

Did you know that EDA (Egyptian Drug Authority) has enforced getting preliminary approvals for Online Promotional, Educational & awareness materials activities?

EDA recently developed a new platform under the name "Promat" and enforced applying for reviewing all materials activities targeting to be published online to all customer's populations (physicians, patients, end users at home) whether it's printed material or electronic using any marketing media: Radio/TV, Internet & social platforms (facebook, LinkedIn, Instagram, ...etc.) through marketing authorization holders/scientific offices.

Classification of online material according to targeted audience:

All activities have to be targeted to a specific audience group based on the message, language and content. Whether the targeted group is Healthcare professionals or Patients or Public for awareness.

Classification of Online Content:

Classification of online content could be either:

Static through Static website of the applicant or static materials without interaction tools or disabled interaction with target audience

Or Dynamic content (interactive) that allows real-time communications, where reactions on the content can be made either by HCP's (Healthcare professionals), patients or public (interaction tolls activated).

For more in-depth information please contact us: info@hadina4trade.com

Responsibilities:

General rules: When content is developed by the material applicant (MAH or SC. Office), he will be responsible for submission to RMA (General Administration for Regulation of Marketing & Advertising Materials) via the submission pathway.

The responsibility includes also controlling of the content and taking action towards correction if needed or removal of wrong information. The applicant is responsible for materials on websites/social media and pages/mobile apps owned, controlled or influenced by the MAH/Sc. Office

For more details about responsibilities, please get in touch with us: info@hadina4trade.com

Submitting Online content:

Submitting material for approval depends on its type and repeating rate!

Weather its a single material submission or master file for a certain campaign for a product or topic, the applicant should take into consideration many aspects like: if for example the content is dynamic, the applicant of material must submit a list of responses for the UGC's (User Generated Content) to be approved by RMA. For in-depth information please get in touch with us at: info@hadina4trade.com

Notification Files:



For all materials at the time of initial display, when submitting the SGC (Site Generated Content), RMA recommends that applicant of material takes formatting factors (e.g., appearance, layout, visual impression) into consideration to enable RMA to view the communications as a whole.

Notification file shall include:

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

For more details on Notifications please get in touch with us at: info@hadina4trade.com

Monitoring by RMA:

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 content is in line with issued approval.

RMA will also investigate validity and truth of disclaimers attached to pre-approved published online content. In case of violation to the requirements, the material should be removed and/or stopped and re-submitted to RMA as a new file for review.

If a material is published online & not submitted to RMA for preliminary review and approval an attention letter will be sent to sponsor to stop the current and future sponsorships in case of repeating this violation. In case of noncompliance or recurrence, precautionary measure shall be taken/applied against all parties in question according to applicable laws and chairman of EDA decrees.

For further details on RMA monitoring and types of letters and corrective actions required, please contact us at: info@hadina4trade.com