Introduction

About Osteogenesis Imperfecta

Osteogenesis Imperfecta – also known as OI or ‘brittle bone disease’ – is a rare genetic disease of bone and connective tissue. The diagnosis is known all around the world and occurs regardless of gender or ethnic origin.

At present, OI cannot be cured. Treatment is aimed at preventing or correcting its symptoms. This usually involves orthopedic surgery and physiotherapy, possibly the prescription of certain drugs and sometimes audiological or dental treatment.

Mutual support through the exchange of experience and information is of prime importance, both for those affected and for their families.

About OIFE

The Osteogenesis Imperfecta Federation Europe (OIFE) is an umbrella association for organizations dealing with OI. The non-profit organization was established in 1993 by six founding OI-organizations and is registered as a charity in the Netherlands.

We have more than 30 member organizations in three main categories:

- European OI-organizations (ordinary members)
- OI-organizations outside Europe (associate members)
- Supporting member organizations
  - Aid organizations
  - Research foundations

Our MISSION is to connect and empower organizations, professionals, and individuals to improve the lives of people with OI.
About the funding of OIFE

As any other organization, OIFE needs funds to carry out its mission. Our main core of funding comes from the membership fees that our ordinary member organizations pay annually. At the moment our financial situation does not allow us to hire staff, so all our work is done on a volunteer basis, and usually, these annual fees cover the very basic costs of administering the OIFE. However, like many other patient organizations, the OIFE is currently confronted with increasing workload and participation in initiatives that require additional funding that we try to secure through various sources, expanding the financial support we receive from commercial companies.

To maintain its independence, the OIFE has set itself the objective to balance revenues, both monies and in-kind, from different sources. The ideal goal is to reach the following distribution:

- 1/2 from Non-profit or Patient Organisations including membership fees, donations, grants and the economic valorization of volunteers contribution,
- 1/2 from the private sector including commercial companies, both from the health and non-health sectors.

In its annual budget, OIFE limits the total financial support it receives from commercial companies in the health sector to the total amount of funding provided by Patient Organisations including its membership fees and volunteers. To avoid the risks inherent in an economic relationship with a single company, or a limited number of companies, from the health sector, the OIFE tries to diversify the types of financial support it receives.
Financial Policy

Financial and Control Policies

INTRODUCTION

The purpose of this financial policy is to fulfill the organization’s mission in the most effective and efficient manner and to remain accountable to stakeholders, including member organizations, partners, volunteers, supporters, and the community. In order to accomplish this, the OIFE commits to providing accurate and complete financial data by the Executive Committee and the Board, for internal and external use.

The OIFE will keep and update all financial policies current and relevant.

These policies and procedures apply to all stakeholders.

AUTHORITY

• The Executive Committee (EC) is ultimately responsible for the financial management of all activities.
• The Treasurer is authorized to act on the EC’s behalf on financial matters when action is required in advance of a meeting of the EC.
• The President is responsible for the day-to-day financial management of the organization. The EC authorizes the President and the Treasurer to hire services, pay bills, receive funds, and maintain bank accounts.
• The President is authorized to enter into contracts for activities that have been approved by the Board as a part of budgets or plans. The EC must authorize any contracts outside of these parameters and all contracts with a financial value greater than 15000€.
• The President is authorized to manage expenses within the parameters of the overall approved budget.
• The EC must approve any use of the Board designated cash reserve fund.

RESPONSIBILITIES

The President, assisted by the Treasurer, shall:
• Account for donor-restricted and Board designated funds separately from general operating funds, and clearly define the restrictions applicable to these funds.
OSTEOGENESIS IMPERFECTA
FEDERATION EUROPE

• Report the financial results of the OIFE’s operations according to the budget established and approved by the Board.
• Pay all obligations and produce required reports in a timely manner.
• Make no contractual commitment for bank loans, corporate credit cards, or for real estate leases or purchases without specific approval of the Board.
• As the main rule, obtain competitive bids for items or services costing in excess of 2500€ per unit. Selection will be based on cost, service, and other elements of the contract. The OIFE may award the bid to any provider that offers a proposal that better suits the interest of the organization and is not required to accept the lowest cost proposal.

The Executive Committee shall:
• Review financial status at each meeting.
• Provide adequate training to EC members to enable each member to fulfill his or her financial oversight role.

FINANCIAL TRANSACTIONS WITH INSIDERS

Direct and necessary expenses, including travel for meetings and other activities related to carrying out responsibilities, shall be reimbursed. Advances of funds to collaborators, volunteers, EC members, organizations, or others are only possible after approval by the EC.

BUDGET

To ensure that planned activities minimize the risk of financial jeopardy and are consistent with Board-approved priorities, strategic plan, and long-range organization goals, the Executive Committee shall:

• Submit operating and capital budgets in time for reasonable approval by the Board each fiscal year.
• Use responsible assumptions and projections as background, with the general goal of an unrestricted surplus.

GIFT and CELEBRATORY EVENTS

To the OIFE:

The OIFE can accept contributions of goods or services other than cash that are related to the programs and operations of the OIFE. Any other contributions of non-cash items must be reviewed and approved by the Executive Committee before acceptance.
From the OIFE:
The OIFE may occasionally spend modest amounts from appropriate funding sources to recognize collaborators under certain circumstances.

Allowable collaborators recognition may take the form of celebratory events or gifts for the following occasions:
• Work-related achievement;
• Recognition of contributions to the OIFE (lectures, event organizers,...);
• Sympathy upon the death or serious illness of a collaborator or its immediate family member.

The EC must use prudent judgment and also follow the rules outlined below. The OIFE’s funds may not be spent in recognition of personal events or achievements unrelated to work, such as birthdays, weddings, baby showers, housewarming, etc., or for gifts in recognition of holidays rather than work-related achievement.

Collaborators Gifts and Celebratory Events Policy
1. Ensure the gift or event is for an allowable occasion
2. Comply with the limits previewed in the budget
3. Use an appropriate funding source
4. Record the gift or event expenses to the proper object/financial code

ASSET PROTECTION
In order to ensure that the assets of the OIFE are adequately protected and maintained, the President shall:

• Avoid actions that would expose the organization, its Board, or its staff to claims of liability.
• Protect intellectual property, information, and files from unauthorized access, tampering, loss, or significant damage.
• Receive, process, and disburse funds under controls that are sufficient to maintain basic segregation of duties to protect bank accounts, income receipts, and payments.
PROCEDURES

Any of the following financial transactions can only be undertaken after their approval by the Authorised Person. Where an additional policy is noted, this policy must also adhere to the finance transaction.

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Bank Account Policy
Policy Number: FP01

Purpose of the Policy
This policy sets out the requirements for use of bank accounts, including opening, closing authorization, variations to terms and conditions, reconciliation of bank accounts, and bank account transactions.

Procedures

Opening Bank Accounts
Any new bank accounts to be opened for the business must have the authorization of the Executive Committee. For each new bank account opened, the financial system must be updated and the bank account registered by the Treasurer.

Bank Account Authorisations
For debit transactions from any bank account, by any payment method, there must be at least two EC members authorizing for each payment, but with the need of only one signature, usually the Treasurer or the President. Each payment made must be supported by invoice, receipt, or other appropriate documentation and the authorizations must be attached to this documentation prior to payment.

Changes to Bank Account Terms and Conditions
Any changes to banking arrangements can be made or changed by the Executive Committee as long as they are in the best benefit of the OIFE. The treasurer is responsible for updating the financial system and/or bank account register with the new information.

Closing Bank Accounts
Where it is decided that a bank account is no longer necessary the EC will authorize the closure of the bank account. The Treasurer will then be required to complete the following:
- ensure all transactions with respect to the account have been completed;
- lodge with the bank a letter, signed by the President and the Treasurer advising of the closure of the account;
- meet the bank’s requirements with respect to account closure; and
- update the financial system and bank account register.

Bank Account Transactions
Unallocated direct deposits, longer than one month, will be investigated fully to determine the source of deposit. Where the source cannot be identified, the deposit will be allocated to a «general or non-purpose related donation» account.
Purchasing Policy
Policy Number: FP02

Purpose of the Policy
This policy provides guidelines for the purchase of goods, services, equipment, and assets for the OIFE or its collaborators. This policy is applicable to all purchases.

Procedures

Request for Purchase
All items must be chosen according to the best interests of the organization, taking into account that it suits the purpose for what it's meant, its quality, it’s accessibility, it promotes environmental sustainability and the best price. As the main rule, obtain three competitive quotations for items or services costing in excess of 2500€.

Equipment Asset Purchases
All equipment and asset purchases must be entered in the financial system by the Treasurer with the following details included:
- Date of purchase;
- Supplier; and
- Make, model, warranty/guarantee information.

Service Agreements
All agreements for the provision of services to the business are to abide by this policy.

Staff Communication Tools Policy

Reason for Policy
The OIFE wants to improve its communication skills and networking providing its staff (EC members and volunteers) with the right technology tools they need to do their OIFE’s jobs and to use its resources wisely. The OIFE recognizes that different gadgets are omnipresent and that most of the users want a single device that supports both their OIFE’s work and personal lives. The OIFE seeks to support its staff business technology needs while allowing users enough flexibility to choose devices and service plans that meet their personal and family requirements.

Who Must Comply
This policy applies exclusively to EC members and volunteers (secretary, webmaster,...) or to someone because of a particular given OIFE project needs to work in close cooperation with the OIFE EC.
1. Procedures
   A. Eligibility requirements. The OIFE defines “eligible” staff as day to day job responsibilities that require routine work or response on a daily/weekly basis - e.g., management of the organization, communication, marketing, and fundraising, etc.
   B. Other business cases proposed and justified by the OIFE EC and approved by the Board; must meet at least ONE of the following criteria.
      a. The role requires the staff members to routinely respond to routine work or responses for a particular period of time and to develop an OIFE project; the OIFE President must explain business necessity.
      b. In other business cases; the President must explain business necessity.

2. Support program:
   A. The support of this policy intended to reimburse staff for the incremental cost of business use of personal mobile phones and thus represent nontaxable compensation.
   B. The stipend amount will be set and reviewed periodically by the OIFE EC.
   C. Mobile phone equipment or computer, accessory, and app costs are the responsibility of the staff member; the staff member is responsible for any loss, theft, or damage
   D. A recompensation for the acquisition of this hardware can be given by the OIFE, according to the acquisition receipt and the Business Expense Reimbursements Policy.

3. Forms of payment:
   A. Reimbursements for regular monthly mobile phone or internet use for covered staff will be paid by bank transfer after the return of the reimbursement claim form.
      - Reimbursement for infrequent, extraordinary business: may submit an expense report with proper supporting detail reimbursement claim form of the cost.
      - As a good practice, backup data on the phone regularly. All staff who have OIFE data on their phones or computers are strongly encouraged to back up their data regularly.
      - Protect OIFE data: staff must protect OIFE’s business-related data, and delete or preserve OIFE data as required.
      - Staff must wipe OIFE data from their phones or computers when they are no longer actively using that data for their current OIFE role.
Business and Travel Expense Reimbursement Policy
Policy Number: FP03

Purpose of the Policy
This policy establishes when the OIFE will reimburse business expenses of any individuals conducting business on OIFE’s behalf and it also establishes how OIFE will reimburse individuals for travel expenses incurred conducting the organization’s activities. The OIFE shall not be liable for any material, non-material or physical damage suffered by an invited collaborator or those responsible for accompanying a disabled collaborator in the course of their journey or stay in the place where the activity is held unless such harm is directly attributable to the OIFE.

As a nonprofit organization that benefits from gifts by donors and sponsored awards, the OIFE has a stewardship obligation to use its funds prudently; all of OIFE’s collaborators and volunteers must use OIFE’s resources wisely and in the fullest support of its mission. The OIFE will reimburse allowable, reasonable, properly substantiated expenses that are necessary and appropriate in the conduct of OIFE’s representation or business. Business expenses paid by any method must comply with this policy. While no policy can address every situation, this document is intended to cover the most common business expense scenarios; where unusual circumstances arise, the spirit of this policy – along with good judgment – must prevail and the final decision will be made by the EC.

Procedures

Travel Expenses Policy and Rules for reimbursement:

All OIFE collaborators or invited experts shall be entitled to the reimbursement of their travel expenses from the place specified in their invitation (work or home address) to the place of the meeting, by the most appropriate means of transport given the distance involved.

The treasurer shall scrutinize particularly closely any requests for reimbursement involving abnormally expensive flights. They shall have the right to carry out any checks that might be needed and to request any proof from the individual required for this purpose. The treasurer shall also have the right, where it appears to be justified, to restrict reimbursement to the rates normally applied to the usual journey from the expert's place of work or residence to the meeting place.
A) **Travel costs**

Travel expenses shall be reimbursed on presentation of original supporting documents: tickets and invoices or, in the case of online bookings, the printout of the electronic reservation and boarding cards for the outward journey. The documents supplied must show the class of travel used, the time of travel, and the amount paid. Travel tickets for the participants must be booked by using the most appropriate and cost-effective means of transport to attend the event. Tickets must be booked at the earliest opportunity in order to take advantage of the best rates.

For participants with a disability, their circumstances will be taken into account in determining the most appropriate means of transport and the terms of travel. Travel expenses shall be reimbursed on presentation of original supporting documents. Under specific approval, the travel costs of an accompanying person/assistant may be accepted.

**By rail**
Travel by train is reimbursed to an amount equivalent to a 2nd class train ticket. Whenever applicable, advanced booking is also highly recommended.

**By air**
Journeys covering distances of more than 400 km (one way) may be made by air, economy class, or equivalent, at the lowest available price taking the date of the event into account. Advanced booking is highly recommended, and low-cost airline tickets are preferable. One piece of luggage is allowed if needed. Seat reservations are not covered.

**By car**
Participants who choose to use their own cars for mission-related travel remain fully liable for any accidents involving their vehicle and for any traffic offenses. In this case, the OIFE will not accept any requests for compensation or reimbursement. Participants are required to use appropriate, safe, and properly serviced vehicles and to comply with the relevant safety rules: rest times, highway code, etc.

**Whenever the route is served by a train, but the participant prefers to use its private car, the cost of travel shall be reimbursed at the same rate as the first-class rail ticket.**
The use of a car is authorized where, in view of the specific features of the mission, it improves the cost-effectiveness of travel and/or of the event itself, particularly where the vehicle is shared by a number of participants.

**If the route is not served by a train the cost of a journey by private car (personal or company cars) is calculated at a rate per km up to a maximum of € 0.22 per kilometer.**
Other expenses (motorway tolls, parking, ferry crossings, etc.) can also be reimbursed on presentation of the corresponding original supporting documents.
By taxi
OIFE encourages the use of public transport. Only where public transport is not a suitable alternative (for example, for safety reasons or disability) or not available, taxis may be used and are considered as eligible costs for transfers to airports or stations at the place of the event. Taxi fares are reimbursed on presentation of the original supporting documents duly and clearly completed.

Travel by boat
The appropriate class and cabin supplements will be authorized in accordance with the needs of the service and in line with the length and cost of the trip and considerations of cost-effectiveness.

Travel Insurance
Travel insurance connected to any travel reservation or accident protection may be included only upon previous approval.

Accommodation
Individuals who have to spend one or more nights at the place where the activities are held because the times of meetings are incompatible with the times of flights or trains shall also be entitled to an accommodation reimbursement.

The number of nights may not exceed the number of meeting days + 1, however, an additional can exceptionally be accepted and paid if prolonging the stay would enable the individual to obtain a reduction in the cost of transport worth more than the amount of these extra nights.

All other personal expenses (e.g.: mini bar, telephone, laundry, e-mail) are not covered by the OIFE.

Meals
Expenses with meals for the period covered by OIFE’s activity may be considered on an economic basis. They must be pre-approved.

Reimbursement Claim Procedure

This reimbursement policy was specifically developed to improve financial support standards:
- To allow OIFE to manage its accounts with foresight and care.
- To ensure that reimbursement claims are efficiently processed.
Expenses are exclusively reimbursed to individuals who successfully applied for support. For the EC members or any collaborator representing the OIFE, expenses are reimbursed upon approval. All reimbursements of travel expenses and/or accommodation shall be made to one and the same bank account.

Please consider the following when addressing a claim to OIFE: If you have several expenses to claim, complete only one claim form (please do not send several individual claim forms!) including all expenses that occurred:

- Receipts for expenses must be attached to the form
- Send your request for reimbursement within one month after the event occurred and on December 15th at the latest. Should you need assistance, please send an email to treasurer@oife.org
- The payment order shall be drawn up on the basis of the request for reimbursement, duly completed and signed by the individual and after confirmation of its participation/registration in the event/meeting, he/she represented the OIFE. If needed, the individual must provide the treasurer with the documents necessary to confirm this.
- In some cases, other criteria must be fulfilled by the claimant before reimbursement can take place e.g. a written report of the meeting or other things that have been agreed beforehand.
- Travel expenses shall be reimbursed in euros, where appropriate at the rate of exchange applying on the date inscribed in each receipt.
  - For those claimants whose country’s currency is not the Euro, please do not convert expenses incurred in your country’s currency into Euros. OIFE will perform the conversion when receiving the claim using the Foreign Exchange Rate Currency Converter OANDA.
  - For the EC Member Reimbursement Claims, whose country’s currency is not the Euro, direct conversion of the currency is accepted and can be included in the Claim form, as long as:
    - either the Foreign Exchange Rate Currency Converter OANDA is used to calculate the daily currency exchange at the date of the purchase, or
    - a copy of the bank transaction where the total amount paid is attached to the claim.
  - If a specific project will get more applications to support and the budget is not enough to cover all the expenses claimed, then the EC will decide either on the equal division of all participants or on the financial need of the national organization.
About your claim:

a. All claim forms are subject to approval by OIFE’s Executive Committee and in special circumstances by the OIFE Board

b. Make sure to indicate your international bank details (IBAN and BIC/SWIFT)

c. The OIFE will not be held responsible for any incorrect or missed information of your reimbursement claim, that may delay or make the reimbursement impossible. In this case, the Treasurer is responsible to contact you and inform you about the situation and a deadline of one month is given to correct this situation. If no reply or action is done, the reimbursement is considered void or canceled.

One commitment: to send a short report

As a general rule, all beneficiaries of reimbursement are requested to send a short report after their visit, summarising the topics discussed, the main outcomes, and the plans for future collaboration. A one-page report is sufficient, two pages maximum.

This reporting is essential for three reasons:

. To justify the use of funds to our funders and write our year-end report;
. To evaluate the usefulness of financial support and be able to consolidate or expand it;
. To learn from your projects, potentially share useful information and identify new collaborations.
Financial Support
Policy Number: FP04

This policy includes terms and conditions for the application of financial support for participating in OIFE projects, activities, or meetings by national OI organizations and individuals.

**Purpose of the Policy**

The policy hereby detailed is aimed to allow more active participation from individuals and organizations in OIFE’s activities, to stimulate young people to get involved and to help build better strategies for OI support. We also want to promote patient empowerment through capacity building and European networking between patient organization representatives and medical advisory boards to enhance the dialogue between these patient organizations representatives and clinicians or academic leaders in Osteogenesis Imperfecta.

All OI organizations that are ordinary, associate or supporting members of the OIFE, other OI related organizations, and individuals can apply for this support, keeping in mind that this is aimed to help finance the participation in an OIFE project and not to support all costs.

The budget for each project will be reviewed and announced every year, after approval by the OIFE Board.

**Procedures**

Individuals or organizations wishing to apply for support should fill out a specific Application Form.

For proposals not included in the yearly OIFE projects, or proposals from OI organizations that are not members of the OIFE, the vote of the OIFE Board can be added to the EC decision.

A written reply will be sent within 30 days following the reception of the application form duly completed.

Financial support will be paid to successful applicants once the “Reimbursement Claim Form” has been returned to OIFE, accompanied by the originals of the relevant invoices, receipts or tickets. All claims will be treated within a one month period after the reception, as described in the FP03. Exceptions can be made, after approval by the EC and based on a detailed budget, in situations where the amount of investment can compromise the financial situation of the person or organization involved.

Please remember that OIFE’s financial support has limited resources. We rely on the national organization's sense of solidarity and fairness to limit the request and well target purpose to
allow support to a significant number of individuals. Financial support will be given with a priority to those organizations or individuals most in need of financial aid.

It is important to note that this program of support to individuals and organizations is not conceived as standalone financial support, but is part of a more global policy intended to empower OI individuals networking.
Financial Support by Commercial Companies Policy
Policy Number: FP05

1. Purpose of the Policy

OIFE is widely recognized for being the voice of people living with Osteogenesis Imperfecta in Europe. Our organization has played a major role in creating a favorable framework for medical knowledge, research development, and representation of the national OI-organizations on an international level. OIFE is therefore bound to attract the attention of companies that have a particular interest in the development of treatments and other services for OI patients.

OIFE has therefore decided to establish clear and transparent rules to regulate its relationships with commercial companies.

1. OIFE’s Position on Transparency: OIFE believes that transparency cannot be restricted to the narrow issue of transparency on funding - a necessary but not sufficient condition of transparency. Any policy on transparency should provide clear answers to the following questions: Who does the Non Profit Organization (NPO) represent? What is its representativeness? How is the NGO funded and which public or private interests does it represent? Does the NGO have a track record of credible work? Does the NGO really contribute to the debate?

OIFE believes that the transparency of an NGO lies primarily in its mission and values; the legitimacy of its membership base; its governance practices; and its internal and public policy practices. Consequently, the transparency of an NGO also lies in the transparency of its financial information; the internal and external financial control; the transparency of its financial relationships with funding sources; the transparency of its financial relationships with commercial companies; the prevention of potential conflicts of interest, both public and private.

In all of its activities the OIFE respects and promotes the fundamental value of transparency, by following the principles of legitimacy, credibility, responsibility, independence, and accountability.

2. The elaboration of the current OIFE Policy: this policy is adopted after several successively revisions in 2020; it does not set out to provide a definition of every possible funding opportunity or relationship, but rather to define a set of principles.
The OIFE believes it is essential to establish transparent rules about financial support from commercial companies, and in particular about what companies may - or may not - expect from the OIFE in return.

2. **Principles to be applied by the OIFE in its relationship with Commercial Companies**

The OIFE welcomes financial support by commercial companies as long as the relationship between the organization and these companies are based on the following principles:

- relevance of a public health objective driven by patient needs
- full independence of the OIFE
- mutual respect
- mutual benefit
- accountability and transparency

OIFE believes it is important to establish and maintain relationships with commercial companies in order to enhance communication between people with OI and their caregivers, whose interests we represent, and companies, whose decisions will affect the provision of health services or treatments to patients.

The OIFE sees corporate donation programs as a good practice in corporate governance and one of the ways commercial companies can support people affected by rare bone disorders, or redistribute to the OI community some of the profits they are making.

The OIFE supports the availability of the widest range of medical products and drugs, treatments, and health services; it does not endorse individual medicinal products or treatments; it encourages active partnership between patients and health professionals as well as discussion of all available options to ensure patients make informed choices.

The relationship between OIFE and commercial companies is based on partnership and collaboration while preserving OIFE’s independence and integrity. To ensure a successful partnership, each partner should learn to understand each other’s internal culture and external constraints.

Financial support resulting from partnerships with companies is dedicated to activities in the areas of rare bone disorders; treatments; public awareness; patient support; capacity-building; and social, health, and educational services.
In any case, funding by commercial companies:
- must be for the benefit of the people with OI, their caregivers and organizations the OIFE represents,
- must not entail product advertisement, specific medicinal product, brand, or health service
- cannot influence in any way the OIFE’s policy, positions or decisions, whether explicitly or implicitly.

The OIFE refuses financial support from companies generating a public health risk, making unsubstantiated or misleading claims about their products, or not taking into consideration the specific needs of people with OI or other rare bone disorders.

Should a company’s strategy evolve over time and potentially conflict with OIFE’s positions and need to maintain its independence, financial support from this company would not be accepted or would be discontinued.

As long as these principles are respected, the OIFE does not foresee any potential conflict of interest with commercial companies at large.

3. **Types of Financial Support by Commercial Companies to OIFE activities**

The specific aims of the support by Commercial Companies are:

- To provide the OIFE with pooled financial support for unrestricted funding with no strings attached, in favor of activities of common interest and benefit, such as:
  - Improving access to information, treatment, care, services, and support for people living with OI or other bone disorders;
  - Raising public awareness on OI and other rare bone disorders, and on the need for more research;
  - Empowering rare bone disorders patient groups and improve their advocacy capacity (through information, training, and networking);
  - promote capacity building programs that allow patient involvement in research & development possible;
  - Improving identification and increasing knowledge of rare bone disorders patient groups at the European level; facilitating networking and supporting them.
• To educate concerned companies on the common goal of facilitating rapid development and availability of treatments and services for people affected by OI and other rare bone disorders.

• To network with leaders of the OI community, patient groups, voluntary health organizations, regulatory agencies, and policymakers, and promote open and frank sharing of information, in a neutral forum, on the process, obstacles, and incentives for the development of treatments.

• To stimulate orphan drug companies to address the needs of people with OI and to encourage other companies not yet involved in this field to develop treatments for OI.

• To offer a venue to educate companies on working with patient groups and help them build partnerships with the patient community and academics.

• To facilitate the exchange of views between patient and industry representatives, in order to promote patient involvement and patient engagement.

1. **Funding of OIFE’s projects:** The OIFE may accept financial or in-kind commercial company support for a specific project. It provides the OIFE with a reliable source of income over a number of years to cover direct costs such as personnel, equipment, consultants or suppliers, mission and travel expenses, as well as related indirect costs (telephone, administrative follow-up of a project...). Companies providing support for a project may be publicly acknowledged by the OIFE (printed documents, website, and electronic communications) to ensure transparency and recognition. The support of the companies has no influence on the design and the conduct of the project, its participants, or publication, which will be the property of the organization. Companies supporting a project may be regularly consulted through transparent ad hoc processes.

2. **Funding of OIFE’s events:** the OIFE may accept financial or in-kind contribution by commercial companies for its conferences, workshops, training, capacity-building sessions and other specific events it organizes, as long as this does not revert in any kind of medical or medical-related product publicity toward the people with OI (patients) and patient representatives. It provides OIFE with a reliable source of income to cover direct and indirect costs. Funding should come from more than one source. Companies providing support for an event may be publicly acknowledged by the OIFE to ensure transparency and recognition. Sponsors do not exercise any control over the program, the choice of speakers, and the selection of attendees.
3. **Funding of OIFE’s communication activities**: The OIFE may accept financial or in-kind commercial companies’ support for its communication activities, including awareness campaigns and communication tools, such as newsletter, leaflets, reports, and websites. It provides the OIFE with a reliable source of income to cover direct costs such as personnel, equipment, consultants or suppliers, mission and travel expenses, as well as related indirect costs. Companies providing support may be mentioned in the paper and electronic materials. If included, the companies’ logo size will be modest to avoid being perceived as an advertisement. Furthermore, the companies’ mention is corporate-related and not product-related.

4. **One-off charitable donations**: One-off charitable donations are not linked to a specific project or activity. They do not create any obligation by the OIFE to publicly acknowledge the financial support it receives. However, this information may be shared at times such as the OIFE’s Annual Financial Report and Annual General Meeting.

5. **Other In-kind support**: Commercial companies may also make non-monetary contributions to the OIFE, such as - temporary staff or professional services provided without charge; legal advice; equipment donations (e.g. computers and other equipment); meeting rooms; or other non-monetary contributions (e.g. furniture, printing services).

4. **OIFE involvement in activities of the health industry**

This section deals with the OIFE’s involvement in activities related to medicinal products, medical devices or services which are marketed or distributed by industry or still under development.

4.1 **Promotional activities related to approved prescription medicines**: All promotional activities related to approved medicines are not permitted within the current EU legislation and industry codes of ethics. The OIFE does not get involved in activities that can be possibly associated with a promotional strategy and always keeps in mind potential conflicts of interest and is guided by its own agenda, lead by the interests of OI patients.
Types of activities that can be considered promotional under European and national legislation include disseminating unbalanced, non-validated or partial information on products or services distributed or marketed by a company; 
- Being quoted in the company’s communication in favor or against a product; 
- Participating in an ad hoc meeting sponsored by an individual company to inform patients on their products; 
- Agreeing that a company displays or disseminates a patient’s organization own material on the company’s exhibition stand at any trade exhibition or scientific conference; 
- Appearing in promotional materials for a certain product or testify as a “consumer” of that medicine.

4.2 Industry press releases: The OIFE refuses to be quoted in industry press releases that relate to a marketed product or a product under development. If the OIFE feels the need to communicate to the media about a product, it will issue its own press release, independently of industry.

If a company quotes the OIFE’s opinion or refers to the OIFE’s own communication materials without its permission, the OIFE will object to the company by registered letter (copy to the national industry association of the company).

4.3 Training organized by industry or a group of companies: We are aware that not all themes for a potential training provided by a commercial sponsor are neutral, either about general themes or on more product-related themes. Some programs may have an influence on OIFE’s representatives’ way of thinking. In this context, it is important that the program is sponsored by several companies, rather than a single one, and that the OIFE’s representatives selected has enough knowledge and experience. Generally speaking, it is preferable to find an equivalent program run by a Patient Group and advisable to ask commercial companies to sponsor the OIFE’s participation in the training.

4.4 Participation in conferences or seminars held by industry: If by particular need or OIFE’s interest an OIFE representative participates in an industry launch or promotion of a product, no photo must be taken or released without prior authorization of the person involved. To this end, arrangements in writing prior to the event are recommended. The OIFE will insist that multiple sources of information are involved in an ad hoc meeting sponsored by a single company, aimed at informing patients about their products. Information meetings without the presence of independent experts could be considered as an infringement of the Pharmaceutical Advertising Directive.
4.5 **Individual compensation:** There are several situations where the industry may propose honoraria to the OIFE’s representatives:
- Participation in meetings or Conferences organized by the company;
- Participation in meetings or Conferences organized by a third party;
- Reviewing industry materials, leaflets, protocols, etc.
- Consultancy on industry policy, advisory committees, and Boards, etc.

We consider that OIFE’s representatives are as much entitled as healthcare professionals to receive honoraria for similar circumstances and/or services. Nevertheless, because the OIFE’s internal policies and agreements guarantee full transparency before receiving any individual compensation, all OIFE’s volunteers will ask clearance approval to the Executive Committee, who will inform the Board of his decisions.

4.6 **Involvement in industry-source websites or other material:** The OIFE may contribute to industry websites, under the umbrella of an officially established partnership or contract, allowing the advertisement of information regarding its meetings or activities. In these cases, all published material must be reviewed and approved by the OIFE’s Executive Committee, which will ensure it is on the OI community interest.

4.7 **Diseases awareness campaigns by industry:** Disease awareness campaigns can be considered as an indirect form of advertising in some Member States. It is unwise that the OIFE be associated unless these campaigns have the backing of the public health authority. The OIFE must ensure that any campaign; is an initiative of a patient group; or, in case it’s an industry initiative, it does respond to a well-characterized public health need. Companies wishing to mention the name of OIFE must ask prior written permission.

5. **Process**

5.1 **Documentation:** When approaching or being approached by a commercial company, the OIFE usually requests information such as the main business activities of the company and does background research such as the company’s reputation with concerned patient groups and regulators.

The OIFE provides companies with its activity and financial reports, and its Financial Policy and requests every commercial company it collaborates with to carefully read and approve this Policy.
5.2 Accountability: Commercial companies supporting the OIFE receive the annual activity report and the annual financial report covering the period of the donation after these documents have been approved at the Annual Membership Meeting. The company should also receive interim and final reports concerning the project or activity they’re supporting.

5.3 Recognition and visibility of the relationship: Companies may wish to be publicly acknowledged for their financial support. The prior agreement will be reached on communication matters and detailed in the contract. As part of its transparency policy and for ‘fair’ partnership reasons, the OIFE may provide adequate recognition to a commercial company for its financial support and commitment.

The level of visibility given to the company, including the logotype used and the wording in the communication material, requires prior agreement from both parties.

When a commercial company does mention the financial support it gives to the OIFE, the wording used and/or OIFE’s name and logotype cannot be used without prior approval by the OIFE EC. Any public information should be jointly agreed between the President of the OIFE and the commercial company.

5.4 Transparency policy: By adopting and publishing a transparency policy on relationships with commercial companies, the OIFE acknowledges that the financial support it receives will never compromise its independence and future policy decisions. The Annual Financial Report of the OIFE reflects the level of financial support it receives from corporate donors and provides fair and reliable information to members and the public. All companies contributions and financial support are described and individually identified in this report and are acknowledged in projects and initiatives reports and documents, as well as in public presentations, other relevant documents, and on the OIFE’s website which includes a section where financial information and the Annual Financial Report are provided.

5.5 Derogation: In case of force majeure or situation not foreseen in this OIFE Policy on financial support by commercial companies, a derogation is possible. Any derogation to this policy, and in particular to the transparency rules applied for commercial companies in the health sector, has to be officially and transparently discussed, duly motivated, and adopted by the Board of the OIFE. If such a decision was to be significant, it would be mentioned in the Annual Report and the members would be informed through the reports at the Annual General Assembly.
This Financial Policy was reviewed, discussed and approved by the OIFE’s EC in September 2020