

Sobi Policy on Interaction with Patient Organisations

General

Patient organisations are essential in improving the opportunities for effective diagnosis and management of rare diseases and in working to secure the best quality of life for people with a particular disease or medical condition. Patient organisations provide services and information to patients, carers and their families and they provide a support system for people with similar experiences.

Especially in the field of rare diseases, patient organisations and patients themselves may often be the best experts in their diseases or conditions. Stakeholders in the rare disease communities are the front-runners in the concept of “patients as experts” or “expert carers” in this respect, and patient organisations in the field of rare diseases are formally invited as members of many of the scientific committees on the European Union and US regulatory bodies responsible for the review of treatments aimed at treating rare conditions, which acknowledges this particular aspect of the contribution that they make in this regard.

Patient organisations may also campaign for better standards of care and access to treatment for the patients they represent. As such, they are actively engaged in the policy-making, regulatory and health technology / value assessment environments. Increasingly, patient organisations are also funding basic research and clinical trials for new treatments and are taking concrete action in the research, development and availability of treatments for a variety of conditions.

Sobi partners with and supports a wide range of patient organisations, nationally and regionally, to achieve our common goals of advancing the best outcomes for patients with rare diseases through research and creating awareness, as well as ensuring patients have access to the treatments they need and that those treatments are reimbursed. In addition, both Sobi and patient representative organisations have a shared goal of providing educational and support services to patients.

It is acknowledged that patient organisations are, for the most part, not-for-profit organisations, reliant on contributions from external sources in order to allow them to carry out this vital work on behalf of the constituencies that they represent. This support may come from a variety of sources, including the pharmaceutical industry.

In addition, collaborations with and support for such representative patient organisations can take many different forms. The most common are direct financial support, support in-kind, or by collaborations such as working together on certain projects where there is a shared interest. In carrying out these activities, which are a key element of mutual collaboration and are based on integrity, trust and mutual respect, it is important that each and every one of us at Sobi do the right thing and that each and every one of us is clear about how we conduct those relationships and what is expected from us as Sobi employees.

Aim of the Sobi Policy on Interaction with Patient Organisations

This Sobi Policy on Interaction with Patient Organisations is intended to provide guidance to Sobi employees in ensuring that our collaboration with patient organisations is transparent, ethical and compliant with the applicable relevant legislation.

The way that we manage these relationships directly reflects on who we are as a company, on the way that we are perceived and, ultimately, on the level of interaction to which patient representatives and organisations are willing to engage in with us. Our reputation and integrity has a direct impact on our ability to do business and to build lasting relationships with those we are here to help and serve. It is important that we are aware of our obligations and that we demonstrate the utmost professionalism and respect when collaborating with all organisations, including those representing the patients.

Furthermore, an increasing level of focus is being placed on the interactions between pharmaceutical companies and patient organisations, which means that we should be thoughtful and transparent about documenting the measures we take at Sobi in order to ensure that we are always demonstrably and visibly compliant with the highest levels of professionalism and transparency.

Guiding Principles

To ensure that our partnerships and relationships with patient organisations are transparent and ethical; and that they are conducted with the highest integrity and according to applicable laws and standards, all Sobi employees are guided by the following principles:

- Sobi and Sobi employees always comply with local laws, rules and regulations in the countries and regions in which we do business, including those related to interactions with patient organisations. This is governed by the Sobi Code of Conduct & Ethics, which all employees are required to read, understand and sign on an annual basis.
- Any interaction Sobi has with a patient organisation will be open, transparently disclosed and ethical.
- Sobi respects the independence of patient organisations in the way in which they operate, their priorities and priority-setting, their internal and external representations and their decision-making. We never ask them to put the interests of Sobi above those of the patients that they represent, or to give any indication that this might be the case.
- It is never a requirement of our collaboration with patient organisations that they receive support solely from Sobi, nor will we seek to prevent anybody else from making contributions to these organisations. Although there may be occasions when Sobi is the sole source of support for a given activity – e.g., if a new organisation is established focusing on a specific rare disease, or in the case that Sobi is the only company engaged in such a field – in general, we strongly encourage patient organisations to pursue and establish multiple funding sources as a cornerstone for their sustainability.
- Sobi will work only with patient organisations which are duly established and organised with the intent to be a representative body on behalf of a disease or condition. Sobi does not make direct payments to individuals.
- Sobi will never ask a patient organisation, directly or indirectly, to promote any Sobi product or service.
- Sobi will not use the logo of a patient organisation or any proprietary material without the organisation's prior written agreement. In making such a request, Sobi will make clear the specific purpose and the way in which the logo or material will be used. The logo or any other branding related to the patients' organisation shall not be used in any other way beyond that which is agreed by the patients' organisation.

- Sobi will work with patient organisations to ensure the privacy and security of any personal information or data we may receive as a result of our interaction and will not expect them to provide us with any personal patient or family information. As members of a range of trade bodies, we are required to publish a list of patient organisations to which we provide financial support and / or significant non-financial support. This information, including the nature and purpose of the support is updated on an annual basis and can be found on the Sobi website: <http://www.sobi.com/Patients/Patient-organizations/>
- Our guiding principles are aligned with those the industry associations of which we are members.

Scope and responsibility

Sobi's Policy on Interaction with Patient Organisations applies to all Sobi employees, temporary personnel, consultants, agents or anyone working on behalf of Sobi. Everyone is required to confirm that they have read and understood the Sobi Policy on Interaction with Patient Organisations. Line managers are responsible for making these principles known and for promoting and monitoring compliance. Violation of this Sobi Policy on Interaction with Patient Organisations will not be accepted, and may result in formal sanctions being applied, according to the nature and severity of the breach.

Any Sobi employee wishing to make an agreement with a patient organisation must:

- Ensure that there is a formal, written request for support – financial or otherwise – on the headed paper of the patient organisation, documenting the rationale for the request and the reason that Sobi would be an appropriate supporting partner for the activity;
- Ensure that the agreement is dated, signed and printed on the headed paper of the patient organisation and that the agreement includes details of the project and the budget, which should be commensurate with the nature and scope of the activities proposed;
- Complete the “Checklist for Cooperation with Patient organisations”, attached as Appendix 1;
- Where appropriate, request sign-off from Sobi's Legal Department and Compliance Officer prior to the conclusion of this agreement with the patient organisation;
- Ensure that the agreement is signed by the relevant Sobi Medical Director and the Legal Representative of the patient organisation. The financial / non-financial agreement can only be implemented when the agreement is duly signed by both parties;
- Ensure that External Affairs Department is notified of agreement, for inclusion in public list to be published on the Sobi website: <http://www.sobi.com/Patients/Patient-organizations/> at least once per year, to check that all records relating to the cooperation with patient organisations are up-to-date on the Sobi website. This is the responsibility of the relationship owner, i.e., in a country or a Therapeutic Area, the lead initiator is responsible for ensuring that the External Affairs & Patient Access department – and, specifically, Corporate Communications, is fully informed and kept up-to-date.

Reporting possible violations of the Policy on Interaction with Patient Organisations

Each and every one of us as Sobi employees are personally responsible for helping to fulfil the objectives of this Sobi Policy on Interaction with Patient Organisations by following all of its

principles, by preventing violations and by reporting all suspected violations. We have an individual and personal obligation to raise our concerns about anything we think may be a violation or a potential violation of Sobi Policy on Interaction with Patient Organisations.

According to Sobi's Code of Conduct and Ethics, it is Sobi's policy to:

- Encourage and support employees who, in good faith, believe that any of Sobi's employees or management are in violation of the Sobi Policy on Interaction with Patient Organisations, any law, or any company policy, to report the possible violation;
- Conduct a prompt investigation of any alleged violation and take appropriate corrective and/or disciplinary action; and
- Prohibit any retaliatory action against any Sobi employee for making a good faith report of a suspected violation of the Sobi Policy on Interaction with Patient Organisations, any law, or any company policy, even if a subsequent investigation proves the report to be unfounded.

Sobi Policy in case of suspected breach of the Sobi Policy on Interaction with Patient Organisations:

If you suspect a possible violation of Sobi Policy on Interaction with Patient Organisations or the local code (if applicable), any law, or any company policy; or if you have concerns about possible ethical misconduct, you should contact any of the following:

- (i) Your Manager as soon as possible;
- (ii) Another managerial employee at your location;
- (iii) Your Human Resources manager;
- (iv) Your compliance personnel;
- (v) Your Legal Department personnel; and/or
- (vi) Your Compliance Hotline (if available for your location, form to be decided).

The Sobi Policy on Interaction with Patient Organisations will be reviewed regularly to ensure that it is current.

Each individual employee is responsible for reading, understanding and acknowledging their personal responsibility in upholding this Policy on Interaction with Patient Organisations in their day-to-day work at Sobi. Each individual employee will be required to read and certify that they have understood and will adhere to this Policy on Interaction with Patient Organisations.

Stockholm, Sweden – 1 July 2013