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1 OBJECTIVE

The objective of this document is to describe the process of managing promotional and nonpromotional content, developed by Grünenthal Spain and Grünenthal Portugal (Cluster Iberia) for external, as well as internal communication, independent of media type and channel used. The process for the recall of all promotional and non-promotional materials is also described

2 SCOPE

This document applies to all Iberia Cluster employees involved in the design, review, approval and distribution and recall of materials, as well as their submission to the Autonomous Community of Madrid (CAM) or INFARMED (Portuguese Authority for Medicines).

The following activities are included in the scope:

- Developing content
- Reviewing and approving content on cluster level
- Maintaining content

In scope of this this PROC are the following materials:

- Promotional materials
 - concerning medicinal products for human use,
 - concerning non-product related training,
 - concerning medical devices used to administer medication.
- Non-promotional materials of a scientific nature.
- Branded and unbranded press releases
- Online content created and/or disseminated by Grünenthal in the Iberia Cluster, independently of the channel used to disseminate the material (face-to-face, web based, social media (for non-branded materials only, etc.).

Out of the scope of this procedure are materials related to market research studies as described in PROC-003193 GSOP_Develop content for Primary Market Researches and Risk Management Plans and related materials due to the fact that these ones are regulated according to the pharmacovigilance applicable regulations. Also, any official documents prepared and used for the Pricing and Reimbursement process (e.g. Core Value Dossier) are not included In this process due to being officially required documents and for a nonpromotional use.

The employees involved have a duty to be aware of all legislation and regulations applicable to the advertising and promotion of medicines and to comply with these in their day-to-day work

3 RESPONSIBILITIES

This section provides information on the functions involved in the process described

Function/Role	Responsibility
Medical Affairs Asset Lead Brand Manager Product Manager Omnichannel Manager Market Access Specialist Communication and Patient Specialist	<p>When acting as sponsor of the material, prepare the material and ensure compliance with the applicable regulations.</p> <p>If necessary, adapt GHQ materials to local needs and regulations, thus ensuring compliance with the applicable regulations.</p> <p>Ensure that all materials are modified in accordance with the comments and observations received, thus ensuring compliance with the applicable regulations.</p> <p>Prepare the material in the review tool to initiate the review process that applies to each material.</p> <p>Prepare the material for a paper-based review by the parties involved if the review tool is not functioning correctly or if review via the tool is not applicable.</p> <p>Make the changes requested by the different departments in the review process.</p> <p>Activate production once the final version of the material has been accepted and signed, with all approved changes.</p> <p>Prepare the documentation for submission to CAM/ INFARMED.</p> <p>Ensure that the material is destroyed when it becomes obsolete or has been subject to a review/ recall, informing the DS team if it was safety-related and the compliance with the timelines required by category.</p>
Medical Affairs (Manager/MSL/Advisor)	<p>In materials prepared by GHQ, make the appropriate adaptations, thus guaranteeing compliance with the applicable regulations.</p>

	<p>In materials proposed by the Brand Manager, Product Manager Asset Lead, Omnichannel Manager, Market Access Specialist or Communication and Patient Specialist, review the scientific content.</p> <p>Ensure scientific accuracy and robustness of claims and data against relevant product information, available data on file or published references.</p> <p>Validity of references (the most up to date), copyrights and suitability of graphics and pictures against label.</p>
Country Regulatory Affairs Manager	Check against the relevant product information texts ("label") and local rules for promotion and advertising of medicinal products.
Medical Information Manager	Review bibliographic references for final approval.
QP/ Technical Responsible for the corresponding MAH	Review materials with information and messages intended for advertising and promoting medical devices used to administer medication.
Drug Safety LRPPV/ Deputy	Check that material safety messages are properly included in accordance with the product information and PV regulations. Review all non-promotional material to follow the applicable pharmacovigilance processes.
Compliance Officer / Local Compliance Liaison/Legal	<p>Check that the material complies with the applicable regulations for approval, with comments and signature. Sanity check of the following areas:</p> <p>Unfair competition laws, medical advertising laws, product- and civil-liability, correctness of corporate Information.</p> <p>Check against the Global Compliance Framework, with focus on ethical behaviour towards patients,HCPs, payers, authorities and other relevant stakeholders as well as Grünenthal's ethical perception in the current context</p>

	and environment and ensure compliance with applicable regulations.
Asset Lead / Brand Manager Product Manager Omnichannel Manager Market Access Specialist Communication Specialist	Check content alignment with source data, check the accuracy of figures, numbers and diagrams, etc., and check the correctness of any claim.
Head Medical Affairs	Check that the content of the material complies with the applicable regulations, with comments and signature.
Head of Marketing	Check that the messages and content are correct and in line with the strategy (both local materials and adapted GHQ materials) and that they comply with the applicable regulations, with comments and signature.
Head of Market Access & Pricing	Check that the messages and content are correct and in line with the strategy (both local materials and adapted GHQ materials) and that they comply with the applicable regulations, with comments and signature.
Legal and Compliance	Submit the approved materials to CAM / Infarmed and upload proof of submission to the tool.

4 TERMS AND DEFINITIONS

Term	Definition
Company	Grünenthal Cluster Iberia
VeevaPromoMats	Grünenthal's Content Management System (CMS)
Non-promotional content	Non brand -related educational content e.g.; disease-related content, advisory board, press releases on milestones regarding research & development, Independent press reports about symposia and statements by scientists (even if organized by Grünenthal).
Promotional content	Any activity or inducement designed to promote the prescription, supply, sale, or consumption of a specific pharmaceutical product.
Module	A combination of claims, general text and digital assets (images, logos,...) used to convey a message

Content asset	A final piece of material intended for engagement with our stakeholders through our different customer channels A detail-aid, leave behind, approved e-mail, physician support materials, webpages are some examples of content asset
Components	Are the creative design elements like images, tables, etc. that are used to create modules and assets
Omnichannel	The use of all available channels (including face-to-face and digital) to reach our customers with the right information at the right time
Sponsor of the material	Role/function that initiates the material or adapts GHQ materials.
GHQ	Grünenthal Headquarters
CAM	Comunidad Autónoma de Madrid (Autonomous Community of Madrid)
DS	Drug Safety
SOP	Standard Operating Procedure
AEMPS	Agencia Española de medicamentos y productos sanitarios (Spanish Agency of Medicines and Medical Devices)
MAH	Marketing authorisation holder
Iberia ROU-B	Iberia Responsible Opioid Use Board
INFARMED	Instituto Nacional da Farmácia e do Medicamento (Portuguese Competent Authority for Medicinal Products)
SmPC	Summary Product of Characteristics for Promotional Material (reduced and prepared for commercial activities as required by regulation)
Timelines based on Label SmPC changes	Please refer to PROC 004879 – Global label Process. Categories and timelines are defined to implement any change to an SmPC. For all the Safety related changes on SmPC depending on category (i.e. urgent, serious, significant, etc..) the timeline shall be indicated to the sponsor of the promotional material in other to be compliant (immediately, 60d or when there is an update needed but not more than one cycle as for a new cycle the material is reviewed and updated) never shall be more than the timeline indicated by the PROC 004879.
LCL	Local Compliance Liaison
RA	Regulatory Affairs

5 PROCESS

In light of our new customer-driven commercial model we embed the process of

review/approval for our material related to the new content creation process in addition to the standard process of review/approval of promotional and non-promotional materials.

5.1 Electronic review and approval workflow

- a) Promotional materials initiated by GHQ departments.

The procedure set out in PROC-002054 must be followed: Manage promotional and non-promotional content.

- b) Materials initiated by local departments:

This requires approval of all roles involved in the approval procedure.

Applies to all other materials.

Opioid-related materials that are not in line with the key documents corresponding to the global opioid product strategy approved by the company (product plan, brand book, value dossier, etc.), such as promotional campaigns, digital campaigns, medical initiatives, etc., must be referred to the ROU-B for evaluation in accordance with PROC-007055 - Communication on opioids in Portugal and PROC-007115 in Spain. In the case of non-promotional materials, notification to CAM/INFARMED is not necessary.

5.2 Electronic approval procedure

The process consists of the following stages:

5.2.1 Creation of the material:

Creation of the material		
Assigned role	Responsibility	Status
Sponsor	1 - Define the material jointly with the other roles involved in each case before submitting it to the review cycle for approval. <ul style="list-style-type: none">• Development of the content• Upload of the draft material in Veeva PromoMats	NA

The roles involved in each material are responsible for ensuring that the material complies with the applicable regulations.

5.2.2 Uploading the material to the tool:

The tool, VeevaPromoMats, holds the documentation necessary to verify the accuracy of the information on the material (articles, photocopies from journals, referenced books, etc.).

Each time the review workflow moves forward, the tool users involved in each material will receive an automatic email notifying them of the task to be performed.

Within the tool itself, the tasks assigned to each user can be seen in “My tasks” and the notifications in the “Notifications” section.

Uploading the material to the tool		
Assigned role	Responsibility	Status
Sponsor	<ul style="list-style-type: none"> Upload the material to the tool, along with the SmPC, and bibliographic references, as applicable. Name the material so that it is identifiable. Minimum information required: - "Name" "subclassification", "Audience", "Promotional/Non-Promotional", "Internal/External", "Channel", "Version" "language", <ul style="list-style-type: none"> "Country" "Product" Enter the references related to the material in the “Supporting Documents” section, highlighting the text that supports the promotional message. Use “links” and “anchors” to associate posts with the part(s) of the post(s) that support each message. 	Draft

The reduced SmPC, or the QR code that links to the updated reduced SmPC for the product, must form part of the promotional material and not solely be included in the “*Supporting Documents*” section.

5.2.3 Reviewing the material in the tool:

Reviewing the material in the tool		
Material initiated by one of the following departments: Marketing, Commercial Excellence, Communications, Medical Affairs, Market Access, Governmental Affairs, Regulatory Affairs, Legal, Drug Safety, Compliance and Finance		
Role	Responsibility	Status
Sponsor	Start the material review process through the tool by sending the corresponding “Start review” task to Medical Affairs.	In review
Medical Affairs	Indicate the necessary modifications (if any) using annotations (“Annotate”).	Review complete
Material initiated by the Medical Department		

Sponsor	Start the material review process through the tool by sending the corresponding "Start review" task to the Medical Affairs.	In review
Medical Affairs	Indicate the necessary modifications (if any) using annotations ("Annotate").	Review complete

5.2.4 Approval by the roles or departments involved:

Once the review is complete, the process continues as follows:

Parallel approval of the material in the tool		
Assigned role	Responsibility	Status
Sponsor	<ul style="list-style-type: none"> Initiate the "Start approval" circuit by distributing the material in parallel to the other roles and departments involved in the review process according to the matrix below Manually enter the number of days the reviewers have to complete their task, always in working days and with a minimum of 72 hours from the moment the material is sent for review by each role, or in accordance with the matrix below. 	In approval

Roles that review according to the material type:

Materials	Minimum Approvers	Minimum Certifiers	Target Timelines <i>Target timeframe for approvers and certifiers to complete tasks (or according with request of the originator)</i>
Asset plan	<ul style="list-style-type: none"> Medical Compliance Marketing 	<ul style="list-style-type: none"> Country Manager 	Approval: 5 working days Certification: 5 working days
Action plan (PDA)	<ul style="list-style-type: none"> Medical Marketing 	<ul style="list-style-type: none"> Medical Affairs 	Approval: 3 working days Certification: n/a

Leave behind, detail aid,, (approved) e-mail, invitation, agenda, core claims document, banner, booth, , GRT website	<ul style="list-style-type: none"> ▪ RA/Drug Safety ▪ Marketing / Market Access/Communication ▪ Medical ▪ Compliance ▪ Medical Information 	<ul style="list-style-type: none"> ▪ Medical Affairs 	Approval: 3 working days Certification: 3 working days
Medical product training, pain external/disease training external	<ul style="list-style-type: none"> ▪ RA/Drug Safety ▪ Medical ▪ Compliance ▪ Medical Information 	<ul style="list-style-type: none"> ▪ Medical Affairs 	Approval: 3 working days Certification: 3 working days
Medical training, advisory board materials, webinar, invitation, agenda,	<ul style="list-style-type: none"> ▪ RA/Drug Safety (PT) ▪ Medical ▪ Compliance ▪ Market Access 	<ul style="list-style-type: none"> ▪ Medical Affairs 	Approval: 3 working days Certification: 3 working days
Local poster, manuscript	<ul style="list-style-type: none"> ▪ RA/Drug safety ▪ Medical ▪ Global medical ▪ Market Access 	<ul style="list-style-type: none"> ▪ RA (PT)/ Compliance (ES) and Pharmacovigilance (ES) ▪ Medical ▪ Global medical if applicable according to PROC-004064 	Approval: 5 working days (global 15) Certification: 5 working days (global 3)
Speaker slides (ref not anchored)	<ul style="list-style-type: none"> ▪ RA/Drug Safety (PT) ▪ Medical ▪ Compliance 	<ul style="list-style-type: none"> ▪ RA (PT), Compliance (ES) ▪ Medical Affairs 	Approval: 1 working days Certification: 1 working days
Training	<ul style="list-style-type: none"> ▪ Marketing ▪ Medical 	<ul style="list-style-type: none"> ▪ Medical Affairs 	Approval: 3 working days Certification: 3 working days
Press release related to opioids	<ul style="list-style-type: none"> ▪ Medical ▪ Compliance ▪ Communication ▪ ROUB Team ▪ Medical information 	<ul style="list-style-type: none"> ▪ Medical Affairs 	Approval: 2 working days Certification: 2 working days

Social media (eg LinkedIn, twitter etc.)	<ul style="list-style-type: none"> • Medical • Compliance • Communication 	• Medical Affairs	Approval: 3 working days Certification: 3 working days
PT abbreviated (mPC	<ul style="list-style-type: none"> ▪ RA ▪ Drug Safety ▪ Marketing ▪ Medical ▪ Compliance 	<ul style="list-style-type: none"> ▪ RA ▪ Drug Safety ▪ Head of Medical Affairs 	Approval: 3 working days Certification: 3 working days

Press releases not opioid related are approved by email by Medical and compliance, DSMN8 and all the content for RRSS are also approved by email by MKT , Corporate Communication, Omnichannel Medical and Compliance.

All people with functions involved in this procedure should make the comments or observations they deem appropriate and choose one of these possible material classifications:

- a) “approved” if no changes are required;
- b) “approved with changes” if any changes are necessary;
- c) “amend and resubmit” if it is considered necessary to restart the workflow from the beginning (i.e. “draft” status).

The review period must not exceed three working days per function involved, except in justified cases, in which case the period may be extended by a further two working days.

For press releases, the review period must not exceed one working day.

Once the parallel review is complete, each role will sign the corresponding box in the tool electronically.

5.2.5 Adaptation and final certification:

Adaptation and certification of the material in the tool		
Assigned role	Responsibility	Status
Sponsor	<ul style="list-style-type: none"> • Enter comments or observations in a corrected version of the material through the “new version” option in the tool. • Send the corrected material (final version) to the final approver through the “start final certification” option. 	In certification
Medical affairs	Certify the validity of the material, provided that the corrected version of the material complies with the provisions of the applicable regulations.	Approved for production

The sponsor of the material will be automatically notified of the final certification through the tool and by an automatic email.

5.2.6 Submission of materials to CAM:

Promotional materials will be submitted to CAM in accordance with the applicable regulations.

Submission of materials to CAM		
Assigned role	Responsibility	Status
SPAIN		
Sponsor	<ul style="list-style-type: none"> In the “Renditions” tab, upload the signed documents needed to submit the material to CAM, in accordance with the applicable regulations: <ol style="list-style-type: none"> Approved promotional material (“viewable rendition”) Advertising communication for medicinal products for human use form in editable format, completed and signed electronically. Copy of the material in PDF. Copy of the drug authorization granted by AEMPS. Through the tool, send the final version of the material and the above-mentioned documents to the Head of Communication with CAM. 	Approved for production
Compliance/ Legal	<ul style="list-style-type: none"> Send the Scientific Service Report to the Drug Advertising Control Division of the CAM Department of Health by electronic means. Include the following with the report: <ol style="list-style-type: none"> Advertising communication for medicinal products for human use form. Copy of authorized DS or, failing that, of the authorized package leaflet. Copy of the material in PDF. Copy of the drug authorization granted by AEMPS. Attach proof of submission to CAM (“submission proof”) in the “Attachments” tab of the tool. 	Approved for distribution

Due to restrictions on CAM's platform, the documents must comply with the technical specifications in force at the time the material is communicated.

Submission of materials to INFARMED		
Assigned role	Responsibility	Status
PORTUGAL		
Sponsor	Responsible for conducting the follow-up required to ensure all approval steps of the Promotional Material are completed in the Veeva Vault system, and to provide to the Local Compliance Liaison the material to be submitted to INFARMED – always before its distribution – or, where applicable, to inform the departments implicated in the approval that the material will not be distributed.	Approved for distribution
LCL	Submission of the promotional materials in the INFARMED's database in the legal timelines, and the archive of those materials, namely of the approval and certification folder, a copy of the material and the Audit Trail document, generated by the Veeva Vault system, for future possible inspections and audits.	
Sponsor	<p>Is responsible for assuring that two original copy of each authorized promotional material (final version) is made available to LCL for archiving.</p> <p>Is responsible recalling any expired material (though a dedicated email to involved business areas) for applying for the destruction of the promotional material when considered no longer appropriate for promotion. The destruction of the material will be requested directly by the sponsor through the web platform of the promotional logistic company. Procurement will supervise the destruction of the material in due time and will receive an email with the confirmation of destruction.</p>	
LCL	<p>In the case the MAH of product is a third party, but marketed or promoted by GRT-PT, the process follows the same steps with the exception of the notification of the material to INFARMED which is performed by the MAH. The LCL will send an email with all the necessary data to the MAH to perform the submission</p> <p>LCL will archive for a period of 5 years all the authorized promotional materials (final version- two specimens) together with a copy of the review and approval folder and the copies of the forms and scientific reports sent to INFARMED for possible future inspections and audits</p>	

5.2.7 Other considerations

- a) Throughout the process, the sponsor of the material will be responsible for undertaking the necessary follow-up to obtain all signatures in the virtual material review tool, as well as for obtaining the documentation that must be submitted to CAM / INFARMED, all before distribution; or, where appropriate, informing the departments involved in the approval process that the material will not be distributed.
- b) An original copy of each authorized material (final version) must be kept by the sponsor of the material for six years from the time they were last used.
- c) The tool will archive all authorized materials (final version) together with a copy of the forms and Scientific Reports sent to CAM (in the case of promotional materials).
- d) To ensure that the information is up to date, all previously prepared material to be reused or reprinted must undergo the approval procedure again.
- e) Support files generated by any of the roles involved in reviewing a material must include the code and the name of the corresponding material.
- f) The sponsor of the material will be responsible for destroying the promotional material when they consider that it is no longer suitable for promotion according to the this procedure and whenever a label update is approved

Promotional Materials | Changes in SmPC (new version) hardcopy and digital or any update of the content of the material:

To provide to the health care professionals with the most updated promotional material. Grünenthal cluster should use the most up to date promotional materials for medicinal product with SmPC). Adequate steps are taken to ensure that relevant information about changes in the SmPC related to safety issues included in the promotional material is communicated quickly to the appropriate members and all measures are taken in the appropriate time.

- Regulatory Affairs sends to the Marketing, the Drug Safety and Medical team; the new SmPC, SmPC version and limit date to implement the changes in the promo materials and destruction or invalidation of the materials using previous versions of the product information. When the label change in the SmPC is classified as a safety change label change category 1 or Label change category 2 the time to implement is more restrictive and can never exceed the time defined to implement according to PROC 004879 and indicated by immediate and 60d respectively (for promotional material 60 d to implement instead of 90 is feasible but shall never be more than 90 d. Drug Safety shall inform the sponsor of the material, as these categories meant a risk, and all the promotional materials affected shall be destroyed or updated and affect to promotional activities.
- The Marketing team sends an email to Sales team informing the code of which materials will be removed from the circulation and the limit date to run off this materials (maximum of 6 month after the new SmPC for label change category 3-4 when applicable, that means when the sponsor of the material considers that an update is needed but not more than one cycle as every new cycle the

material is reviewed and updated. For Digital promotional material shall be updated when the information is received and the users shall refresh their digital material with the new SmPC version.

- 15 days before the end date, the Marketing Team will resend the email to the Sales team and inform that they need to send the promotional materials to the logistics company to be destroyed.
- Marketing Team informs the Procurement Department of what needs to be destroyed by the logistics company, sending the material code (materials that are on the GRT stock + materials that are on the Sales REPs stock and the materials sent by the Sales REPs).
- Procurement Department sends an email to the Asset Lead / Brand Manager / Product Manager/ Market Access Specialist confirming the material destruction. For label change category 1, 2 Drug Safety must be informed that the process has been completed according to the timelines.
- When the update of the SmPC is under the responsibility of a third company (in license agreement), the DSA and the procedure of the third company will be followed. In case the company does not have any procedure, GRT procedures shall be followed

6 REFERENCES

Royal Decree 1/2015 of 24 July, Article 78.

- Last approved version of the Code of Good Practices for the Promotion of Medicines and Interactions Between the Pharmaceutical Industry and Medical Professionals.
- Regulation applicable to self-regulatory bodies in the pharmaceutical industry.
- The Grünenthal Group Code of Conduct.
- Regulations in force in Spain and those of the Autonomous Community of

Madrid.

- Memo of 21 May 2013 (MUH, 8/2013): Information about medicines subject to additional monitoring. (black inverted triangle).
- Estatuto do Medicamento (Decree-Law nº 20/2013, 14th of February)
- Publicity Code (Decree-Law nº 330/90, 23rd of October)
- Regulation nº 655/2013 from the Commission

7 HISTORICAL INDEX

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Revision no.	Description of changes
01	This PROC replaces PROC-002292 (Spain) and PROC- 003230 (Portugal), to have a common approach for the Iberia Cluster.