



Roche

Working with patient groups: Good practice guidelines

Introduction

Roche is proud of its history of working with patient groups. The company wishes to ensure that all partnerships with patient groups reflect common values of integrity, independence of all parties, respect, equity, transparency and mutual benefit. These values act as guiding principles for these guidelines.

Patient groups are increasingly important partners for Roche. We share an interest in helping patients understand and manage their disease/condition, including having timely and equitable access to the treatment they need. Roche is able to contribute a range of skills, expertise and knowledge which might enhance the patient organisation's activities.

Patient groups are critical in helping Roche to gain a greater understanding of what it is like to live with a disease, the challenges facing patients and their families and the role that drug therapies play in the management of the disease. They also provide the company with an insight on how to support healthcare professionals who in turn support patients.

This document sets out the principles which should underpin the relationship between Roche and any patient group. Any agency working with patient groups on behalf of Roche must also follow these guidelines.

Through implementing these guidelines, Roche underscores its role as a true partner working in partnership with the patient group, where a patient group knows explicitly what it can expect from Roche.

Purpose of working with patient groups

Roche has identified three key areas where it seems appropriate to work with patient groups: increasing disease awareness; information (including information related to Roche products - see Appendix A), education and capacity building; and advocacy. Roche prefers to work in partnership with patient groups where there is a common goal: that is, to improve the outlook for patients and their caregivers.

Guidelines

1 *Integrity*

- a. Any activity jointly undertaken with a patient group should benefit the patients whose interests it represents and should fall within the constitution or the articles of association of the group.
- b. Roche should not seek to gain competitor and/or other confidential information from patient groups.
- c. Information about prescription-only medicines which is made available to patient groups must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to safety of the product. Statements must not be made for the purpose of encouraging patients to ask their health professional to prescribe a specific prescription-only medicine.

2 *Maintenance of independence*

- a. The patient group's independence should not be compromised or perceived as being compromised because of partnering with Roche.
- b. Patient groups must not be asked to endorse a specific product.
- c. Any reference to a product should comply with the patient group's practice on nomenclature.
- d. Roche personnel working with patient groups should understand the environment and constraints within which patient groups work. Similarly, Roche personnel must set out clearly for patient groups the boundaries within which the company may work with them.
- e. All agreements with patient groups are subject to local regulations and practices. In the case of international or regional patient groups, the responsible local function (e.g. the compliance officer) in the country affiliate where the group is registered must first approve in writing the proposed partnership before the global team moves forward. For example, a group that is registered in Italy must have the Italian affiliate's consent in accordance with its applicable internal processes, before Global can partner with the group.

3 *Respect*

- a. Roche and the patient group must respect each other's aims, objectives, priorities, and ways of working.
- b. A written agreement between the patient group and Roche should be in place whenever Roche is to provide financial support, and/or significant non-financial indirect support, and/or when Roche will enter into a partnership with a patient group but no resources are provided. The written agreement may take the form of

a letter agreement, a contract or some other mutually agreed upon form. Where patient groups have a standard form of agreement this should be used, if feasible.

- c. Roche may require to gain contracted services from patient organisations such as the participation at advisory board meetings and speaker services for the purpose of supporting healthcare and research. In such cases, Roche should have a written agreement with a patient group which fulfils the following criteria: clear identification and documentation of the legitimate need for the services in advanced of requesting the services and entering into the arrangements; direct relation between the criteria for selecting services, the identified need and the selected expert / advisor; reasonable extent of the service to achieve the identified need; maintaining records concerning, and makes appropriate use of, the services; no inducement to recommend a particular medicinal product; reasonable compensation for the services (fair market value) and transparency (see also section 5 below).
- d. In consultation with the patient group, any written agreement between Roche and a patient organisation should also include some or all of the following: the objectives of the partnership; the contribution each party will make; the anticipated outputs and timelines; confidentiality, where appropriate; the liability for each party involved in the partnership; the support provided – how much and when; how both sides will keep in touch about the partnership (how and how often); how and in what circumstances the partnership would be terminated; a method for determining how any such termination will be reported; what will happen to any funding which has been provided should the project not go ahead or be completed; how long and in what circumstances the company can refer to the partnership once it has been terminated; how the partnership can be described; and how each party's logo can (or cannot) be used.
- e. One person within a team should ideally be identified as the main point of contact with the patient group. A deputy for the contact should be identified to maintain continuity when the primary contact is unavailable.
- f. If agency support is provided to the patient group, the group should be involved in the selection of the agency.
- g. There should be formal sign-off mechanisms in place within both parties for any publication or materials produced during a partnership.

4 *Equity*

- a. Both parties in the relationship should be considered to be of equal importance.
- b. Any financial or other benefit offered to a group should be appropriate to the size of the organisation and the activity undertaken.
- c. Copyright of any publication developed by the patient group must be respected and existing content must not be used without explicit written permission from the patient group.

5 *Transparency*

- a. Roche will be open about its partnerships with patient groups and will expect the patient groups to be similarly transparent.
- b. Any partnership with a patient organisation should comply with any legislative or regulatory requirements applying to Roche and/or to the patient organisation.
- c. Roche will make publicly available a list of all patient groups to whom it provides financial support and/or significant non-financial support. The list must include at least a brief description of the type and purpose of the partnership that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. For activities commenced as of, or on-going on 1 January 2013 this description must additionally include the monetary value of financial support and invoiced costs or, for significant non-financial support that cannot be assigned a meaningful monetary value; the description must clearly describe the non-monetary value the patient group receives. This list will be updated at least once a year. The additional disclosure of the monetary value will be made publicly available for the first time in the first quarter 2014.
- d. For activities commenced as of, or on-going on 1 January 2013 Roche will also make publicly available a list of patient organisations that it has engaged to provide significant contracted services. This should include a description of the nature of the services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the arrangement without the necessity to divulge confidential information. Roche will also make public the total amount paid per patient organisation over the reporting period. This disclosure will take place for the first time in the first quarter of 2014. This list will be updated at least once a year
- e. For Roche Pharma Companies in the EFPIA countries both the additional disclosure of the monetary value of the financial support as set forth in section 5 letter c as well as the publication of a list of patient organisations with significant contracted services (see section 5 letter d) will take place for the first time by the end of the first quarter of 2013 covering activities commenced as of, or on-going on, 1 January 2012. This requirement reflects the provision as set forth in the EFPIA Code of Practice on relationships between the pharmaceutical industry and patient organisations (amended by decision of the General Assembly in June 2011). For clarity a list of the EFPIA countries can be found on the EFPIA website (www.efpia.eu).
- f. The disclosure of any such information pursuant to section 5 letters c, d and e above should be agreed between Roche and the patient group concerned allowing data collection in an internal register and disclosure by the Roche Group.
- g. Appendix B contains clarifications on unclear terms which are subject to further evaluation and confirmation.
- h. Administrative costs should be built in to partnership funding and should in general not exceed 15% of the total cost.

- i. It is not appropriate to make donations for undisclosed purposes because, for transparency reasons, the company must know where its funds are spent. Where allowed based on local laws and regulations an affiliate shall not be the sole sponsor of a patient group's social event.
- j. Any external agency employed by the company to contribute to the partnership must follow these good practice guidelines.
- k. Permission should be obtained from any patient group whose contact details or logo is to be included in any publication or communication used by the company or its agency. Any text referring to the patient group should be approved in advance of publication by the patient group concerned.
- l. The editorial authority of the patient group for any information produced under their name should be respected. However, the company is responsible for ensuring that any information about its own products in patient group materials is correct.

6 *Mutual benefit*

- a. For a partnership with a patient group to be successful, there must be benefit to both sides.
- b. In general, time expended and costs associated with travel and accommodation incurred by patient groups working in partnership with Roche or on a company-project should be fairly compensated. With regard to appropriate venue of and reasonable hospitality at events organised or sponsored by Roche, in principle the same rules apply as for the events attended by healthcare professionals. All forms of hospitality offered to patient organisations and their representatives shall be reasonable in level and strictly limited to the purpose of the event and shall not include sponsoring or organising entertainment (e.g. sporting or leisure events). The venue and hospitality must be conducive to the purpose of the event avoiding touristic/holiday resorts. Where partnerships are in place with patient organizations and meetings are held with these organizations, such meetings must comply with this requirement. Hospitality may only be extended to persons who qualify as participants in their own rights. Where a participant requires a care giver's help to be able to participate in a meeting or event, covering the costs of an accompanying care giver can be acceptable but need to be agreed upon in advanced.
- c. Financial contributions to patient groups can take several forms: donations; one-off sponsorship; educational grants or ongoing general (for specified purpose) or partnership funding. Whatever the funding method, financial support should generally be based on and reflect an ongoing relationship with a patient group.
- d. Donations should be used less often but may be an appropriate form of support for small or start-up organisations or to organisations in need of immediate resources. They are generally made once only; exceptionally, Roche may make a small donation in subsequent years.

- e. Substantial donations to large organisations are not an appropriate form of continued support. Roche will not request to be the sole funder of a patient organization or any of its major programs.
- f. One-off sponsorship contributions are applied to cover the costs of specific projects such as booklet or video production or meeting costs.
- g. Ongoing or partnership funding is appropriate for activities that are jointly agreed by both sides. Such partnerships are based on mutual benefits which are defined by discussion and agreement.

7 *Review & Evaluation*

- a. All projects and partnerships should be evaluated at pre-planned time points. The evaluation should be relevant to the outcomes agreed at the outset.
- b. The evaluation should include short, medium and long term objectives. Even if short term objectives were not met, both parties may choose to continue with a relationship.

8 *Implementation*

- a. Roche employees as well as contractors and agencies working for or on behalf of Roche are directly responsible for applying these guidelines.
- b. The responsible Roche Management has to instruct the Roche employees as well as the contractors and agencies working for or on behalf of Roche in an appropriate way.
- c. All Roche Companies have to ensure the guidelines are implemented locally in line with applicable laws and have to ensure compliance. Violations of these guidelines are not tolerated.
- d. Roche will regularly assess the terms and conditions that determine appropriate behaviour in engagements with patient organizations; if necessary, Roche will amend these guidelines accordingly.

9 *Entry into Force*

These amended Guidelines were approved by the Corporate Executive Committee on February 14, 2012; they entered into force on the same day.

APPENDIX A

Principles for presenting information to patient organisations

Background

Roche and Patient organisations share a common interest in helping patients understand and manage their disease/conditions, including having timely and equitable access to the treatment they need. Roche is able to contribute a range of skills, expertise and knowledge which might enhance the patient organisation's activities.

Roche supports patient organisations by giving them easy access to balanced, accurate and easy-to-understand scientific information about available medicines and services. Patients seeking new clinical trials to participate in can access the information on www.roche-trials.com.

Sharing information with patient organisations

On receipts of a verifiable request by a patient organisation, Roche is willing to provide said patient organisation with information in the following additional circumstances:

1. Where a product has received marketing authorisation, information about clinical trial results that have been presented in a public meeting or published may be shared with patient groups in a fair and unbiased manner. The information must be provided by a clinician, preferably one who has been involved in the trial but this may not always be possible.
2. Where a product is in clinical trials but has not received marketing authorisation, information about ongoing and completed trials may be shared in a fair and unbiased manner with patient organisations provided it is relevant to the patient organisation's remit and information about the trials is available in the public domain (including www.roche-trials.com).
3. Information on pipeline products may be shared with patient organisations only when there has been a request, either in writing or during the course of a meeting, for this information. The information must be presented by a clinician and must be fair and unbiased.

In all circumstances, the information to be presented must be placed in the context of current management strategies and must not be promotional.

APPENDIX B Clarifications

Background

In order to clarify what is meant in respect of interactions between pharmaceutical companies and patient organisations, subject to further evaluation and confirmation, Roche states below its current understanding on several definitions. These clarifications will be updated as further information becomes available.

Definitions

1. Participation of representatives from patient organizations in activities hosted by Roche designed to enable patient organizations to increase their capacity or develop their service delivery

Roche support for patient organizations in Europe must be disclosed whether the support is financial or significant non-financial or indirect support (such as providing agency time, donating computers, etc). Unless it is a national and/or EFPIA Code requirement, participation of representatives from patient organizations in activities hosted by Roche designed to enable patient organizations to increase their capacity or develop their service delivery does not need to be disclosed as support for an individual patient organization. This category includes meetings such as experience exchanges (the annual international experience exchange for patient organizations) or patient group forums where patient organizations have the opportunity to learn from each other.

2. How is “significant support” defined?

The term “significant” is used to describe the non-monetary support that must be listed. Roche will for the moment only list non-monetary support which has a value of, or greater than, 250 Euro per activity.

3. What are examples for indirect financial and non-financial support?

Indirect financial support includes, for example, donation of services from public relations, event management and market research agencies. Non-financial support includes provision of free training by company personnel, donations of facilities and/or equipment, staff secondment, etc.

4. How is “significant contracted services” defined?

Roche will for the moment being only list significant contracted services which have of, or greater than, 250 Euro per activity.