Egyptian pounds is due to be paid by the Applicant of Material with each issued Red-Flagged Letter to continue submitting files to the administration.

Services Considerations (Refer to section XII, part G, points 1&2)

XI. TIMELINE OF ONLINE MATERIALS:

Requested Approval	First RMA Reply	Company Reply	Final RMA Action

New Single/Combined File (<5 slides) with UGCs responses (<20 responses)	**3 WDs**	**20 WDs**	**2 WDs**
New Single/Combined File (<5 slides) with UGCs responses (20:50 responses)	**4 WDs**	**20 WDs**	**3 WDs**
New Single/Combined File (<5 slides) with UGCs responses (>50 responses)	**6 WDs**	**20 WDs**	**4 WDs**
New Single/Combined File (5:15 slides) with UGCs responses (<20 responses)	**4 WDs**	**20 WDs**	**3 WDs**
New Single/Combined File (5:15 slides) with UGCs responses (20:50 responses)	**4 WDs**	**20 WDs**	**3 WDs**
New Single/Combined File (5:15 slides) with UGCs responses (>50 responses)	**6 WDs**	**20 WDs**	**4 WDs**
New Single/Combined File (16:50 slides) with UGCs responses (<20 responses)	**6 WDs**	**20 WDs**	**4 WDs**
New Single/Combined File (16:50 slides) with UGCs responses (20:50 responses)	**6 WDs**	**20 WDs**	**4 WDs**
New Single/Combined File (16:50 slides) with UGCs responses (>50 responses)	**6 WDs**	**20 WDs**	**4 WDs**
Master File (<30 claims)	**6 WDs**	**20 WDs**	**2 WDs**
Master File (30:60 claims)	**12 WDs**	**20 WDs**	**4 WDs**
Extension	**5 WDs**	**NA**	**NA**
Variation One	**3 WDs**	**5 WDs**	**5 WDs**
Variation Two	**3 WDs**	**5 WDs**	**5 WDs**
Variation Three	**3 WDs**	**NA**	**NA**

Notes:

- New files exceeding 50 slide or master files exceeding 60 claims shall be submitted as new separate material.
- Approvals may be issued on first RMA reply (the same timeline for file) if there were no needed requests by RMA team.

XII. SERVICES CONSIDERATIONS

No.	Service	Fees

(A) Submission of New Files		
1	Submission of new single file of an online material of (<5) pages/slides for (6) months approval validity.	1000
2	Submission of new single file of an online material of (5:15) pages/slides for (6) months approval validity.	2000
3	Submission of new single file of an online material of (>15:50) pages/slides for (6) months approval validity.	3000
4	Submission of new single file of an online material of (<5) pages/slides for (12) months approval validity.	2000
5	Submission of new single file of an online material of (5:15) pages/slides for (12) months approval validity.	4000
6	Submission of new single file of an online material of (>15:50) pages/slides for (12) months approval validity.	6000
7	Submission of new single file of an online material of (<5) pages/slides for (24) months approval validity.	4000
8	Submission of new single file of an online material of (5:15) pages/slides for (24) months approval validity.	8000
9	Submission of new single file of an online material of (>15:50) pages/slides for (24) months approval validity.	12000
10	Submission of new combined file (file of the same content & design to be published via ≤5 websites/platforms) of (<5) pages/slides for (12) months approval validity.	5000
11	Submission of new combined file (file of the same content & design to be published via ≤5 websites/platforms) of (5:15) pages/slides for (12) months approval validity.	10000
12	Submission of new combined file (file of the same content & design to be published via ≤5 websites/platforms) of (>15:50) pages/slides for (12) months approval validity.	15000
13	Submission of new master file of campaign of (<30) claims for (24) months approval validity.	10000
14	Submission of new master file of campaign of (30:60) claims for (24) months approval validity.	20000
(B) Submission of Extension Files		
1	Submission of single file extension of (<5) pages/slides for (12) months approval validity.	2000
2	Submission of single file extension of (5:15) pages/slides for (12) months approval validity.	4000
3	Submission of single file extension of (>15:50) pages/slides for (12) months approval validity.	6000

4	Submission of combined file extension of (<5) pages/slides for (12) months approval validity.	5000
5	Submission of combined file extension of (5:15) pages/slides for (12) months approval validity.	10000
6	Submission of combined file extension of (>15:50) pages/slides for (12) months approval validity.	15000
	(C) Submission of Variation Files	
1	Submission of variation file (type one, type two or type three) in case that the remaining duration of the previous approval duration is (<6) months.	1000
2	Submission of variation file (type one, type two or type three) in case that the remaining duration of the previous approval duration is (6:12) months.	1500
3	Submission of variation file (type one, type two or type three) in case that the remaining duration of the previous approval duration is (>12) months.	3000
	(D) Included UGCs & Responses	
1	Submission of an included UGCs & responses file of (<20) responses.	500
2	Submission of an included UGCs & responses file of (20:50) responses.	1000
3	Submission of an included UGCs & responses file of (>50) responses.	2000
	(E) Files Follow-up	
1	Follow-up of new file and the included UGCs & responses after publishing (its fees paid only once, on file submission) for (6) months approval validity.	1500
2	Follow-up of new or extension file and the included UGCs & responses after publishing (its fees paid only once, on file submission) for (12) months approval validity.	3000
3	Follow-up of new file and the included UGCs & responses after publishing (its fees paid only once, on file submission) for (24) months approval validity.	6000
4	Follow-up of file and the included UGCs & responses after publishing (for variation type two, variation type three, or already notified content derived from a master file) (Its fees paid only once, on file submission) in case that the remaining duration of the previous approval duration is (<6) months.	1500
5	Follow-up of file and the included UGCs & responses after publishing (for variation type two, variation type three, or already notified content derived from a master file) (Its fees paid only once, on file submission) in case that the remaining duration of the previous approval duration is (6:12) months.	3000
6	Follow-up of file and the included UGCs & responses after publishing (for variation type two, variation type three, or already notified content derived from a master file)	6000

	(Its fees paid only once, on file submission) in case that the remaining duration of the previous approval duration is (>12) months.	
7	**Follow-up of an already notified disease awareness or educational material file and the included UGCs & responses after publishing (its fees paid only once, on file submission) for (12) months.**	**3000**
(F) Notifications		
1	**Notification of publishing a content derived from a master file.**	**500**
2	**Notification of new UGCs & responses (for every 1:20 responses)**	**1000**
3	**Notification of sponsorship or educational grant for disease awareness provided to medical/pharmaceutical communities for (1) month.**	**1000**
4	**Notification of sponsorship or educational grant for disease awareness provided to medical/pharmaceutical communities for (3) months.**	**3000**
5	**Notification of sponsorship or educational grant for disease awareness provided to medical/pharmaceutical communities for (6) months.**	**6000**
6	**Notification of sponsorship or educational grant for disease awareness provided to medical/pharmaceutical communities for (12) months.**	**12000**
7	**Notification of a disease awareness material without any trade or scientific names of pharmaceutical preparations for (12) months.**	**1000**
8	**Notification of educational material presented by an external speaker not affiliate to the company but under its sponsorship and targeted to healthcare professionals via websites/platforms for (12) months.**	**1000**
(G) Continuing Submission		
1	**Submission reactivation after issuing of a warning letter to the company.**	**20000**
2	**Submission reactivation after issuing of red-flagged letter to the company.**	**50000**