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Approval of Promotional Materials				

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1 Objective

The objective of this document is to define the promotional material approval procedures of GRT-PT, to adapt to the applicable regulations and to the company structure.

2 Scope

This document applies to product and no product related promotional materials generated by GRT-PT for local use. It applies to all company employees involved in the request, revision, approval and distribution of promotional materials. These specifically comprise: Marketing, Sales, Medical Affairs, Market Access (if applicable), Regulatory Affairs, Drug Safety, Compliance and Procurement.

3 Responsibilities

All company employees are obliged to know and comply in their daily work with all the legislation and norms applicable to the promotion of medicinal products.

The responsibility for complying with this procedure corresponds to each and every one of the company employees identified in section 2. Specifically, it's the responsibility of Medical Affairs and Marketing to ensure that all promotional material is adapted according to the comments and observations received, thereby guaranteeing compliance with the applicable rules and regulations.

The responsibilities of roles listed in this document are as follows:

Role	Responsibility
Promotional Project Owner (PPO) (namely, but not exclusively, Marketing, Medical Affairs and Market Access)	<ul style="list-style-type: none">- Responsible for completing the promotional project planning and creating the review and approval folder, based on the specific requirements of the promotional project.- Ensure that the promotional material is aligned with the relevant brand strategy and according to the Summary of Product's Characteristics (SmPC).- Ensure the appropriate input in the review and approval of the promotional project from the relevant internal and/or external experts to ensure compliance with the applicable legislation and regulation and final distribution of the promotional material to its users.- Manage any contractors in the creation of the promotional material (if applicable).- Manage the withdrawal/ destruction of the material in the logistics web platform.- To communicate the sales force and HAS the

Role	Responsibility
	withdrawal/ destruction of the material that should no longer be used.
Head of Department of the PPO	<ul style="list-style-type: none"> - Mandatory reviewer and approver. Direct supervisor of the PPO that ensures the promotional material is aligned with the company's business strategy and with the budget available.
Medical Affairs	<ul style="list-style-type: none"> - Mandatory reviewer and approver responsible for checking that the promotional material is according to the SmPC, meets Grünenthal's internal scientific standards and quality expectations and is compliant with the relevant promotional material requirements of the applicable legislation and regulation. - Supervises the registration of the material in INFARMED's database and manages the archiving of these materials.
Regulatory Affairs	<ul style="list-style-type: none"> - Mandatory reviewer and approver responsible for ensuring that the promotional material is aligned with the SmPC and meets the required standards of the applicable regulation. - Provide the updated version of the SmPC and the respective "Abbreviated Product Information".
Drug Safety	<ul style="list-style-type: none"> - Mandatory reviewer responsible for checking the existence of adverse events and proceeded with the respective reporting if applicable.
Compliance	<ul style="list-style-type: none"> - Mandatory reviewer responsible for ensuring that the promotional material is aligned with the applicable national and European legal framework and APIFARMA's and EFPIA's codes of conduct.
Procurement	<ul style="list-style-type: none"> - Manage the contractors used to supply the promotional materials.

4 Definitions and abbreviations

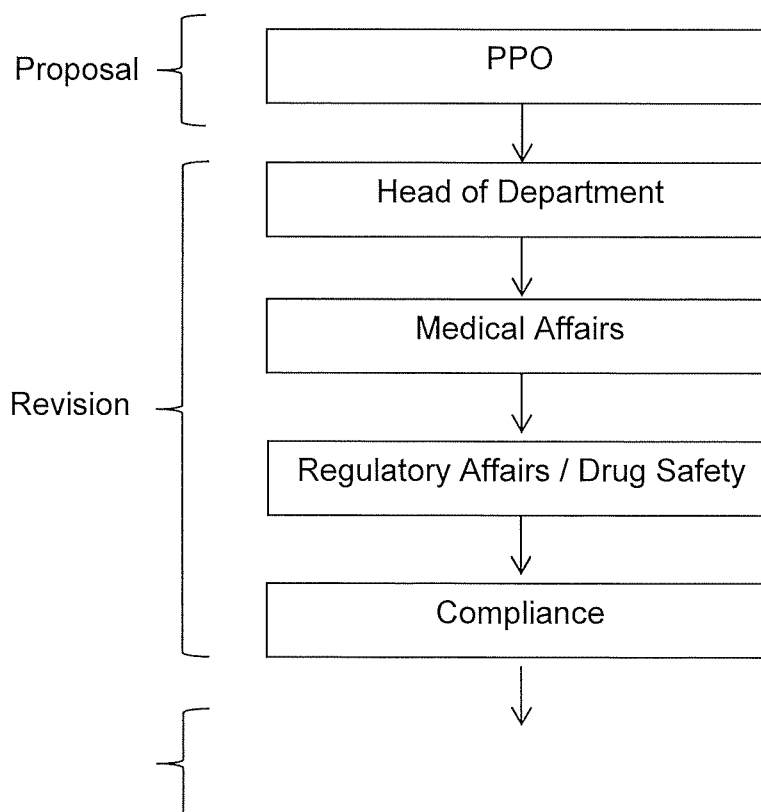
Definitions and abbreviations of terms used in this document are explained here.

Term	Definition/Explanation
GRT-PT	Grünenthal Portugal

Term	Definition/Explanation
INFARMED IP	Portuguese Health Authority
Promotional cycle plan	Comprises a period of 4 months (Jan-Apr; May-Aug; Sep-Dec) with a specific promotional grid with products and respective promotional materials.
Promotional Material	All materials used to promote medical products and medical devices marketed by GRT-PT and also no-product related promotional materials.
Review and Approval Folder	Folder containing the promotional material, the documentation necessary to check the truthfulness of the promotional information (articles, copies of journals, referenced books, etc.), the copyright statements where applicable and the Material Review and Approval Sheet (Attachment1). The texts contained in the approval folder are to be legible in order to facilitate review on the part of all the implicated areas. An electronic archive can be applicable.
SmPC	Summary of Product's Characteristics

5 Process description

5.1 Flowchart



Adaptation (if applicable)

PPO

Final aproval

Medical Affairs

Notification of the promotional materials in the INFARMED's database (or via email) by the Commercial Executive Assistant (CEA)

5.2 General

The process comprises the following phases:

Proposal: The PPO is responsible for ensuring that the material complies with the applicable rules and regulations. In this phase, he/she may ask for counseling of the Medical Affairs, Regulatory Affairs or Compliance, that should attend the possible request as soon as possible.

When the promotional materials are created by a contractor, the content of a briefing pack is defined which describes all the information that contractor will require to create the materials (e.g. branding, source data, study reports, expert reviews, etc.)

For scientific materials dedicated to help promotional activities, namely no product related materials, the responsibility of the proposal is from the Medical Affairs Department.

The PPO prepares the review and approval folder and completes his/her part in the Promotional Material Review and Approval Sheet, including the material code and the planned date for distribution of the corresponding material. The Review and Approval folder should be organized according to the List of minimum information per type of promotional activity for approval and archiving (Attachment 1).

Revision: The Review and Approval Folder will circulate among all those implicated departments, specifically:

- Head of Department
- Medical Affairs
- Regulatory Affairs / Drug Safety
- Compliance

All mandatory reviewers must review and provide comments, if applicable. All the implicated people must sign the Promotional Material Review and Approval Sheet and make the comments or observations deemed opportune (on a separate sheet if there is not enough room in the space reserved to the effect). Usage of references will be double checked by Medical Affairs for medically and scientifically correct citation (the references for this check must be a part of the review and approval folder). Regulatory Affairs will check the validity of the SmPC or the Abbreviated Product Information. Drug Safety will check the content for possible reportable information. Compliance will be responsible to

review the accuracy of the material in terms of general regulations and codes of conduct. The review should take no longer than three working days per implicated operator, except where longer periods are justified, due to the complexity of the promotional material or to vacation reasons, per example.

Adaptation: On the basis of the comments or observations made by the reviewers, the PPO will be in charge of incorporating all the comments or observations received in a final version of the material, and will certify such incorporation by signing the Promotional Material Review and Approvals Sheet. If no comments or observation are made by the reviewers, this step will not be necessary.

Final Approval: Medical Affairs will verify that the PPO correctly adapted the original promotional material according to the comments or observations made by the reviewers. He/she will sign the "Final approval" box on the Promotional Material Review and Approval Sheet.

Registration of Promotional Materials and archiving: Is under the responsibility and supervision of Medical Affairs the registration of the promotional materials in the INFARMED's database in the legal timelines, and the archive of those materials, namely of the review and approval folder and a copy of the material, for future possible inspections and audits.

Back-up Rule: In the absence of the Medical Affairs Manager responsible for the review his/her duties will be taken by one of the MSL of the Medical Department of GRT-PT. In the Absence of the Compliance Officer, his/her duties will be taken by Regulatory Affairs in Portugal.

Other considerations:

- a) Throughout the process, the PPO will be in charge of conducting the follow-up required to ensure all the signatures on the Promotional Material Review and Approval Sheet, and to present to Medical Affairs 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.
- b) Only the Promotional Material Review and Approval Sheet and the artwork or model of the promotional material must circulate in paper. The rest of the documentation of the Promotional Material Review and Approval folder, namely the scientific papers, can be made available electronically.
- c) The PPO is responsible for assuring that an original copy of each authorized promotional material (final version) is made available to Medical Affairs for archiving.

- d) Medical Affairs will archive for a period of 5 years all the authorized promotional materials (final version) 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.
- e) In every promotional cycle plan the promotional materials must be approved even if already approved in the past (e.g. a promotional material approved and used in a specific cycle plan proposed to be used in another cycle plan), to ensure that the contained information is always updated.
- f) In a specific cycle plan any promotional material should not be used without the necessary approval given by this procedure.
- g) The PPO will be responsible for applying for the destruction of the promotional material when considered no longer appropriate for promotion. The PPO will be responsible 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 PPO 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 information.
- h) 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 the notification of the material to INFARMED which is performed by the MAH. The CEA will send an email with all the necessary data to the MAH to perform the submission.

6 Cross references

6.1 References to standard procedural documents


- SOP HQ-MA-304-0003-02 – Medical Affairs Policy
- SOP HQ-MA-304-0007-01 – Procedure for the Initiation, Review and Approval of Promotional Materials

6.2 Legal references (frames)

- Estatuto do Medicamento (Decree-Law n° 20/2013, 14th of February)
- Publicity Code (Decree-Law n° 330/90, 23rd of October)
- Regulation n° 655/2013 from the Comission

6.3 Other references

- Grünenthal's Code of Conduct
- Code of Ethic for the promotion practices of pharmaceutical industry and interactions with healthcare professionals - APIFARMA

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- EFPIA Code on the Promotion of Prescription-only Medicines to, and interaction with healthcare professionals
- Deliberation n° 044/CD/2008 and subsequent guidelines and clarification notes from INFARMED.

7 Attachments

Attachment no.	Title	Number of pages
1	List of minimum information per type of promotional activity, for approval and archiving	1

8 Historical index

Version/ document no.	Description of changes	Valid from
01	<ul style="list-style-type: none"> - Adaptation of the process to the new GRT structure - Clarification on the details regarding the destruction of the promotional materials 	16 JUN 2011
02		15 FEB 2015
03	Inclusion of the revision from the MKT dept	01 SEP 2017



Attachment 1 of PT-MA-531-0002-03
List of minimum information per type of
promotional activity

page
1 of 1

Tipo de Compra	Materiais impressos para promoção a profissionais de saúde (MSRM e MNSRM participados ou não)							Eventos organizados pela GRT (ex: sessões clínicas, cursos, reuniões, etc.)			Eventos não organizados pela GRT (ex: congressos, simpósios, etc.)						
	Reminder	Arq.	Aprov.	Folder	Arq.	Aprov.	Separatas, literaturas de visita e outros (entrega ao médico)	Arq.	Aprov.	Arq.	Aprov.	Arq.	Aprov.				
Documentação																	
RCM reduzido (informações compatíveis com o RCM)			✓			✓											
Classificação do medicamento para efeitos de dispensa			✓			✓											
PVP (apenas para MSRM e MNSRM participados)			✓			✓											
Regime de participação			✓			✓											
Menção: Informação adicional e RCM disponível a pedido								✓									
Menção: "Para mais informações deverá contactar o titular da autorização de introdução no mercado" ou "Para mais informações deverá contactar o titular da autorização do registo"			✓			✓											
Data da última revisão do material			✓			✓		✓									
Referências bibliográficas			✓			✓											
Indicação do patrocínio											✓		✓				
Programa do evento																	
Identificação das entidades que realizam, patrocinam e organizam o evento											✓		✓				
Identificação dos participantes																	
Identificação dos palestrantes e respectivos CVs											✓		✓				
Resumos das comunicações											✓		✓				
Cópia das comunicações científicas												✓					
Custos detalhados do evento												✓	✓				
Declaração de apoio												✓	✓				
Nome do medicamento + DCI (se 1 s.a)	✓							✓			✓						
Identificação do titular de AIM/Registo	✓							✓									
Informações indispensáveis ao uso racional do medicamento (inc. indicações terapêuticas e precauções especiais)										✓							
Aconselhamento ao utente para ler cuidadosamente as informações constantes do acondicionamento 2.º e 3.º e em caso de dúvida ou persistência de sintomas consultar o médico ou farmacêutico																	
Código interno	✓		✓			✓		✓			✓						
Exemplar do material/foto/pdf				✓		✓											
Destinatários (Público-alvo)	✓		✓			✓					✓						
Modo de difusão	✓		✓			✓					✓						
Data de 1.ª difusão	✓		✓			✓					✓						