

NP4
update'08



NOVARTIS PHARMA

Principles & Practices
for Professionals (NP4)



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1 PREAMBLE

Responsible behaviour 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 Pharma and supports our ambition to do business with integrity.

2 TERMS

The term “**Novartis Pharma**” includes Novartis Pharma AG, its affiliates and subsidiaries and all respective associates which form part of the Pharma Division.

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

The term “**promote/promotion/promotional**” includes any activity/content whose purpose is to encourage the prescription, dispensing, supply, purchase, administration, recommendation or consumption of products.

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 product.

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

The term “**grant/grants**” means a substantial and tangible benefit conveyed to a third party, without agreement or intent to receive a tangible return in exchange.

3 SCOPE*

This document applies to all Novartis Pharma associates in all of their professional activities.

4 COMPLIANCE WITH LAWS AND INDUSTRY CODES*

Novartis Pharma must at all times comply with the principles contained in this document. The document defines global minimal standards for the most common practices. In addition, any practice must comply with all applicable international and national law and industry codes, as well as with local Novartis Pharma standards, which may impose more stringent requirements.

All companies that are part of Novartis Pharma will adopt Principles and Practices consistent with this document in accordance with their statutory governance processes and local law. The respective guidance and SOPs that are part of those Principles and Practices will be at least as stringent as the Principles and Practices contained in this document.

* Chapters/sections marked with an asterisk are explained in the ‘*Guidelines for the interpretation and implementation of NP4*’

5 COMMON PRINCIPLES

5.1 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.

5.2 Interactions with Healthcare Professionals

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

5.3 Separation between promotion and non-promotion*

Activities/interactions which are motivated by the objective to promote products must be openly considered as promotion and be managed accordingly.

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

5.4 Promotional content

All promotional content produced/disseminated by Novartis Pharma (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).

5.5 No pre-approval and off-label promotion*

Novartis Pharma 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.

5.6 Adverse events reporting*

All Novartis Pharma 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.

5.7 Privacy of patient data

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

6 STANDARDS FOR MOST COMMON PRACTICES

6.1 Events*

The purpose of Events is to inform HCPs about products and/or to provide scientific/educational information. They must comply with the following requirements:

Funding

Novartis Pharma may fund HCPs to attend events 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 Pharma must not pay for any costs associated with persons accompanying HCPs.

Venue

Events should be held in appropriate venues only, which are suitable to achieve the purpose of the meeting. Novartis may not organize or fund events at extravagant places.

Hospitality/Entertainment

Hospitality is limited to refreshments and/or meals, which must be modest and secondary to the event's purpose.

Entertainment of modest nature in connection with and secondary to meals/refreshments is permitted. Stand-alone entertainment is not allowed.

As a general rule, the value of hospitality/entertainment should not exceed what HCPs would be prepared to pay for personal purposes.

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.

International Events

Rules relating to events (funding the organisation and/or attendance of/to events, venue, hospitality, engagement of speakers, promotional content) may differ significantly from one country to another. Therefore international events must be reviewed by qualified Novartis Pharma Associates (see Guidelines for further details).

6.2 Promotional Content*

6.2.1 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.

6.2.2 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.

6.2.3 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.

6.3 Promotional interactions with HCPs

Promotional interactions must not interfere with the independence of HCPs.

6.3.1 Gifts*

Promotional Gifts

The purpose of promotional gifts is to raise awareness of Novartis Pharma and its products. Promotional gifts must not be given with the intention of interfering with the independence of HCPs or to provide a personal benefit to HCPs. Therefore, they must be relevant to the practice of medicine and useful in HCPs' day to day practice.

They should not be given frequently and should be inexpensive compared to local average HCPs salaries. If appropriate, promotional gifts should be branded with the Novartis and/or a product name.

Courtesy Gifts

The purpose of courtesy gifts is to abide by local cultural customs. These gifts are permitted only on culturally recognized occasions, such as significant national, cultural or religious holidays. While these gifts do not necessarily need to be relevant to the practice of medicine, they have to be socially acceptable, i.e. in good taste and accepted under local culture. They must be inexpensive compared to local average HCPs salaries.

No cash

Payments in cash or cash equivalents (e.g. vouchers) are not allowed.

6.3.2 Samples*

Samples are defined as products supplied to HCPs to be given to patients for free. Samples shall enable HCPs to familiarize with products and to gain experience on the efficacy, tolerability and side effect profile, in order to enhance the practice of medicine. Sampling must strictly follow applicable law. Samples may not be sold under any circumstances.

6.4 Non-promotional interactions with HCPs

Novartis Pharma'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.

6.4.1 Consultants / Advisory Boards*

The purpose of engaging HCPs as consultants and/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 6.1).

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.

6.4.2 Studies in humans*

Any types of studies/research programmes involving humans (pre- and post-authorisation, interventional and non-interventional) must be conducted in compliance with the principles of Good Clinical Practice as laid down 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.

6.4.3 Market Research

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

Market research must not have the promotion of products as its purpose. Statistics and data derived from market research may subsequently be translated into marketing activities/promotional content.

6.4.4 Investigator meetings

The purpose of investigator meetings is to discuss clinical studies of Novartis Pharma products 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 (see 6.1).

6.5 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.

6.5.1 Direct-to-consumer (DTC) promotion

Promotion of prescription-only products to patients (so-called direct-to-consumer promotion, "DTC") is not allowed in most countries. Where such promotion is allowed, it must strictly follow the applicable law, industry codes and local Novartis standards.

6.5.2 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.

6.5.3 Disease awareness programs

Any pre- and post-launch disease awareness programs targeted at potential patients must be accurate, balanced and written in appropriate language for the public. The purpose of such programs is to enhance public awareness of disease, to encourage members of the public to seek treatment for their symptoms and thereby save and/or improve the lives of potential patients while not promoting the use of any specific product¹

6.5.4 Patient compliance programs

The purpose of patient compliance programs is to ensure patients who have been prescribed products are provided with information to enhance their compliance/concordance with prescribed medication. Such programs must not have the promotion of products as their purpose¹. Confidential patient data obtained through patient compliance programs may not be held by Novartis Pharma and such programs may only be conducted through third parties unaffiliated with Novartis Pharma².

6.6 Interactions with patients as a source of knowledge to Novartis Pharma

Novartis Pharma's interactions with patients as a source of knowledge aim at the exchange of information on disease and treatment experiences with Novartis Pharma, 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.

6.6.1 Consultants / 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

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

² Unless permitted by local law

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 6.1).

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.

6.6.2 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.

7 GRANTS*

Grants can only be given to reputable institutions, organizations or associations related to healthcare but 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.

Grants³ must be given only to further research (research grants), to support education (educational grants) or as a gesture of goodwill (image-building grants).

7.1 Research / Educational grants

The purpose of research and educational grants is to enhance the practice of medicine by supporting basic or applied research (research grants) or by supporting the education of HCPs and/or patients (educational grants).

Educational grants relating to events

Funding events and/or funding participation to events constitutes an educational grant if the event organiser is solely responsible for developing and delivering the content of the event.

Educational grants relating to patient associations

Funding patient associations, without agreement or intent to receive a tangible return in exchange constitutes an educational grant; further details relating to Novartis Pharma's relationship with patient associations are contained in a separate guideline ("Practical Guidelines for Patient Group Interactions").

³ *Donations are regulated by the Management Authorization Levels. A donation is defined by its altruistic purpose.*

7.2 Image-building grants

The purpose of image-building grants is to support healthcare institutions in improving infrastructure.

8 RESPONSIBILITIES*

8.1 Global level

Overall responsibility for ensuring compliance with this document at global level is allocated to the Business Franchise Heads, Development Franchise Heads and Business Unit Heads respectively. In particular, they are responsible for the implementation and oversight of appropriate processes in their respective areas of responsibility, including 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 global level⁴ and (4) 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 DRA, Medical, Marketing, Finance, Legal and Compliance functions.

For grants approved and funded on global level but carried out in CPOs, the respective local legal function must be involved.

8.2 CPO / local level

Overall responsibility for ensuring compliance with this document at local level is allocated to the CPO Heads. In particular, they are responsible for the implementation and oversight of appropriate processes in their respective areas of responsibility, including 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 level⁴ and (4) associates are trained on NP4.

Delegation of responsibilities, as well as review, approval and documentation processes must be clearly defined in SOP's. These SOPs must be approved by qualified representatives from the DRA, Medical, Marketing, Finance, Legal and Compliance functions.

Local review shall also include activities initiated and/or content provided by global functions to ensure compliance with local law, industry codes and local Novartis Pharma standards.

8.3 Interpretation and implementation

The Divisional Compliance Committee (DCC) is ultimately responsible for providing guidance on the interpretation, implementation of and deviation from this document. Written guidance on implementation and interpretation is contained in the "Guidelines", which will be updated from time to time by the DCC.

⁴ *In some countries the marketing/sales function should not oversee the grants process.*

9 PUBLIC OFFICIALS/INSTITUTIONS*

9.1 Additional standards for interactions with HCPs which 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 Pharma 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.

9.2 Additional Standards relating to Grants to Public Institutions

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, grants to public institutions, organizations or associations 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 grants made to private institutions)

- All grants to public institutions must be fully transparent, properly documented and accounted for; and
 - Grants should be made pursuant to a formal agreement endorsed by responsible representatives of the public institution. The existence of similar agreements between the public institution and other private sector parties may be a useful factor in determining whether the proposed grant is acceptable in a certain country; and
 - In addition to the internal review of grants, a formal process should exist for the selection, implementation and ongoing supervision of grants, involving representatives from the public institution; and
 - Any grant to a public institution would be particularly sensitive if Novartis Pharma conducts or is anticipating specific business with the public institution;
 - In case of educational grants providing for scholarships or participation to similar long-term programs, the public institution should select the HCPs who will be invited to participate; and
 - Any grant to both public and private institutions that is suggested by a government official of a public institution who is in a position to influence Novartis Pharma's business interests has to be considered carefully.
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