CSL	Intercontinental Promotional Material Guideline			
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Applicable to: Intercontinental Commercial Operations on a regional and affiliate level, including General Managers, Marketing, Medical Affairs, Market Access, Regulatory Affairs, Regulatory Coordination, Sales.

Refers to: SOP-ComOps-PM-01 "Implementation of up-to-date labeling information in Promotional Material and Medical Information and forwarding of updated labeling information to investigators of IIS and company-sponsored NIS in Commercial Operations"

SOP-ComDev-PM-01 "Standard Operation Procedure: Approval of Promotional Material in ComDev".

WRAW008E "Standardized Regional and Local Labelling Creation and Implementation Process for GRALA-Regional Labelling Experts (GRALA-RLE)"

WRAP004E "Labelling Governance Policy"

SOP WRAS0011E "Company Core Data Sheet Global Roll-Out"

ICO-SOP-MAF-04-tracking_list_template.xls

Revision Interval 3 years

Authored by:

22.10.2018
Gunnar Philipp
Dir Medical Affairs Intercontinental

Approved by:

Signature on file 05.11.2018
Juan Foliu
Exec. Dir Latin America

31.10.2018
Camilla Shen
Exec. Dir Eastern Central Intercontinental

30.10.2018
Thomas Hauck
Sr. Dir Marketing & Medical Affairs

6. NOV. 2018
Markus Stämpfli
VP and GM Intercontinental Com Ops

5.11.18
Niklaus Krähenbühl
Exec Dir Legal Affairs

Frank Schöne de la Nuez
Trademark Counsel

Signature on file 07.11.2018
Neama Baho
Snr Dir, Reg Head Aus/int & GRA site
BMW, Global Regulatory Affairs

Distribution to:

- Sales Sr. Director(s) and (Associate) Director(s)
- General Managers & Country Mangers Intercontinental
- Medical Managers Intercontinental -- country and regional level
- (Sr.) Marketing Managers - country and regional level
- Regulatory Affairs & Regulatory Coordination
- Safety Officer(s) (SO)

Table of Content

REVISION HISTORY				
VERSION	**SECTION**	**SHORT DESCRIPTION OF CHANGE**	**CHANGED BY**	**DATE**
1.0	All	Initial document	N/A	05.08.2015
2.0	Various	Adaption to updated Global SOP ComOps-PM_01	G. Philipp	10.12.2017
2.1	Various	Adaption to new Global SOP ComOps-PM_01 - Deletion references to “core promotional material(s)” - New definition of requirements for distributors compliance with promotional material requirements - Communication of label changes - Withdrawal process for outdated promotional material - Additional Reviewer: Trademark counsel - Maintenance of database: “promotional material tracking list”	G. Philipp	05.02.2018
2.2	Sections 2.3, 4, and 6	Implementation due to CAPA in PV-audit. - clarification of applicability (section 2.3) of local processes in affiliates. - Definition of escalation steps (section 4 & section 6.1) - New document number to meet GDRS standards: ICO-SOP-MAF-04	G. Philipp	18.11.2018

1 Purpose

The purpose of this Guideline is to describe the management of Promotional Material in Intercontinental ComOps. It ensures that the scientific, medical and safety information provided is accurately balanced and appropriately referenced; consistent with the approved product labeling and where applicable with marketing and corporate strategy; aligned with Intellectual Property strategy and compliant with any legal and regulatory requirements as well as presented in the approved format. It describes functions involved in the approval process and accountabilities for a particular aspect of the approval process.

This guideline is a regional implementation of the Global SOPs:

SOP-ComOps-PM-01 "Implementation of up-to-date labeling information in Promotional Material and Medical Information and forwarding of updated labeling information to investigators of IIS and company-sponsored NIS in Commercial Operations"

and

SOP-ComDev-PM-01 "Standard Operation Procedure: Approval of Promotional Material in ComDev".

2 Audience & Scope

2.1 Audience

This Guideline **ICO-SOP-MAF-04** applies to staff in Intercontinental Commercial Operations if involved in the preparation, update, approval, maintenance, distribution or retraction of promotional material, including the following functions: General Managers. Marketing , Medical Affairs, Market Access, Regulatory Affairs / Regulatory Coordination, Safety officers (LSO), Sales.

This guideline also applies to third parties (e.g. external service providers and distributors), if part or all of the above responsibilities have been contracted to them. It is in the responsibility of the manager responsible for the contract with such third parties to ensure that the respective contract covers the roles and responsibilities outlind in this document and that external staff is sufficiently trained.

2.2 In Scope

The scope of the SOP covers promotional materials prepared in Intercontinental ComOps, e.g. for international congresses or for use in countries with no local promotional material process in place.

The term promotional material includes materials directed at HCPs. The term 'promotion' is defined as any activity undertaken by a pharmaceutical company, directly or with its authority, which promotes the prescription, supply, sale or administration of its medicines.

2.3 Out of Scope

The following types of material are out of scope of this document:

- CSL Behring country-specific promotional material prepared by a CSL Behring affiliate with a local CSL Behring Promotional Material SOP in place. If a local promotional material process has been implemented by an affiliate to fulfill local requirements, the local process must be followed in this respective affiliate.
- Publications in scientific journals.

- Documents which are “for internal use” or “confidential” i.e. not to be shared with external audience.
- Documents of personal communication to single individuals like letters, contracts, or emails if these are addressed to single individuals with no promotional purpose.
- Urgent Safety Restrictions and the communication of new or emerging safety information

3 Definitions

3.1 Promotional Material

The term “promotional material” means any material used for the activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

3.2 Local Promotional Material

The definition of “local promotional material” used in this SOP refers to any promotional material to be used by Intercontinental ComOps in a clearly defined local/regional market.

Local promotional material is developed either by the affiliate organization, the Intercontinental ComOps regional function or a contracted third party (e.g. a distributor). In either case, local promotional material must be compliant with the local/regional labeling, licensing dossier and regulations as outlined in this process ICO-SOP-MAF-04.

3.3 Company Core Data Sheet (CCDS)

The CCDS is part of the core labeling texts, which include the Company Core Data Sheet (CCDS), Company Core Package Insert (CCPI) and Company Core Labeling (CCLAB). The core labeling texts are the sole globally valid reference documents per product. The CCDS is prepared by the GRALA-CCDS Owner in agreement with Global Labeling Review Committee (GLRC). Only Core Labeling Texts are rolled out to regional/local markets for submission (ref. WRAS0011E).

3.4 Country Specific Labelling

Country specific Labelling is defined as the labelling and prescribing information version currently approved by the competent regulatory authority of a country. Country specific labelling may be in languages other than English.

3.5 Project Initiator

The Person who identifies the need for preparing a promotional material item and initiates preparation automatically becomes the project initiator and is responsible for activities as outlined in chapter 4 “Responsibilities”.

3.6 Submission package

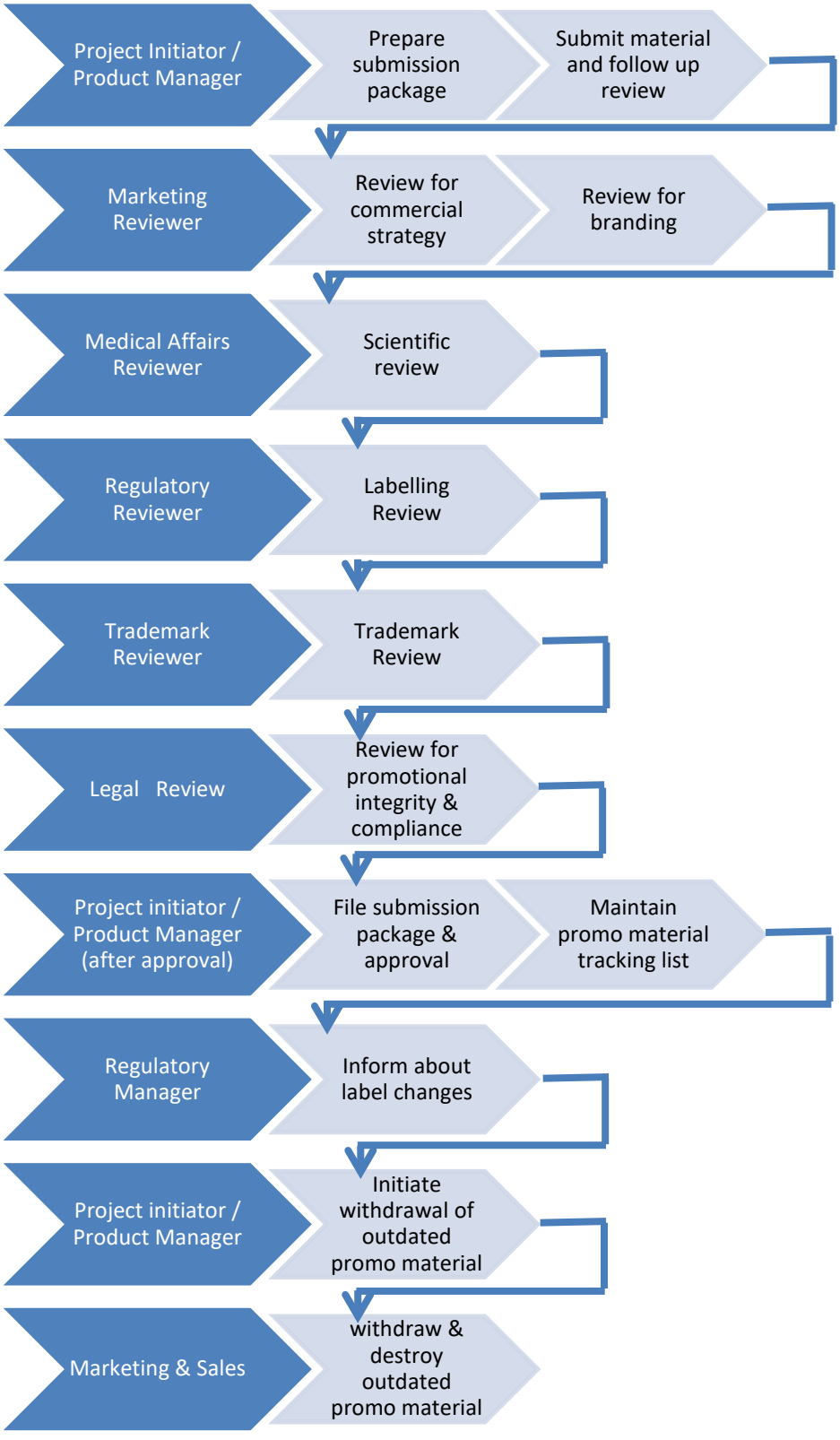
The complete submission package is required for initiating the review process. It includes:

- promotional material item to be reviewed
- supporting references
- applicable SPC
- review forms i.e. completed attachments 1 and 2 of this process document

4 Responsibilities

Person/ function	Responsibilities
Project initiator / Product Manager	• Prepare “submission package” • Verify the submitted promotional material draft complies with Pre-Submission Checklist (attachment 1) • Assign a Tracking Code and an expiry date for Promotional Material items and have it printed on the material. • Submit to marketing, medical, regulatory and legal compliance reviewers and follow up review process. • Revise Promotional Material draft per input from review process and re-submits for review as necessary for approval • Archive the approved promotional material and review documents for 5 years after approval • Maintain promotional material tracking list when promotional material is shared with CSL employees or contracted 3rd parties. The template “ICO-SOP-MAF-04-tracking_list_template.xls” should be used. • Communicate withdrawal of outdated promotional material based in promotional material tracking list • Present promotional material tracking list in audits & inspections • escalation to the responsible General Manager and the LSO, if the 6 months timeline for the implementation of updated promotional material cannot be met.
Marketing Reviewer (or deputy)	• Ensure product positioning and branding in the promotional document are consistent with the product marketing and corporate strategy • Ensure compliance with the brand vocabulary / scientific lexicon.
Medical Affairs Reviewer (or deputy)	• Ensure that the scientific information contained is accurate, balanced and able to be substantiated by evidence and cited references.
Regulatory Reviewer (or deputy)	• Ensure references of the product information are in line with the applicable Labelling (SPC). • Inform Marketing & Medical Affairs about label changes for CSL Behring Products in Intercontinental ComOps region.
Trademark Reviewer (or delegate)	• Reviewing trademark related questions, e.g. infringements, trademark marking issues and ownership attribution statements.
Legal Reviewer (or deputy)	• Review for compliance with legal obligations, Industry codes and other relevant compliance requirements.
Managers of distributor contracts	• Ensure that the respective contracts with 3rd parties / distributors address the roles and responsibilities outlined in this SOP
Marketing & Sales function	• Only use up-to-date promotional material in customer interactions • Withdraw and destroy outdated promotional material items • Inform involved 3rd parties about withdrawal of promo materials.

5 Promotional Material Review Process Map



6 Review Process for Promotional Material

6.1 Country-specific Promotional Material prepared by CSL Behring

The Project Initiator for country specific Promotional Material must ensure that the local adaptation of Core Promotional Material is compliant with the local labeling and local legislations.
The Promotional Material Review Process Map (Chapter 5) illustrates different stages of reviews of country-specific promotional material in Intercontinental ComOps, as well as different functional groups involved in review and withdrawal at each stage.
The Project Initiator or a designated person of the Therapeutic Area ensures:

- the Promotional Material and all references (hardcopies and electronic versions), are included in the “Submission package”. The Submission package may either be an electronically based file or any kind of binder.
- the internal approval cycle is initiated and the submission package is forwarded to the Reviewers nominated by Marketing, Medical Affairs, Trademark, and Legal Department for approval.
- archiving all approval documents and “Submission package” once it is approved.
- uploading of approved core printing data to Digital Media Management (DMM) no later than two (2) weeks after approval and release.
- Maintainance of a promotional material tracking list when promotional material is shared with CSL employees or contracted 3rd parties. The template “ICO-SOP-MAF-04-tracking_list_template.xls” should be used. Documentation of Sharing the promotional material with external customers or clients is not mandatory.
- withdrawal of outdated promotional material, e.g. in case of changes to the applicable SPC.
- escalation to the responsible General Manager and the LSO, if the 6 months timeline for the implementation of updated promotional material cannot be met.

6.2 Country-specific Promotional Material prepared by external Service Providers

If the preparation, update and maintenance of local promotional material for a CSL Behring product has been contracted to an external service provider (e.g. distributor), it is the responsibility of the CSL Behring contracting party in the region or country to ensure that the contract covers all relevant roles and responsibilities and that the specific sections of this SOP have been sufficiently trained.

The contracted external service provider must have an SOP or similar process document in place for management, release and withdrawal of promotional material. This process has to meet the standards of CSL Behring as outlined in ICO-SOP-MAF-04 and referred SOPs. The external service provider is responsible to ensure adequate documentation of process implementation for audits and inspections.

If CSL Behring Promotional Material is provided to a distributor as a template for country specific Promotional Material, the project initiator must be informed. The project iniotiator maintains a promotional material tracking list when promotional material is shared with contracted 3rd parties. The template “ICO-SOP-MAF-04-tracking_list_template.xls” should be used.

7 Implementation of a updated labeling information into country-specific promotional material and withdrawal of outdated promotional material.

Any relevant change in the local labeling must be implemented into the local promotional material as soon as possible, but not later than within six (6) months (may be subject to shorter

timelines in some local jurisdictions) after the date of approval of the local labeling by the Health Authority. A respective local procedural document must be in place to define this process.

Regulatory Affairs / Regulatory Coordination is responsible to communicate country specifc label changes to the responsible Medical Affairs and Marketing function within 2 weeks after approval by the responsible authority.

Whenever updated labeling information for a product is received, all promotional material for the respective product must undergo a thorough evaluation to determine whether the change(s) in the labeling are relevant to trigger a modification of the promotional material. Promotional material with the old labelling becomes outdated and must be withdrawn.

Any labeling change which is considered as safety relevant and/or changes the benefit risk ratio of the CSL Behring product must be evaluated with special care and, if reflected in the promotional material, cannot be omitted or postponed.

For withdrawal of outdated promotional material, e.g. in case of safety relevant label changes, the promotional material tracking list is used. The document can also be used to be inspection ready for audits and inspections. It is the project initiators responsibility to keep the tracking list updated and complete.

If the labeling change affects more than one country in a region, a harmonized regional decision may be sought. The process owner is determined by the region and is responsible to inform concerned General Managers on the decision, as needed.

8 Operating Principles

8.1 Tracking Codes

Each Promotional Material shall be assigned a Tracking Code to be generated by the responsible product manager. The tracking code consists of a product name, and the month and year of approval. Items that are not dedicated to a single product shall have a tracking code consisting of CSLB (for CSL Behring), month and year of approval and an additional letter starting with a, b, etc.
Examples:
A promotional material dedicated to Zemaira and released in November 2012:
The tracking code should be: Zemaira-11-2012.
Two promotional materials for corporate promotion released in January 2013 :
The two tracking codes should be: CSLB-01-2013a and CSLB-01-2013b.

8.2 Review Timelines

Promotional Material reviews should be completed by a reviewer within 10 working days (2 weeks) from the day of submission of the complete package to the reviewers (draft of material including all references).
Reviewers are to ensure a deputy is available in case of absences in order to make sure that review timelines are safely met. The date of submission and the sign-off date are documented in the release form shown in attachment 1.

8.3 Review process

The approval and review comments on the draft promotional item are documented in the respective Release Form shown in attachment 1. Respective reviewers confirm the completion of their review and approval or lack of approval by signature.

If drafts of promotional items are considered not approvable, the reviewer must inform the responsible product manager within the timeline defined in section 8.2, mandatory providing an explanation of the underlying issue.
Reviews should result in a positive and helpful comments and suggestions. Whenever possible, the reviewer should make a suggestion how identified issues can be overcome or circumvented.
Example:
If a promotional claim is identified as being not approvable for legal or scientific reasons, the reviewer should make a suggestion for a sustainable alternative.
If comments/suggestions to change are received during review process, the draft promotional material will be modified accordingly and the reviewers will be provided with final version of the promotional material for approval.
If drafts of promotional items are considered not approvable, the reviewer should inform the responsible product manager as early as possible, but not later than the timeline defined in section 8.2 together with an explanation of the underlying issue and suggestions for correction.