



Novartis Innovative Medicines (IM) Principles and Practices for Professionals (NP4)

NP4

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1. Preamble

Responsible behavior of all associates is vital to support our mission “to discover, develop and successfully market innovative products to prevent and cure diseases, to ease suffering and to enhance the quality of life.” This document serves as a guide to ethical business practices in Novartis Innovative Medicines (IM) and supports our ambition to do business with integrity.

2. Purpose

Novartis IM Principles and Practices for Professionals (NP4) establishes global principles and policies for the professional activities of the Novartis IM division. It is intended to communicate what action(s) or conduct is expected of Novartis IM associates with regard to their professional activities.

3. Scope

NP4 applies to all Novartis IM associates and all professional activities conducted by, or on behalf of, Novartis IM.

4. Definitions

The term “**Novartis IM**” includes Novartis Pharma AG and its subsidiaries and all respective associates who form part of the IM Division and do work on its behalf.

The term “**product/products**” includes all products marketed by Novartis IM.

The term “**promote/promotion/promotional**” means any activity undertaken, organized or sponsored by Novartis IM that is intended to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all methods of communication, including the internet and social media.

The term “**Healthcare Professionals/HCPs**” includes any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, dispense, recommend, purchase, supply or administer a pharmaceutical product.

The term “**patient/patients**” includes any person who may purchase, consume or receive a prescription for a product.

The term “**patient organization**” means typically a not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers.

5. Compliance with Local Laws, Regulations and Industry Codes

NP4 defines global minimal standards for the most common practices. In addition, any practice must comply with all applicable laws, regulations, and industry codes, as well as with local Novartis IM standards, which may impose more stringent requirements.

All companies that are part of Novartis IM will adopt policies and/or procedures consistent with this document in accordance with their local laws, regulations and codes. Any local policies or procedures must be at least as stringent as policies in NP4.

6. Responsibility and Interpretation

6.1. Global/Regional Responsibilities

Worldwide Franchise Heads, Development Franchise Heads, General Managers and Business Unit and Global Function Heads are responsible for ensuring compliance with NP4 at global level. In particular, they are responsible to instruct qualified representatives from Medical, DRA, Marketing, Finance, Compliance and Legal (as appropriate and available) to design processes for the implementation and training of NP4 and to monitor their efficiency. They are also responsible for the implementation and oversight of appropriate processes in their respective areas of responsibility, including, but not limited to, ensuring (1) sufficient review and approval of all promotional content produced, (2) appropriateness of interactions with HCPs and patients, (3) sufficient review and approval of grants, donations and other funding provided at global level and (4) relevant associates are trained on NP4.

Delegation of responsibilities, as well as review, approval and documentation processes must be clearly defined in SOPs. These SOPs must be approved by qualified representatives from the relevant Global/Regional functions.

6.2. CPO/Local Responsibilities

CPO Heads are responsible for ensuring compliance with NP4 at local level. In particular, they are responsible to instruct qualified representatives from Medical, DRA, Marketing, Finance, Compliance and Legal (as appropriate and available) to design processes for the implementation and training of NP4 and to monitor their efficiency. They are also responsible for the implementation and oversight of appropriate processes in their respective areas of responsibility, including, but not limited to, ensuring (1) sufficient review and approval of all promotional content produced, (2) appropriateness of interactions with HCPs and patients, (3) sufficient review and approval of grants provided at local level and (4) relevant associates are trained on NP4.

Delegation of responsibilities, as well as review, approval and documentation processes must be clearly defined in SOPs. These SOPs must be approved by qualified representatives from the relevant CPO/local functions.

General requirements for processes

Mandatory inclusion of DRA and Medical functions in review/approval of promotional material/content:

- Processes for the approval of promotional material are often determined by detailed local requirements. However, as a global minimal standard, the review/approval process of promotional material/content must always include qualified representatives from the DRA and Medical functions.

Self-responsibility for compliance with NP4:

- Any Novartis IM associate who works on promotional material/content is responsible for the same and must ensure that NP4 policies and procedures are respected before submitting documents to the review/approval process.

Relation between global and local review/approval:

- All documents created on global level (e.g., global visual aids, advertisements, press releases, etc.), which could be used by CPOs fully or partly for promotional purposes need to be reviewed/approved on global level prior to their dissemination.
- In addition, the documents have to be reviewed and approved on CPO level in order to cover specific local regulation.

Which documents need NP4 approval?

- All documents/content which have promotion (as defined by NP4, see Section 4. Definitions) as their purpose need to be reviewed/approved for compliance with NP4.
- Internal communication (e.g., instruction on how to prepare and use promotional documents/ content), tactical memos, strategic documents, which primarily outline promotional concepts (e.g., Brand Plans), do not need formal NP4 review/approval. However, every Novartis IM associate working on such documents is responsible for ensuring that the content is in line with the principles and the spirit of NP4.

General advice on processes

Approval processes are often determined by detailed local regulatory requirements. However, processes can generally be divided into two different approaches:

- Approval of activities which require specific expertise (such as the review of promotional material, scientific materials, patient programs and the organization of national/international events), should be delegated to qualified functional representatives. In order to ensure efficiency and consistency in decisions, it is advisable to establish committees (e.g., Global Materials Clearance Committee).
- Frequent day-to-day business activities may not necessarily need individual review/approval by committees. It may be sufficient to establish and communicate clear standards relating to such activities, and monitor for compliance with those standards. Efficiency can also be improved by issuing checklists and templates.

6.3. Interpretation

The Novartis IM Divisional Compliance Committee (“DCC”) is responsible for providing guidance on the interpretation, implementation of and deviations from this document. Routine questions regarding NP4 may be directed to the appropriate Compliance contact, Legal representative or to an associate’s manager.

6.4. Implementation and Training

It is the responsibility of every Novartis IM manager to implement these policies within his or her areas of functional responsibility, to lead by example, and to provide guidance to associates reporting to him or her. Novartis IM Managers must also seek to structure incentives and conduct performance assessments accordingly.

Novartis IM associates must regularly familiarize themselves with NP4 and participate in training sessions that will be periodically held.

7. NP4 Architecture and Maintenance

7.1. Revisions to Policies

NP4 shall be reviewed and updated every three (3) years. The Global Compliance Officer for the IM Division may authorize minor changes to NP4 at other times if there is a significant need or if external changes require it. Major changes to NP4 require stakeholder review by representatives of affected groups. Such changes must be approved by the Divisional Compliance Committee.

The Global Compliance Officer may also authorize minor changes including, but not limited to, technical clarifications, updates to reflect organizational changes or new structures, minor adjustments to more clearly state the intention of the policy that was present at the time the policy was adopted, or to correct typographical errors.

7.2. NP4 Implementing Procedures

Global Pharma NP4 Implementing Procedures (“Implementing Procedures”) provide operational clarity regarding certain business activities that are governed by NP4 policies. They are intended to communicate how a policy is to be implemented or how a task should be accomplished. Implementing Procedures apply to the IM Division globally and are part of the NP4 framework. Each Implementing Procedure will undergo a regular review to ensure it is up-to-date and consistent with applicable laws, regulations and codes.

7.3. Global Operating Procedures and Local Procedures

Global Pharma Operating Procedures (“Operating Procedures”) convey specific action steps and identify who is responsible for performing each step for global functions or processes that are governed by NP4 policies. Operating Procedures generally only apply to global functions within the Pharma Division, but may be used as a reference for local procedures.

Local procedures shall be established, where necessary, to ensure compliance with NP4, its Implementing Procedures, and local laws, regulations and codes.

7.4. Frequently Asked Questions

From time to time, Novartis IM may provide updated guidance on the application of NP4, Implementing Procedures and other policies and guidelines through the issuance of Frequently Asked Questions (“FAQs”) and other guidance documents. These FAQs will be made available to all Novartis IM associates and are intended to provide guidance on how NP4 and/or its Implementing Procedures should be applied in day-to-day business operations. Novartis IM associates are responsible for reading and understanding these FAQs and, if they need further clarification, contacting their manager or responsible Compliance or Legal representative.

8. Raising a Concern

Any person who learns of a potential violation of these policies or applicable laws must report it promptly in accordance with the Novartis Code of Conduct section “How to Report Potential Misconduct.” Anyone who reports a potential violation will be protected from retaliation of any form.

9. Exceptions

The IM Division Compliance Committee may grant exceptions to NP4. No exceptions can be granted from compliance with applicable laws and regulations.

10. Common Principles

10.1. Independence of Healthcare Professionals

Nothing may be offered or provided to a HCP intended to have an inappropriate influence on the HCP’s decision to prescribe, dispense, recommend, purchase, supply or administer products.

10.2. Interactions with Healthcare Professionals

The ultimate purpose of all interactions with HCPs is to enhance patient care and/or the practice of medicine.

10.3. Separation between Promotion and Non-Promotion

Activities and interactions which are motivated by the objective to promote products must be openly considered as promotion, not disguised, and be managed accordingly.

Activities and interactions that are conducted to foster scientific exchange or non-promotional medical education must be structured and managed accordingly.

Activities and interactions with the purpose to receive knowledge-enhancing information and advice or to obtain important scientific input or data, such as advisory boards and postmarketing studies, must not have the promotion of products as their purpose.

Non-promotional activities, such as advisory boards, market research, clinical studies, etc., must have as their genuine objective to obtain needed, scientifically relevant and unbiased information and may not be designed in a way to achieve promotional objectives.

Care should be taken that in some jurisdictions even if a single aspect of an activity can be construed as promotion then the entire activity might be considered promotional.

10.4. Promotional Content

All promotional content produced/disseminated by Novartis IM (in printed/electronic form and communicated orally) must be accurate, scientifically sound, objective, reflect the current state of knowledge and must be consistent with the prescribing information as approved by local regulatory authorities (or the Core Data Sheet in case of global use).

10.5. No Pre-approval and Off-label Promotion

- Novartis IM shall not promote a product until all necessary approvals have been received. Products must only be promoted for use in indications as approved by local regulatory authorities.
- Promotion and advertising of a product prior to marketing authorization is prohibited. However, this provision is not intended to limit the right of the scientific community to be fully informed concerning scientific and medical progress. It is also not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product including appropriate dissemination of investigational findings in scientific communication and at scientific, non-promotional events. Nor should it restrict public disclosure of information to investors/shareholders concerning products in accordance with law or regulation.
- Information on unapproved drugs and indications in the form of off-prints from scientific and medical journal articles, may be given to HCPs only by the medical department/function and only upon unsolicited HCP request. The response, including any off-prints, provided by the medical department, function must be accurate, not misleading and not promotional in nature. It must relate solely to the subject matter of the inquiry.
- Whilst it is legitimate and useful to inform HCPs on scientific/medical progress at events, care must be taken to ensure full transparency with regard to approved indications and unapproved uses. Trademarks, brand logo, brand colors and tag lines must not be associated with any unapproved indications in order to clearly separate promotion from non-promotion.
- The risk of unintended pre-approval/off-label promotion is especially high at international events, due to possible differences in product registrations/approval status. Compassionate use programs, extended access programs and clinical trials do not constitute promotional activities and must comply with all applicable laws, regulations and codes relevant for human research studies. Care should be taken to ensure that communications relating to such programs are not, in effect, advertisements for an unlicensed medicine or use.

10.6. Adverse Events Reporting

All Novartis IM associates are required to inform local Clinical Safety and/or Medical Departments without delay of any adverse event information or new data on products which they receive.

Regulatory requirements relating to content, format and timing of adverse events reporting to health authorities and other professional bodies (e.g., Ethics Committees) may vary between countries and sometimes even within a given country. All adverse experience with any product must be locally reported without delay to local Clinical Safety and/or Medical departments.

Also, different functions at Novartis have different roles in this process. For details relating to specific regulations in each legislation and the roles of Novartis functions in this process, please contact Integrated Medical Safety/Pharmacovigilance Operations.

10.7. Privacy of Patient Data

Novartis IM must safeguard all confidential patient data in its possession against misuse or inappropriate disclosure and avoid any unauthorized access in accordance with applicable laws.

11. Policies for Professional Activities

11.1. Events

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings for healthcare professionals organized or sponsored by Novartis IM should be to provide scientific or educational information and/or inform healthcare professionals about products. Events must comply with the following principles.

11.1.1. Funding

Novartis IM may fund HCPs to attend events and congresses in the HCP's country of practice (or home country) and/or associations to organize events under the following conditions:

- Funding must not interfere with the independence of HCPs.
- Funding is limited to travel, meals, accommodation and registration fees; HCPs must not be compensated for time spent.
- Novartis IM must not pay for any costs associated with persons accompanying HCPs nor facilitate their attendance.

Please see section 11.1.2 for funding of HCPs to attend events and congresses which would require the HCP to cross a border, i.e. international congresses and events.

Service payment to HCPs or Healthcare Organizations HCOs (e.g., for congress sponsorship, institutional fees, display fees) may not be made in cash, or processed via associate Travel and Expenses (T&E) claims. The purpose of such services payments must be documented and accounted for (e.g. via invoice or service agreements).

No private funds may be used by Novartis IM associates to engage in professional activities that are not allowed under NP4.

11.1.2. Funding of HCPs to attend International Congresses and Events

Novartis IM may fund HCPs to attend international congresses and events for the full duration of the event under the following conditions:

1. The HCP is a speaker or chair in a Novartis sponsored session or symposium
2. The HCP is a presenter of data from Novartis sponsored trials (poster, oral presentation)
3. The HCP is attending the international congress to capture insights and present to local HCPs via post live congress meeting under the following conditions:
 - The insights of the congress would be shared in a non-promotional post congress local meeting/event with other HCPs within 6 weeks of the international congress which the HCP attended
 - Post congress local meeting content should not violate any copyright laws, remain independent and scientific without any Novartis influence
 - A signed service agreement with the HCP clearly defining and outlining the scope of service (post congress local meeting) is in place
 - The HCP funded to attend the international congress is qualified to meet the Service Agreement requirements
 - The number of congresses per HCP per year should not exceed 2 per division
 - The number of HCPs engaged per congress, per market, per division should not exceed 6
 - All engagements under section 3 must be tracked, consolidated and reported to the relevant divisional compliance committee bi-annually.

The local medical function is responsible for managing the process to oversee this policy.

All engagements under 11.1.2 (1-3) must be documented in a contract or engagement letter, aligned with the business franchise team's strategic objectives and follow all the general requirements to events and speaker engagements in section 11 especially concerning qualifications and expertise.

When intending to engage HCPs as speakers which are practicing medicine external to an event's host country, approval from suitably qualified Novartis IM associates from the HCP's practicing country must be sought before making any commitments. Applicable local law and regulation from the country where the HCP is licensed to practice concerning travel, accommodation, FMV (see the CPO Compliance Index and local country approval processes) and transfer of value reporting / disclosure obligations must be complied with. In some countries, employers need to be notified of the intended HCP engagement.

Novartis does not fund HCPs to attend International Congresses/Events unless they strictly fulfill the requirements under 1, 2 or 3 above.

Advisory Boards are considered in section 11.5.3 of this document.

Preceptorships are not considered International Congresses or Events for the purpose of section 11.1.2. For further guidance on what is considered an International Congress or Event in scope of this policy ask legal or compliance or see the Step Change portal.

11.1.3. Promotional Information at Events

Promotional information that appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to products that are not registered in the country where the event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- Host country regulations should not prohibit such an arrangement;
- The meeting should be a truly international, scientific event with a significant proportion of the speakers and attendees from countries other than the country where the event takes place;
- Promotional material for a product not registered in the country of the event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;
- Promotional material that refers to the prescribing information (indications, warnings, etc.) authorized in a country or countries other than that in which the event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally.

11.1.4. Appropriate Venue

All events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the event or meeting. Novartis IM must avoid using renowned or extravagant venues.

11.1.5. Hospitality and Entertainment

When Novartis IM organizes a meeting, refreshments and/or meals incidental to the main purpose of the event may be provided. Refreshments and/or meals may only be provided: (1) exclusively to participants of the event; and (2) if they are moderate and reasonable as judged by local standards. As a general rule, the value of hospitality should not exceed what the HCPs would be prepared to pay for personal purposes.

No entertainment or other leisure or social activities should be provided or paid for by Novartis IM. It is not permitted to fund the attendance to a concert, purchase of entertainment tickets or pay for entertainment in any form. However, if there is background music or a local performance at the event where the meal is taking place, which is not paid for by Novartis IM, this is permitted. Any other entertainment, even if secondary to the meal is prohibited.

11.1.6. Speakers

The purpose of engaging HCPs to speak at events is to share relevant scientific/educational information. Accordingly engaged HCPs must be experts in a given field. The engagement

must be based on a written contract containing a clear description of tasks and responsibilities. Fees and expenses must be reasonable and fair market value in relation to the services rendered. The engagement of HCPs as speakers must not interfere with their independence. Additional requirements apply to Speakers and Presenters engaged under section 11.1.2.

Speaker Programs

External HCPs may be engaged as speakers regarding Novartis products for **up to 18 months**. For purpose of this policy, the 18 month window applies to HCPs promoting product information.

The 18 month **start date should be determined on a Country-by-Country basis** and must be the date the product is available for patients in the Country (date of registration, date of first reimbursement, start date of sampling, etc.). Country decisions must be well-grounded and documented.

For newly acquired Novartis products (that were marketed before) the 18 month start date shall be the 3 months after the globally defined deal closing day.

This 18 month limitation *does not apply* to the following activities:

- Activities conducted directly by Novartis associates (e.g., product detailing; disease-state education);
- Engaging HCPs for non-promotional activities, such as providing advice and expertise to Novartis (e.g., advisory boards, market research, internal training); or
- Engaging HCPs for the non-promotional activities carried out by the Medical function.

Upon the release of significant new Novartis product-related data (e.g., new indication, label change, new formulation, other data release) about which there is information that can be used in product promotion, or the approval of a new indication, an additional promotional period can be requested.

To address specialties in local reimbursement systems, an additional promotional period can be requested.

The **Divisional Compliance Committee** will evaluate and review these requests. The committee can approve a new period up to 18 months in consideration of the following factors:

- does the significant new data create a high educational need for information on the product/indication to improve patient health and ensure safety;
- is additional information sharing necessary for the safe and effective use of the product;
- can the demand for education be met by the existing Novartis resources, or are external resources necessary;
- would engaging HCPs, in this context, be perceived as having an inappropriate influence on their decision to prescribe, purchase, supply or administer our products and
- uniqueness of local reimbursement system and related impact on availability to patients.

Such requests can only be **submitted by or via Global Franchises** on the request template **together with the opinion of Global Medical Affairs**. The Divisional Compliance Committee can either define the start date of the new period (e.g. publication of data) or the end of the extended period.

11.1.7. Organizing and Sponsoring of International Congresses and Events

Rules relating to events (funding the organization, venue, hospitality, engagement of speakers, promotional content) may differ significantly from one country to another. Therefore, international events must be reviewed by qualified Novartis IM associates.

In addition to the requirements described under section 11.1.2, Novartis IM may not organize or sponsor an event for healthcare professionals (including sponsoring individuals to attend such an event) that takes place outside of their home country unless it is appropriate and justified to do so from the logistical or security point of view. International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted (usually sponsored by Global functions).

Novartis IM may organize events (e.g. by Global or Regional functions) involving travel outside of a home country if:

- it makes greater logistical or security sense to hold the event in another country and the requirements of section 11.1.2 concerning funding of HCPs to attend International Congresses and Events are complied with; or
- the relevant resource or expertise that is the object or subject matter of the event, is located outside of the home country.

Product registrations might be different in various countries. Therefore, when presenting/disseminating promotional information at events abroad or with foreign HCPs at events in the home country, promotional material must be reviewed by qualified Novartis IM associates to avoid off-label and/or pre-approval promotion. Promotional material for a product not registered in a host country should be accompanied by a suitable statement indicating the countries in which the product is registered, making clear that such product is not available locally.

Any hospitality, promotional items, or medically relevant items must be in compliance with local law/industry code and local Novartis standards. Therefore, when providing hospitality or distributing items to HCPs at events abroad or to foreign HCPs at events in the home country, the specific requirements must be reviewed by qualified Novartis IM associates.

11.1.8. Accompaniment of Invited HCPs

Invitations to events should only be extended to the HCPs. No entertainment or other leisure or social activities should be provided or paid for by Novartis IM for healthcare professionals.

If permissible under local law/industry code and local Novartis standards and upon initiative of the HCP only, Novartis IM may accept spouses to accompany invited HCPs but at no additional cost to Novartis IM. Please note that some countries do not permit spouses to accompany HCPs to events, even at no cost. This restriction may be applicable both for events in that country and for HCPs from that country attending events outside of that country. Therefore, when organizing events abroad or when inviting foreign HCPs to the home country, the specific requirements relating to accompaniment must be reviewed by qualified Novartis IM associates.

11.2. Promotional Content

11.2.1. Consistency with Approvals

Promotional content must be consistent with the prescribing information as approved by local regulatory authorities or otherwise meet the requirements of local regulatory authorities. Processes for the approval of promotional material are often determined by detailed local requirements. However, as a global minimal standard, the review/approval process of promotional material/content must always include qualified representatives from the Drug Regulatory Affairs and Medical functions.

Any Novartis IM associate responsible for promotional material/content should apply all content standards set forth in NP4 to all materials before submitting them into the review/approval process. All documents created on global level (e.g., global visual aids, advertisements, press releases etc.), which could be used by CPOs fully or partly for promotional purposes need to be reviewed/approved on global level prior to their dissemination. In addition, the documents have to be reviewed and approved on CPO level in order to cover specific local regulation.

11.2.2. Accuracy

Promotional content must be clear, balanced, and sufficiently complete to enable the recipient to form his/her own opinion of the therapeutic value of a product. It must be based on an up-to-date evaluation of all relevant evidence. It must not be false or misleading.

11.2.3. Substantiation

Promotional content must be substantiated by reference to prescribing information as approved by local regulatory authorities or by additional scientific evidence meeting the requirements of local regulatory authorities. Such additional evidence should be made available to HCPs upon request.

11.2.4. General Requirements of Promotional Material

The following general requirements might be amended by specific local requirements.

- Any promotional material (in printed/electronic form) must include in legible print size:
 - ✦ trade name and generic name of the product.
 - ✦ name, logo and address of the company marketing the product.
 - ✦ succinct statement (brief profile of the essential product characteristics).
 - ✦ date of production (month/year) together with a unique identifier.
- Abbreviated or “reminder” advertisements, i.e., advertisements containing no more than a simple statement of indications and/or pharmacological class to designate the therapeutic category of the product must include:
 - ✦ trade name and generic name of the product.
 - ✦ name, logo and address of the company marketing the product.

✦ note: “Full prescribing information available from ...”.

- On web pages, appropriate measures must be taken to assure access to information is restricted to targeted audiences.
- It is forbidden to show actual HCPs or patients in any promotional material without their explicit written approval.

11.2.5. General Requirements for DTC Promotion

In most countries direct-to-consumer promotion is not allowed. Where such promotion is allowed, the above mentioned general requirements for promotional material apply. In addition, all product-related information must be truthful, balanced, accurate and in appropriate language for lay persons. The same applies to information targeted at the general public.

11.2.6. Correct Use of Quotations

- Quotations, for example from medical literature, must not change or distort either the meaning intended by the author or the significance of the underlying work or study.
- All claims must represent accurately the content of the substantiating sources. However, if an author’s statement is not in compliance with NP4, the statement cannot be used. Direct quotes must be in context and verbatim and if spoken words are quoted, written permission from the author is required.
- When quoting from publications, the person quoting is responsible for the way in which the quote is being used.
- For extensive quotations, permission from copyright holders must be assured.
- Any information or quotation derived from publications must mention the complete source (at least in a footnote), i.e., name of the author, title of the publication, name of the journal, volume and page number, year of publication.

11.2.7. Correct Use of Data from Clinical Studies

- When research data including data from clinical studies is being used in promotional material it should represent a fair and balanced reflection of the available knowledge regarding risk and benefits of the product in the relevant setting.
- Data from *in-vitro* and animal tests should be clearly marked as such.
- The following information or a reference to where it can be found should be included:
 - ✦ number of patients involved (n values).
 - ✦ dosage regimen.
 - ✦ duration of treatment.
 - ✦ trial design, e.g., double blind, randomized study.
 - ✦ clinical endpoints.
 - ✦ statistical significance.
 - ✦ reference to relevant publications.

11.2.8. Use of Visuals, Graphics and Tables

- Visuals must be accurate and consistent with the text, must not contain misleading graphs, tables or artwork and should be in good taste in relation to the information conveyed.
- Graphs and tables must be accurate and not misleading, and they should give a description of the axes. They must also be adequately referenced. Misleading scales or dimensions must not be used.
- Copyright permission must be obtained and acknowledgement given where appropriate.

11.2.9. Use of Unpublished Data

- The use of unpublished data is permitted if referred to as “data on file”. All such data must be made available to HCPs on request. Therefore it should be on hand before the promotional material is published, and be kept for future reference.
- Publications and manuscripts accepted for publication or in press must be on hand, in complete length, before the promotional material is printed.

11.2.10. General Requirements Relating to Claims

- All claims must be consistent with the Core Data Sheet (in case of global use) or the prescribing information as approved by the local regulatory authorities (in case of national use).
- All claims must be true and substantiated/referenced from sources that can be made available upon request.
- One sided information, or any conclusive statement based on inadequate or truncated evidence is not permitted.
- Superlatives, exaggerations, and hanging comparatives without unequivocal supporting data, which merely claim that a product is better etc., must not be used.
- “Drug of first choice” claims and the like, must be supported by adequate and relevant clinical evidence.
- Unsupported comments about competitors or their products are not allowed.

11.2.11. Additional Requirements Relating to Comparative Claims

In addition to the general requirements relating to claims, the following requirements relating to comparative claims must be respected:

- Comparative claims are allowed when properly supported by data and in accordance with local regulations.
- The use of trade names of competitors’ products is guided by local regulations.
- The comparative use of adverse drug reaction data in promotional material is recommended only as part of a comprehensive and fair comparison of drugs and if otherwise allowed.
- Comparative superiority claims are allowed only if they are based on data from adequate and well-controlled clinical trials, and if they are consistent with the body of other clinical data.

- Claims referring to differences in efficacy between drugs are permissible only if the difference is statistically significant ($p \leq 0.05$) and clinically relevant.

11.2.12. Prohibited Words, Phrases and Activities

The following is prohibited:

- Use of the word “safe” without proper qualification.
- Use of the word “effective” without proper qualification.
- The word “new” unless the product or indication is really new i.e., up to 1 year, or less depending on local requirements, after local launch.
- Use of the words “non toxic”, “no side effects”.
- Unspecified, unreferenced claims about side effects and safety.
- Absolute statements (i.e., the only product ..., no other product ... etc.) unless supported and referenced by scientific data.
- Superlatives unless substantiated by scientifically sound and appropriately interpreted data.
- Use of third party copyright-protected material including logos, if not otherwise permitted.

11.2.13. Updating of Promotional Material

Promotional material must be reviewed on a regular basis to ensure that it is still up to date and in accordance with the current prescribing information as approved by the local regulatory authorities. In certain countries, promotional material must be cleared by the local regulatory authorities. Promotional material with an outdated succinct statement must not be used.

11.2.14. Approval of Media Material

Media material such as press releases, standby statements and Q&As, which contain information relating to products and which are intended for direct or indirect communication with the media need to undergo NP4 approval. Some materials will also need further approval before use (e.g., press releases require approval by Senior Management), and all global media materials must be locally approved before they can be used by CPOs.

11.3. Risk Management Plan (“RMP”) Educational Materials

The Safety Management Team (“SMT”) for each product is responsible for developing the global RMP strategy of identifying risks and risk management options as well as preparing and writing the Core (Global) RMP. Any educational materials required to be provided to patients and/or HCPs by the Global RMP strategy must be created and/or updated by the Global Brand Leaders or Directors (“GBL” and “GBD”). These materials must also be reviewed and updated, if needed, annually or whenever there is a change to the safety data in the RMP risks or commitment activities, a change in the Core Data Sheet (“CDS”) or in

the event of a major safety concern for the product. RMP educational materials shall be reviewed, approved and distributed or made available within the timelines set forth in any action plan communicated by the SMT or Regulatory function.

11.4. Promotional Interactions with HCPs

Promotional interactions must not interfere with the independence of HCPs.

11.4.1. Promotional Aids

Promotional aids are non-monetary items intended to be given to HCPs related to their work. Such items (e.g. pens and notepads, microfiber cloth, etc.), regardless of value and quantity, whether branded or unbranded, may not be provided or offered to HCPs.

Promotional literature, such as detail aids, leave behind pieces, booklets, etc. are not promotional aids.

11.4.2. Items of Medical Utility

Items of Medical Utility are items that are: (1) intended for the direct education of HCPs or patients and (2) do not have value to HCPs outside of the scope of their practice and educational need.

Note that Medical Devices used for evaluation or demonstration purposes, product samples, and items given directly to patients are not Items of Medical Utility, and may be provided in accordance with the appropriate review and approval as required by NP4.

Unless restricted by local law, regulation or industry codes, unbranded (no product or company logo) Items of Medical Utility may be provided to an HCP provided the items:

- do not offset the operating or routine business expenses that an HCP might otherwise incur;
- are offered only on an occasional basis to an HCP, even if each individual item is appropriate; and
- are modest in value, as judged by local standards, but never to exceed a locally or regionally defined cap that cannot exceed the equivalent of 200 USD per item

Items of Medical Utility may include the Novartis or product name, logo or contact information only if:

- required by local law or regulation; or
- the Items of Medical Utility are intended for use by patients to assist them in the administration of their treatment or management of their conditions and including the information is important for the educational need, proper treatment, or condition management.

All Items of Medical Utility must undergo the appropriate review and approval as required by NP4.

11.4.3. Cash, Cash Equivalents, and Personal Gifts Prohibited

Payments or gifts in cash or cash equivalents, such as gift certificates, must not be provided or offered to HCPs or Healthcare Organizations. Gifts for the personal benefit of the healthcare professional (such as sporting or entertainment tickets, electronics items, etc.) must not be provided or offered.

11.4.4. Courtesy Gifts and Cultural Acknowledgment Items

A Cultural Acknowledgement Item is a small, inexpensive item, not related to the practice of medicine, which is given to acknowledge significant national, cultural or religious events. These are sometimes referred to as Courtesy Gifts. Such items may not be given to an HCP under any circumstances.

11.4.5. Samples

In accordance with local laws and regulations, free samples of Novartis products may be supplied to HCPs authorized to prescribe that product in order to enhance patient care. Samples should be marked as such so that they cannot be resold or otherwise misused. Adequate systems of control and accountability must be in place for samples provided to HCPs including how to look after such samples while they are in the possession of sales representatives.

11.5. Non-promotional Interactions with HCPs

Novartis IM's non-promotional interactions with HCPs aim at exchanging scientific/educational information with HCPs as experts in order to enhance patient care and the practice of medicine. Such interactions must not interfere with the independence of HCPs.

11.5.1. Clinical Research and Transparency

Novartis IM is committed to the transparency of clinical trials that it sponsors. It recognizes that there are important public health benefits associated with making clinical trial information more publicly available to HCPs, patients and others. Such disclosure, however, must maintain protection for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

Novartis publishes both positive and negative trial results as set out in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2005 & 2009) and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010) issued by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

11.5.2. Distinct from Promotion

All human subject research must have legitimate scientific purpose. Human subject research, including clinical trials and observational studies, must not be disguised promotion.

11.5.3. Consultants and Advisory Boards

The purpose of engaging HCPs as consultants or members of advisory boards is to receive specific, knowledge-enhancing information and advice. Accordingly engaged HCPs must be experts in a given field. The engagement must be based on a written contract containing clear tasks and responsibilities, compensation and confidentiality stipulations. Fees and expenses must be reasonable and fair market value in relation to the services rendered. Venue of meetings and hospitality provided must comply with the standards described in this document (see Section 11.1).

Interactions with consultants and advisory board members must not have the promotion of products as their purpose. The information derived from such interactions may subsequently be translated into marketing activities/promotional content.

In some countries, employers need to be notified of the intended HCP engagement.

11.5.4. Studies in Humans

Any types of studies/research programs involving humans (pre- and post-authorization, interventional and non-interventional) must be conducted in compliance with Good Clinical Practice and needs to adhere to principles set forth in the Declaration of Helsinki. All such studies must address meaningful medical or scientific topics, e.g. the clinical profile of a product such as safety, efficacy, modes of action or performance related to other treatments. The well-being and personal integrity of participants must always be of highest priority.

Studies in humans must not have the promotion of products as their purpose. Data derived from such studies may subsequently be translated into marketing activities/promotional content.

All clinical studies (pre- and post-approval, interventional and non-interventional) must be conducted with the objective of answering meaningful medical or scientific questions. The informed consent document must appropriately convey all relevant aspects of the study to potential subjects.

For all clinical studies (local or multinational, pre- or post-approval, interventional or non-interventional) processes must be in place locally which ensure full compliance with applicable adverse event reporting requirements. In addition the Novartis Clinical Quality Procedures apply.

The safety and well-being of study participants have the highest priority for any Novartis Clinical Trial including post-approval studies. Voluntary informed consent by the research participant is required as well as the review and approval of the trial documentation after an assessment of the benefits and potential risks by the relevant ethics committees. Regulatory approval should be obtained according to local regulations.

Novartis IM will conduct or support studies only if they are ethically defensible and scientifically valid. They must be conducted in compliance with Good Clinical Practice and

with applicable international and national regulations, laws and guidelines such as the Declaration of Helsinki, ICH guidelines and privacy regulations.

The patient's right to privacy must be respected. Any written or verbal usage of any identifiable patient information such as name, initials, photos or patient testimonials, requires appropriate consent from the patient.

The details of conducting and financing studies must be set out in a written contract. Novartis will only pay remuneration to HCPs which reflects fair market value for study-related activities.

Advertisements in public media in order to improve patient recruitment must not be misused for the promotion of a product.

The conduct of studies must not be conditional on the purchasing or prescribing of products.

All study data must be statistically evaluated. Investigators have in principle the right to publish their data consistent with the pre-agreed study protocol; authors should have access to all relevant data and statistical assessments to support publication. Novartis IM will not, subsequent to adequate confirmation by Novartis IM of the relevance of the findings, prevent or inappropriately delay publication, even in the case of a negative study outcome. The Novartis Policy on Communication and Publication of Clinical Research Results also apply to post-approval studies.

11.5.5. Market Research

Market research must be consistent with EPhMRA or comparable local guidelines.

Market research must not have the promotion of products as its purpose, must not be disguised promotion. Statistics and data derived from market research may subsequently be translated into marketing activities/promotional content. Any payment to individuals participating in market research must be fair market value for the services performed.

If market research involves the collection of patient data, steps should be taken not to cross over into observational or non-observational studies. If market research involves the collection of information and data from patients, the following principles must be adhered to:

- All safety data processing and reporting obligations must be fulfilled;
- Patient or caregiver data must only be collected, used and disclosed in accordance with applicable privacy laws and policies, and all notice and other privacy requirements must be met;
 - ✦ Novartis IM must be transparent, clear and unambiguous with patients or patient caregivers about the collection of the data and how it will be used.
 - ✦ All required consents must be obtained; and
 - ✦ Only the minimum amount of data needed for the disclosed purposes should be collected and retained for only as long as needed to achieve the disclosed purpose.

11.5.6. Investigator Meetings

The purpose of investigator meetings is to initiate, periodically update, or close-out Novartis IM sponsored or supported studies with an audience entirely composed of the investigators who are participating in the studies. Venue of meetings and hospitality provided must comply with the standards described in this document.

11.5.7. Communication with Patients

Communication with patients should aim at supporting better healthcare. As consumers or caregivers have not received the same medical education as HCPs, careful consideration needs to be made about the appropriateness, language and style of communication. Therapeutic decisions must be made by HCPs only.

11.5.8. Unsolicited Queries

Upon unsolicited request, information relating to the administration of products may be given by the Medical function to patients who have been put on therapy by an HCP. Such information must be accurate, balanced and in suitable language for a layperson. Advice on personal medical matters must be refused and the enquirer should be recommended to consult his/her prescribing HCP.

11.5.9. Disease Awareness Programs

Disease Awareness Programs (DAPs) are activities concerned with providing information, promoting awareness or educating about health, diseases, their management and treatment to the public, potential patients or HCPs. The primary purpose of a DAP must be to increase awareness of a disease or diseases and to provide health educational information on that disease. DAPs may make reference to the availability of treatment options (e.g. reference to classes of drugs) but cannot reference INN, specific product names or be of such a nature that an individual would be encouraged to approach a prescriber to request a particular medicinal option.

DAPs must not promote the use of a particular medicinal product or products¹. The emphasis of the communication or activity should be on the condition and its recognition rather than on the treatment options.

To avoid the perception that DAPs are intended to promote a particular product, the following limitations apply:

- ✦ Where Novartis is the only manufacturer of a commercially available medicinal product that is the only drug in its therapeutic class for a particular disease or health condition, DAPs cannot include any references to class of drug or even drug treatment options generally.
- ✦ DAPs cannot be conducted as part of or adjacent to a promotional program. Disease education / communication provided as part of a scientific or promotional program is not considered a DAP for the purpose of this policy.

¹ In countries where direct-to-consumer promotion is allowed, disease awareness and patient compliance programs may refer patients to product specific information.

DAPs must include information that is:

- ✦ **Accurate:** The information in a DAP should be carefully checked for accuracy so that the public or HCPs are not misled.
- ✦ **Up-to-date:** Every effort should be made to ensure that information contained in a DAP is current.
- ✦ **Scientifically sound:** The information in a DAP should be capable of substantiation by reference to the medical literature or other authoritative sources.
- ✦ **Comprehensive:** DAPs should cover the key characteristics of the disease.
- ✦ **Objective and fair:** DAPs should ensure that the impact/implications of the disease are realistically conveyed without being alarmist.
- ✦ **Balanced:** Management options which may also include reference to relevant classes of drugs that are available (where Novartis is not the only manufacturer of a commercially available medicinal product that is the only drug in its therapeutic class), should be presented in a balanced and fair manner that does not unduly emphasize particular options.
- ✦ **Readable/accessible/style:** The language used should be designed to convey key messages clearly, supported by appropriate design and formatting without using brand colors and or any other indirect references or mentioning of Novartis products.
- ✦ **Identifiable/Attributable:** For DAP publications, the source(s) and Novartis involvement of the DAA should be clearly identified on the publication itself.

CPOs should determine which function(s) is the most appropriate to organize, execute and fund disease awareness programs based on local laws and regulations. In addition, DAPs must be locally reviewed and approved in order to ensure compliance with local laws and regulation.

11.5.10. Patient Support Programs

Patient Support Programs (“PSPs”) should be designed with clearly stated objectives and to protect the rights and privacy of the participants. PSPs must not be designed or used to encourage the use of Novartis products in a manner that is inconsistent with the approved product labeling (e.g., no targeting of patient populations outside of the approved product label). If PSPs involve the collection of patient data, steps should be taken not to cross over into clinical outcomes research. All PSPs must comply with applicable laws, regulations and industry codes in the countries where they are conducted (including laws relating to data privacy, drug safety reporting, drug advertising laws, etc.). In the event of conflict between local industry codes, laws and regulations and this Guideline, the stricter rule must be followed.

If a PSP involves the collection of information and data from patients, the following principles must be adhered to:

- All safety data processing and reporting obligations must be fulfilled;

- Patient or caregiver data must only be collected, used and disclosed in accordance with applicable privacy laws and policies and all notice and other privacy requirements must be met;
 - ✦ Novartis IM must be transparent, clear and unambiguous with patients or patient caregivers about the collection of the data and how it will be used.
 - ✦ All required consents must be obtained; and
 - ✦ Only the minimum amount of data needed for the disclosed purposes should be collected and retained for only as long as needed to achieve the disclosed purpose.

11.6. Interactions with Patient Organizations

Novartis IM has many common interests with patient organizations. All interactions with patient organizations must be ethical. The independence of the patient organization must be respected.

11.6.1. Declaration of Involvement

When working with patient organizations, Novartis IM must ensure that its involvement and the nature of that involvement is clear from the outset. No company may require that it be the sole funder of the patient organization or any of its programs. It is acceptable for Novartis IM to be the only company providing funding to a patient organization, as long as it did not make its support conditional on it being the sole funder.

11.6.2. Written Documentation

Novartis may provide financial support or in-kind contributions to patient organizations. There must be written documentation in place setting out the nature and duration of the support, including the purpose of any activity and its funding.

11.6.3. Events

Novartis IM may provide financial support for patient organization meetings provided that the primary purpose of the event is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organization. When Novartis IM holds meetings for patient organizations, it must ensure that the venue and location is appropriate and conducive to information communication. In addition, any meals or refreshments provided must be modest as judged by local standards.

11.7. Novartis IM Interactions with Patients to Obtain Information

Novartis IM's interactions with patients as a source of knowledge aim at the exchange of information on disease and treatment experiences with Novartis IM, other patients, HCPs, caregivers and the public in order to enhance patient care and the practice of medicine. Such interactions must adhere to all relevant data privacy requirements.

11.7.1. Consultants and Patient Advisory Boards

The purpose of engaging patients as consultants and/or members of patient advisory boards is to receive specific, knowledge-enhancing information and advice. Accordingly, engaged patients must have experience with a specific disease and its treatment. The engagement must be based on a written contract containing clear tasks and responsibilities, compensation and confidentiality stipulations. Fees and expenses must be reasonable and fair market value in relation to the services rendered. Venue of meetings and hospitality provided must comply with the standards described in this document (see Section 11.1).

Interactions with Consultants and Patient Advisory Board members must not have the promotion of products as their purpose. The information derived from such interactions may subsequently be translated into marketing activities/promotional content.

11.7.2. Speakers

The purpose of engaging patients to speak at events is to share relevant experiences. The engagement must be based on a written contract containing a clear description of tasks and responsibilities. Fees and expenses must be reasonable and fair market value in relation to the services rendered.

11.8. Grants, Donations, Sponsoring and Other Funding

11.8.1. Grants

Grants can only be given to reputable healthcare or healthcare-related organizations, and not to individuals.

Grants must be provided without agreement or intent to receive a tangible return in exchange and they must not have the promotion of products as their purpose. Grants must not interfere with the independence of grants recipients and their associates. All grants must be properly documented.

Grants are not promotional activities and no return on investment analysis may be conducted.

11.8.2. General Requirements for Grants

- Grants must be provided without agreement or intent to receive a tangible return in exchange and they must not have the promotion of products as their purpose. In order to avoid any connection with promotion, Novartis IM associates with a sales/marketing function should not lead the review/approval process for grants and they should not deliver grants.
- In some countries, associates with a sales/marketing function must not be involved in the grants process at all. Therefore, when planning to make a grant to a foreign healthcare institution, the grant must be reviewed by qualified Novartis IM associates of the home country of the receiving institution.
- Funding must be given only to reputable healthcare or healthcare-related institutions. Reputation should be well assessed by considering prior experience with the funding

recipient or publicly available information such as organizational documents (e.g., bylaws, annual reports, etc.), the organization's website, or recent media coverage.

11.8.3. Types of Grants

Novartis IM may provide grants in the following categories: infrastructure grants, educational grants, patient association grants, professional society grants and healthcare policy research grants.

Infrastructure grants are contributions to healthcare-related institutions that are in need of improving their medical infrastructure. Such support needs to address an identified unmet need or absence in a community's healthcare services or systems. Infrastructure grants must enhance patient care and should not underwrite a commercial business or be intended to generate income for the recipient. The value of the grant needs to be reasonable in light of the identified need.

Educational grants are contributions to healthcare or healthcare-related institutions or organizations to support independent educational activities (accredited or non-accredited) where the grant recipient is responsible for developing the content and for managing the educational event. Novartis IM may not control the content of the program or the faculty, and the grant recipient controls the selection and invitation of any healthcare professionals.

A patient association grant is a contribution to a patient organization that focuses on services to patients, caregivers, and the health and well-being of the general public. Supported activities are limited to disease state and treatment education and awareness; psycho-social support during and after diagnosis or treatment; or advocacy/research regarding healthcare public policy, health economics or outcomes research. Novartis IM may not fund initiatives that solely focus on awareness of Novartis clinical trials and may not provide funding that results in Novartis associates being placed on the organization's board of directors. Any Novartis IM associate sitting on the board of directors of a patient association may not be involved in the submission or approval of a grant to that association.

A professional society grant is a contribution to a professional healthcare or healthcare-related organization or association whose members consist primarily of healthcare professionals. Supported activities are limited to disease state and treatment education and awareness; psycho-social support during and after diagnosis or treatment; or advocacy/research regarding healthcare public policy, health economics or outcomes research. Novartis IM may not fund initiatives that solely focus on awareness of Novartis clinical trials. Novartis IM may not control the activity, invitees and selection of any fellowships.

A health policy research grant is financial support for healthcare or healthcare-related organizations that educate policy makers, conduct health policy research, or perform legislative and/or regulatory advocacy. Novartis shall not gain access to intellectual property rights and shall not have exclusive access to the research data.

There is a large category of daily business activities that are managed under other funding arrangements. In other funding arrangements, Novartis receives a tangible benefit in exchange for funding provided to healthcare-related institutions, and the arrangement is defined in appropriate supporting documentation. A mere display of the Novartis logo or name is not enough to constitute a tangible benefit. The tangible benefit must not constitute any form of inappropriate inducement. Other funding arrangements can be for a commercial or non-commercial purpose, and must always follow Novartis' customer contracting processes, Management Authorization Levels, and local processes.

11.8.4. Donations

Donations to healthcare or healthcare-related institutions are governed by NP4. Donations to non-healthcare institutions are governed by the “Novartis Sponsoring & Donations Review and Approval Operational Procedure to non-healthcare institutions”.

Novartis IM may make donations to reputable healthcare or healthcare-related institutions for an altruistic, non-business related purpose, and where Novartis does not receive or will not be perceived to receive a direct or indirect consideration or service in return. The overall purpose of a donation is to support activities/projects with an affinity to our mission in the fields of healthcare and medicine or to support various initiatives, projects or non-profit organizations in communities where Novartis IM has a presence, in line with our commitment to Corporate Citizenship.

11.8.5. Differentiation between Grants and Donations

Grants must serve a specific purpose as defined by NP4, e.g., to support the education of HCPs (educational grants) or to support healthcare institutions in improving infrastructure (infrastructure grants). Donations must have an altruistic, non-business purpose.

11.8.6. Sponsoring

Sponsoring is an agreement with a non-healthcare institution or company with the purpose of enhancing the general image or reputation of Novartis IM. Measures related to products of Novartis IM, in particular marketing and sales activities are not sponsoring but are service agreements.

The purpose of sponsoring is not product promotion and it should be a very infrequent activity. Sponsoring must comply with the additional requirements as described under Evaluation Criteria in the “Novartis Sponsoring & Donations Review and Approval Operational Procedure to non-Healthcare institutions”.

11.8.7. Differentiation between Grants and Sponsoring

Sponsoring is defined by conveying a benefit to a non-healthcare institution for general purposes that are not product-related. The basis for sponsoring is a contract, under which Novartis IM may receive some tangible return for the financial support; the typical example for sponsoring is financial support of a sports team. Sponsoring has to undergo a specific approval process as defined by MALs.

11.9. Public Officials/Institutions

11.9.1. Additional standards for interactions with HCPs who are Public Officials

HCPs working at public hospitals or government institutions may be defined as ‘public officials’ by anti-corruption laws. In order to ensure strict compliance with national and international anti-corruption laws, such as the US Foreign Corrupt Practices Act (FCPA) and the OECD Anti- Bribery Convention, interactions with public officials must comply with the

following additional requirements (please note that an increasing number of countries have changed/are changing their laws to extend the applicability of these anti-corruption requirements to interactions with private persons):

- All benefits conveyed to public officials must be fully transparent, properly documented and accounted for; and
- If required by local law, Novartis IM shall demand written assurance from the relevant public hospitals/government institutions, that benefits conveyed (e.g. funding attendance to events or engaging public officials as experts/speakers) do not violate applicable local law and regulations. If obtaining that written assurance is unduly complicated, the invited Public Official shall confirm in writing that the collaboration is in line with his or her professional duties.
- Appropriate documentation may include an invitation and agenda.

Approval History

Version	Approval Date	Approval Committee
of October 29, 2012 including changes as requested by DCC	November 21, 2012	Divisional Compliance Committee (DCC)
of November 21, 2012 (with exception of changes requested by PEC)	December 14, 2012	Pharma Executive Committee (PEC)
of December 17, 2012 including changes as requested by PEC	January 18, 2013	Sub-group of PEC as requested on December 14, 2012
of January 18, 2013	February 1, 2013	Pharma Leadership Team (PLT)
of June 1, 2013 (“Due diligence” wording replaced with the “reputation assessment”, section 11.8.2)	October 2014	Pharma Executive Committee (PEC)
of October 1, 2015 (ban of promotional and courtesy gifts, details on items of medical utility, section 11.4.)	June 2015	Pharma Executive Committee (PEC)
of September 2015 (addition of 18 month speaker program limitation – section 11.1.5; minor grammatical corrects; revision of section 7.1; addition of Service payment paragraph to section 11.1.1; addition of Healthcare Organization to section 11.4.3)	September 17, 2015	Divisional Compliance Committee (DCC)
of February 18, 2016 (18 month speaker programs limitation on Disease State Education Programs was removed)	February 18, 2016	Divisional Compliance Committee (DCC)
of August 16, 2016 (update of Disease Awareness Programs – section 11.5.9; minor correction to Studies in Humans – section 11.5.4, first sentence)	August 16, 2016	Divisional Compliance Committee (DCC)
of January 1, 2017 (new section 11.1.2 Funding of HCPs to attend International Congresses and Events; minor updates in sections 11.1.1, 11.1.7; reference to new section 11.1.2 in sections 11.1.1 and 11.1.6; replacement of Pharma with Innovative Medicines)	December 30, 2016	Divisional Compliance Committee (DCC)