

FREQUENTLY ASKED QUESTIONS SUNSHINE ACT

1. What exactly is the obligation of transparency?

The obligation of transparency imposes amongst others pharmaceutical and medical devices companies, both Belgian and foreign, to document and annually publicise the premiums and benefits that they grant directly or indirectly to healthcare professionals, healthcare organisations or patient organisations ("beneficiaries").

If the beneficiary has a practice or a registered office in Belgium, the documentation and publication of the premiums and benefits must be done in the Belgian Transparency Register of betransparent.be (regardless of where the company is established).

2. Some definitions in the context of the transparency obligation

a) Sunshine Act: chapter 1 of title 3 of the Law of 18 December 2016 regarding various provisions on health, *Belgian official Journal* 27 December 2016.

b) RD Sunshine Act: Royal Decree of 14 June 2017 executing the Sunshine Act, *Belgian official Journal* 23 June 2017.

c) Company subject to notification: any entity that carries out an economic activity, irrespective of its legal form and the manner in which it is financed, as referred to in Title VII of the Treaty concerning the functioning of the European Union, in particular holders of Placing on the market of medicinal products for human or veterinary use, importers, manufacturers and distributors of medicinal products for human or veterinary use, persons engaged in the brokering of medicinal products for human or veterinary use, and distributors, retailers and manufacturers Medical devices (art. 41, §1, 1^o, Sunshine Act). Both companies established in Belgium as abroad are included in the concept of "company subject to notification".

i) What if a company is part of a group with different entities?

Companies that consist of different legal entities, whether or not in different countries, may choose to combine their disclosures in a single publication. In this case, the company subject to notification that performs the disclosure must explain in an explanatory note which legal entities (both Belgian and foreign) were exactly grouped in this single disclosure. This explanatory note can be consulted in the transparency register. In addition, the company concerned that has made the disclosure, must at all times and at the first request be able to provide all the details to the competent authority in the context of a control (the FAMHP) regarding the disclosed premiums and benefits (which entity has done exactly what for the benefit of whom).

ii) What about companies that also have other products in their portfolio?

If, in addition to medicinal products and medical devices, companies also have other products on the market, e.g. food supplements and cosmetics, these other

products also fall within the scope of the Sunshine Act, unless these other products are part of a separate legal entity with a separate company number.

iii) What about companies that are not based in the European Union?

Companies subject to notification which are established outside the European Union must notify the notification by and in the name of an affiliated company within the meaning of Article 11 of the Company Code, which is established in the European Union, or, failing that, by a legal representative established in the European Union (Article 3, paragraph 1, 3°, RD Sunshine Act). A legal representative is a person (preferably a legal entity) who has been mandated lawfully and in writing by the company subject to notification on behalf of and for its account. The legal representative must contact the platform in order to create an account in the name of the company subject to notification.

d) Premiums and benefits: all that is made public, see FAQ 3.

e) Premiums and benefits granted directly: premiums and benefits that are granted directly by a company subject to notification to a beneficiary.

f) Premiums and benefits granted indirectly: premiums and benefits that are granted indirectly by a company subject to notification to a beneficiary, including premiums and benefits granted by or through an intermediary. In case of an indirect sponsorship of participation in a scientific event (also called "educational grant") (see diagram in FAQ 5), the premium or benefit to be notified is the hospitality received by the final beneficiary (healthcare professional) (e.g. registration fee, hotel, transport) and not the "educational grant" previously transferred by the company subject to notification to the intervening healthcare organisation (see also definition of "reference year").

g) Beneficiary (art. 41, §1, 3°, Sunshine Act):

- o healthcare professional (see below)
- o healthcare organisation (see below)
- o patient organisation (see below).

h) Healthcare professional: any natural person practicing medical, dental, pharmaceutical, veterinary or nursing art or who, in the course of his professional activities, may prescribe, purchase, deliver, recommend, lease, use or administer medicines or medical devices and whose practice is established in Belgium (Art. 1, 4°, RD Sunshine Act).

Some examples: doctor, dentist, nurse, paramedic, veterinarian, hospital director, etc.

i) Healthcare organisation: any association or organisation with a seat or fixed place in Belgium active in health, medical or scientific care, whatever its legal or organisational form, as well as any legal entity through which one or more healthcare professionals provide services (Art. 41, §1, 2°, Sunshine Act).

Some examples: hospital, medical practice, scientific association of doctors, organiser of scientific congress, PCO (Professional Congress Organiser) who organises a scientific event, etc.

Some examples that should not be considered as healthcare organisation: industry associations (e.g. BRAS, APL, ...), travel agencies, etc.

j) Patient organisations: a healthcare organisation that is responsible for patient representation (Art. 1, 5°, AR Sunshine Act).

This also includes organisations that act in the form of an "umbrella organisation" grouping different patient organisations, as well as patient support groups.

A patient organisation that is composed of both patients and healthcare professionals should be considered as a patient organisation if it is composed mainly of patients and/or volunteer caregivers (non-professional) and if it supports and/or defends the interests of patients and/or volunteer caregivers (non-professional).

k) Scientific research: the experiments as referred to in Article 2, 11°, of the Law of 7 May 2004 on experiments on human persons, non-clinical studies as defined in the OECD Principles on Good Laboratory Practice and clinical trials referred to in Article 6quinquies of the Law of 25 March 1964 on medicinal products (Art. 1, 3°, RD Sunshine Act and Art. 42, §1, paragraph 2, Sunshine Act):

i) Non-clinical studies as defined in the OECD Principles on Good Laboratory Practice: *"Non-clinical health and environmental safety study, henceforth referred to simply as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities."*

ii) Experiments on the human person (as referred to in Article 2, 11°, of the Law of 7 May 2004 on experiments on human persons): any trial, study or investigation carried out on the human person whose objective is the development of knowledge specific to the exercise of the healthcare professions as referred to in Royal Decree No 78 of 10 November 1967 on the exercise of Healthcare professions.

This definition covers experiments, with or without medicinal products, including -with respect to experiments with medicinal products- clinical trials and *prospective* non-interventional studies.

On the other hand, premiums and benefits that relate to non-interventional (observational) *retrospective* studies are made public individually. Where it is impossible for companies subject to notification to distinguish retrospective from prospective non-interventional studies, the amounts must be made public on an individual basis.

iii) Clinical trials as referred to in Article 6quinquies of the Law of 25 March 1964 on medicinal products: clinical trials with veterinary medicinal products.

l) Reference year: the full calendar year in which the premiums and benefits were granted (Art. 42, §2, Sunshine Act).

The date which determines the reference year in which a premium or benefit was granted is the date of the financial transaction relating thereto and not the date on which the beneficiary actually benefited from the premium or benefit if this would not be the same date (Art. 3, clause 1, 6°, RD Sunshine Act). In case of an indirect sponsoring of participation in a scientific event (also called "*educational grant*") (see diagram in FAQ 5), the date that determines in which reference year a premium or benefit was made, is the date on which the hospitality was effectively paid by the intervening healthcare organisation (e.g. time of payment of flight ticket, hotel, registration fee) and not the date on which the company subject to notification transferred the "educational grant" (or advance payment) to the intervening healthcare organisation (art. 3, par. 1, 8°, Royal Decree Sunshine Act).

Companies subject to notification must notify these data by 31 May of the year following the reference year (Art. 42, §2, Sunshine Act). The data shall be published no later than 30 June of the year following the reference year (Art. 43, §1, clause 4, Sunshine Act). The first reference year is 2017 (Art. 7, §1, RD Sunshine Act).

Example: premiums and benefits granted between 1 January 2017 and 31 December 2017

- shall be communicated by the company subject to notification to betransparent.be no later than 31 May 2018,
- shall be made public in the Transparency Register no later than 30 June 2018.

As an exception however, an additional period is granted for premiums and benefits for medicinal products for veterinary use. Their first reference year is 2018, with a first publication in June 2019.

m) Premiums and benefits in kind: premiums and benefits granted in kind are also subject to transparency requirements (Art. 41, §2, Sunshine Act).

A few examples: the payment of the registration fee for participation in a congress to the congress organiser (no payment directly to the participating healthcare professional); organising a (e.g. in-house) product training by a company subject to notification whereby the participating healthcare professionals do not have to pay a registration fee or where the costs of the training are not fully covered by the registration fee.

For the publication of these premiums and benefits in kind the company subject to notification must estimate the cost based on the normal market value, the Belgian market being taken as a reference. The company subject to notification must at all times be able to demonstrate how it calculated the cost of the benefit in kind.

The date that determines the reference year in which a premium or benefit in kind was granted, is the date on which the premium or benefit concerned was granted by the company subject to notification and not the date on which the beneficiary actually benefited from it if it were to be different.

3. What exactly is made public?

A. Publication on an individual basis

All premiums and benefits are made public on an individual basis (on behalf of the recipient who received them directly or indirectly). In particular, each company subject to notification shall make public, for each beneficiary, the amounts of the premiums and benefits granted to that beneficiary during a calendar year.

These premiums and benefits are grouped by category (see below), so that a total amount per category and per beneficiary appears per calendar year in the Transparency Register. The details of the publication shall be communicated by the company if the beneficiary concerned or the competent authority so requests.

The categories of premiums and benefits as referred to above are as follows:

I. With regard to premiums and benefits granted directly or indirectly to healthcare professionals :

- a) The contributions to the costs of **scientific manifestations**, such as registration costs and travel and subsistence costs.

Offered meals are not to be made public, as this is already subject to several strict criteria and maximum amounts. However, where it is not possible to distinguish such costs into the total of the contribution to the costs, they can be made public (e.g. if they are part of a package).

- b) The fees, payment and reimbursement of costs for **services and consultancy**.

This can be a reasonable compensation for e.g. giving a scientific lecture, participation in an expert meeting, writing a scientific publication.

II. With regard to premiums and benefits granted directly or indirectly to healthcare organisations:

- a) Contributions to the **cost of scientific manifestations**, such as registration and travel and subsistence costs, and sponsorship agreements with healthcare organisations or with third parties appointed by these organisations to organise the scientific event.

This concerns contributions from pharmaceutical and medical devices companies to hospitals or associations of healthcare providers to cover the costs of organising a scientific congress.

In the case of contributions to a patient organisation to organise a scientific event, publication takes place under category III, b (see below).

- b) Fees, payments and reimbursement of costs for **services and consultancy**.

This may include reasonable compensation, for e.g. to give a scientific lecture, to participate in a meeting of experts, to write a scientific publication, for which the compensation is being paid on the account of a healthcare organisation.

However, if the fees paid to the healthcare organisation are fully or partially transferred to one or more individual healthcare professionals, the publication will take place on behalf of the healthcare professionals concerned as they are the beneficiaries of the fees. In this case, the company publishes the total amount of the fees paid on behalf of the healthcare professionals concerned, unless the healthcare organisation has communicated, if applicable, to the company the distribution of fees between the healthcare organisation and the healthcare professional, in which case the company will publish the fees partly on behalf of the healthcare organisation and partly on behalf of the healthcare professional, according to the agreed key.

For premiums and benefits granted to a healthcare professional who acts as a company or who is part of a de facto association, see FAQ 5 below.

- c) **Donations and grants** that support healthcare.

This includes, among other things, the means that the industry puts at the disposal of healthcare organisations to support healthcare or scientific research. In no event shall these means be granted as a means of stimulating the recommendation, prescription, purchase, sale, delivery or administration of medicinal products or medical devices.

III. With regard to premiums and benefits granted directly or indirectly to patient organisations:

a) Fees, payments and reimbursement of expenses for **services and consultancy**:

This can be a reasonable fee granted to a patient organisation for its services as an expert or consultant, e.g. participation in a meeting with patient experts; speaker services; giving advice to a pharmaceutical or medical device company on priorities for patients in clinical trials or the relevance of specific research for patients.

b) Financial or other **support**:

This includes amongst others financial support granted to a patient organisation for the organisation of a scientific event; to support disease awareness campaigns; to support the development of informative material for patients or a website for patients.

This may also involve non-financial support (in kind), such as the provision of manpower or space. For the purpose of disclosure, the company subject to notification needs to value the in kind granted premium or benefit on the basis of the normal market value, using the Belgian market as a reference. The company subject to notification must be able to demonstrate at all times how it was calculated.

The nature of the financial or other support may, if necessary, be further described by the company subject to notification in an "Explanatory Note" which can be consulted in the Transparency Register for every company subject to notification if it uploaded one.

A diverse framework of applicable legislation, deontological codes, and internal corporate policies is aimed at ensuring a transparent and honest cooperation that leads to medical progress in the interest of the patient. The transparency register therefore includes the support of pharmaceutical and medical device companies, but support from other bodies to patient organisations is beyond the scope of this register.

B. Publication on an aggregate basis

There is only one legal exception to the publication on an individual basis: **premiums and benefits granted in the context of scientific research**. These premiums and benefits are published in an aggregated, non-individual way, per company, without mentioning the identity of the beneficiaries (Article 42, §1, clause 3, Sunshine Act). Each company will therefore annually make public one total amount for scientific research in Belgium.

See below for a summary:

BENEFICIARY	PREMIUMS AND BENEFITS TO BE PUBLISHED <u>NOMINATIVELY</u>
Healthcare professional	a) The contributions to the costs of participation to scientific manifestations , such as registration costs and travel and subsistence costs b) The fees, payment and reimbursement of costs for services and consultancy .
Healthcare organisation	a) Contributions to the cost of scientific events , such as registration and travel and subsistence costs, and sponsorship agreements with healthcare organisations or with third parties appointed by these organisations to organise the scientific event b) Fees, payments and reimbursement of costs for services and consultancy c) Donations and grants that support healthcare

Patient organisation	a) Fees, payments and reimbursement of expenses for services and consultancy b) Financial or other support
PREMIUMS AND BENEFITS TO BE PUBLISHED ON AN AGGREGATE BASIS	
Healthcare professional or healthcare organisation (not nominatively)	premiums and benefits granted in the context of scientific research : a) Clinical trials as referred to in Article 6quinquies of the Law of 25 March 1964 on medicinal product b) Experiments on the human person (as referred to in Article 2, 11°, of the Law of 7 May 2004 on experiments on human persons c) Non-clinical studies as defined in the OECD Principles on Good Laboratory Practice

4. What is not made public?

Anything that is not listed under FAQ 3.

The following exceptions are mentioned in the Sunshine Act (Art. 41, §3, Sunshine Act):

- Gifts of negligible value related to the practice of the profession (already governed by strict legal and/or ethical provisions);
- Meals and beverages offered as part of scientific events (already governed by strict legal and/or ethical provisions);
- The economic margins and discounts that are part of the usual purchases and sales of medicinal products or medical devices by a company subject to notification or between the latter and a beneficiary (this concerns the purely commercial aspect between the players in the healthcare sector, which is not consistent with the objective of the transparency);
- Drug samples.

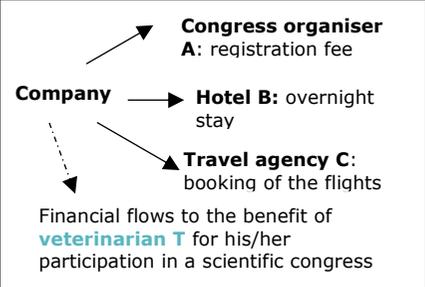
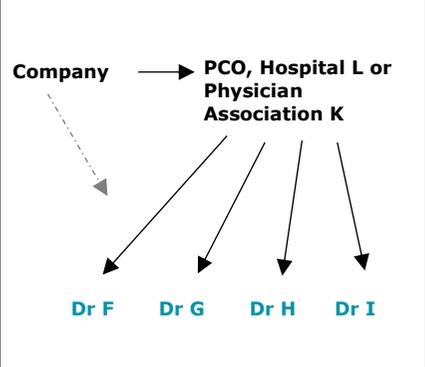
5. On whose behalf the premiums and benefits are made public?

The publication shall always take place on behalf of the direct or indirect **beneficiary** of the granted benefit (Art. 41, §2, Sunshine Act), taking into account the following (see Art. 3, clause 1, 4°, RD Sunshine Act):

- a) regarding fees, payments and reimbursement of costs for services and consultancy to healthcare organisations, the beneficiary is the latter, except if it concerns a healthcare professional who acts as a company or who is part of a de facto association, in which case the beneficiary is the healthcare professional who provided the services that led to the fees and payments;
- b) regarding contributions to the costs of participation in scientific events, the beneficiary is the healthcare professional who has actually participated in the scientific event even if the healthcare professional has received this premium or benefit through a healthcare organisation;
- c) regarding contributions to the costs of organising scientific events, the beneficiary shall be the healthcare organisation or the patient organisation that received the contributions.

See below for a **diagram** with examples and explanations:

BENEFICIARIES			
SITUATION	EXAMPLES		EXPLICATION
	Given premium or benefit	Publication on behalf of	
FEEES, PAYMENTS AND REIMBURSEMENT OF COSTS FOR SERVICES AND CONSULTANCY			
A healthcare professional is the beneficiary of the fees			
Fees, payments and reimbursement of costs granted directly to a healthcare professional : publication on behalf of the healthcare professional beneficiary (Art. 3, par. 1, 4°, RD Sunshine Act)	Company → Pharmacist X	Pharmacist X	Pharmacist X performs a scientific service for the company (giving a presentation at a congress, writing a scientific article, participating in a meeting of experts, etc.) and the fees are paid directly to the pharmacist's account (natural person). The publication takes place on behalf of the pharmacist. If the fees are paid into the account of a bvba/sprl, the publication will still take place on behalf of the pharmacist (see below).
Fees, payments and reimbursement of costs granted indirectly to a healthcare professional : publication on behalf of the healthcare professional beneficiary (Art. 3, par. 1, 4°, RD Sunshine Act)	Company → Hospital ↓ Dr. B works for the hospital and receives a part or the totality of the fees paid by the hospital	Dr B	Dr B performs a scientific service for the company. The fees are paid to an account of the hospital for which Dr B works and the hospital then <u>transfers the fees fully or partially</u> to Dr B. In this case, Dr B is the (indirect) beneficiary of the fees and the publication must therefore take place under his name. The company shall publish on behalf of Dr B the total amount of the fees it paid, unless the hospital has communicated to the company the distribution of fees between the hospital and Dr B (cf. the obligation to communicate as set in Art. 3, par. 1, 8°, RD Sunshine Act), in which case the company will publish the fees partially (i) on behalf of the hospital and (ii) partially on behalf of Dr B, according to the distribution key.
A healthcare organisation is the beneficiary of the fees			
Fees, payments and reimbursement of costs granted to a healthcare organisation : publication on behalf of the beneficiary healthcare organisation, except in the case of a healthcare professional who practices as a legal entity or is part of a de facto association, in which case the beneficiary is the healthcare professional who actually performed the services originating the fees and expenses (Art. 3, par. 1, 4°, a, RD Sunshine Act)	Company → Belgian Nurses Association	Belgian Nurses Association	The "Belgian Nurses Association" performed a scientific service for the company. Fees were paid to the healthcare organisation <u>without any retrocession to individual healthcare professionals</u> . The healthcare organisation is therefore the final beneficiary of the fees and the publication takes place on behalf of the healthcare organisation.
	Company → bvba/sprl <i>(single person legal entity)</i> Dr Y performed a scientific service	Dr Y	The publication takes place on behalf of the (individual) healthcare professional who performed the scientific service and not on behalf of the company (sprl/bvba or other) on whose account the fees were paid.
	Company → GP Practice <i>(consisting of dr N, O and P: Dr O receives a compensation for his participation in an Advisory Board)</i>	Dr O	The publication takes place on behalf of the (individual) healthcare professional who performed the scientific service (in our example Dr O) and not on behalf of the company in which he/she works (here "GP Practice"), even though the fees were paid into the "GP Practice" account.
A patient organisation is the beneficiary of the fees			
Fees, payments and reimbursement of costs granted to a patient organisation : publication on behalf of the patient organisation (Art. 3, par. 1, 4°, RD Sunshine Act)	Company → Patient organisation	Patient organisation	The patient organisation is the direct beneficiary (e.g. a contribution paid to the patient organisation's account).

DONATIONS AND GRANTS THAT SUPPORT HEALTHCARE (only granted to a healthcare organisation)			
Donation or grant granted to a healthcare organisation : on behalf of the healthcare organisation (Art. 3, par. 1, 4°, RD Sunshine Act)	Company → Hospital	Hospital	The hospital is the direct beneficiary (e.g. a grant paid to the hospital's account).
FINANCIAL OR OTHER SUPPORT (only granted to a patient organisation)			
Financial or other support granted to a patient organisation : on behalf of the patient organisation (Art. 3, par. 1, 4°, RD Sunshine Act)	Company → Patient organisation	Patient organisation	The patient organisation is the direct beneficiary (e.g. a contribution paid to the patient organisation's account).
CONTRIBUTIONS TO THE COSTS OF PARTICIPATION IN SCIENTIFIC EVENTS			
Direct sponsorship of the participation of healthcare professionals in scientific events: on behalf of the healthcare professional who actually participated in the scientific event (Art. 3, par. 1, 4°, b, RD Sunshine Act)		Veterinarian T	Even if veterinarian T does not receive any money (the company has made payments to the hotel, the congress organiser and the travel agency), it is indeed the veterinarian T who is the final beneficiary because he/she is the one who attended the congress, took advantage of the overnight stays and took the flight.
Indirect sponsorship of the participation of healthcare professionals in scientific events: on behalf of the healthcare professional who actually participated in the scientific event, even though this healthcare professional received this premium or benefit through a healthcare organisation (Art. 3, par. 1, 4°, b, RD Sunshine Act)		Dr F, Dr G, Dr H and Dr I	<p>In the case of indirect sponsorship, the company offers an overall amount (also called an "educational grant") to a healthcare organisation (in this example: a PCO, Hospital L or Physician Association K) that chooses itself which healthcare professionals will benefit from this sponsorship. The company does not know <i>in advance</i> which healthcare professionals will be sponsored to participate in the scientific event organised by a healthcare organisation. However, since it are the individual healthcare professionals who are the final (indirect) beneficiaries of the sponsorship, the publication must take place on their behalf.</p> <p>To this end, Art. 3, par. 1, 8°, RD Sunshine Act provides that the healthcare organisation that actually received the funds (in this example the PCO, Hospital L or Physician Association K) must communicate to the companies that have granted a sponsorship, by 31 December of the reference year concerned at the latest, the identity of the final individual beneficiaries and the amount of the premiums or benefits they have received. The companies concerned will thus be able to publish on behalf of the healthcare professionals in accordance with the provisions of the Sunshine Act.</p>

CONTRIBUTIONS TO THE COSTS OF <u>ORGANISING</u> SCIENTIFIC EVENTS			
<p><u>Direct sponsorship of a healthcare organisation</u> for the organisation of a scientific event: on behalf of the healthcare organisation that received the contributions (Art. 3, par. 1, 4°, c, RD Sunshine Act)</p>	<p>Company → Paramedic Association</p>	Paramedic Association	<p>In this example, the "Paramedic Association" (= healthcare organisation) organises a scientific event and the company offers a financial contribution to cover the costs of the organisation. In this case, it is clear that the "Paramedic Association" is the beneficiary of the sponsorship.</p> <p>Attention: if the healthcare organisation or the patient organisation organising the scientific event uses the contributions received from the company to cover fees, transport costs, overnight stays or registration fees of individual healthcare professionals at the request of the sponsoring company, then these amounts must be made public on behalf of the concerned healthcare professionals in accordance with Art. 3, par. 1, 4° a or b RD Sunshine Act.</p>
	<p>Company → PCO</p>	PCO	<p>In this example, a PCO ("Professional Congress Organizer") organises a scientific event on its own initiative. This PCO is therefore the beneficiary of the sponsorship, since a PCO meets the definition of a healthcare organisation.</p>
<p><u>Indirect sponsorship of a healthcare organisation</u> for the organisation of a scientific event: on behalf of the healthcare organisation that received the contributions (Art. 3, par. 1, 4°, c, RD Sunshine Act)</p>	<p>Company → PCO</p> <p>Mission: organise a congress</p> <p>Scientific Association of Oncologists</p>	Scientific Association of Oncologists	<p>In this example, a healthcare organisation ("Scientific Association of Oncologists") mandates a PCO ("Professional Congress Organizer") to organise a scientific event. To this end, the PCO (or the Scientific Association of Oncologists) requests a sponsorship from companies to cover the costs of the scientific activities. The company pays a sponsorship to the PCO (not to the healthcare organisation). But since the request comes from an healthcare organisation (the Scientific Association of Oncologists), the publication must take place on behalf of this healthcare organisation which is the final beneficiary of the sponsorship.</p> <p>There are thus two different healthcare organisations involved: the PCO on the one hand and the Scientific Association of Oncologists on the other. In such a case, it is the healthcare organisation that is the <u>final</u> beneficiary of the sponsorship on whose behalf the publication must take place (in our example: the Scientific Association of Oncologists and not the PCO which acts in this case as an "intermediate").</p>
<p><u>Sponsorship of a patient organisation for the organisation of a scientific event</u>: on behalf of the patient organisation that received the contributions (Art. 3, par. 1, 4°, c RD Sunshine Act)</p>	<p>Company → Patient organisation</p>	Patient organisation	<p>In this example, the patient organisation organises a scientific event and the company offers a financial contribution to cover the costs of the organisation. The patient organisation is the direct beneficiary of the sponsorship.</p>

6. How can I consult the Transparency Register?

By clicking [here](#).

7. I do not find some data in the Transparency Register. How can this be explained?

A. I am a healthcare professional and I cannot find my name in the Transparency Register while I have received premiums and benefits :

This can be explained because of the fact that the received premiums and benefits do not fall into a category to be published in a nominative way (e.g. meals, remuneration received for scientific research, gifts of negligible value and related to the practice of the profession).

B. I am a patient and I cannot find the name of my healthcare professional or healthcare organisation in the Transparency Register:

It is possible that you cannot find a healthcare professional or healthcare organisation in the Transparency Register. This can have several reasons:

- this healthcare professional / healthcare organisation did not receive premiums or benefits from a pharmaceutical or medical devices company,
- this healthcare professional / healthcare organisation has received premiums or benefits from a pharmaceutical or medical devices company, but from a different nature than those to be disclosed on this website (e.g. in the context of scientific research in which case there is no nominative publication).

Moreover, it is not because a healthcare professional is not mentioned in the transparency register that he/she is not continuously being educated. While it is true that the costs of the participation in scientific events are often sponsored by the industry (subject to strict legal and ethical rules), this is not always the case. Healthcare professionals can also follow continuing education at their own expense.

C. I am a patient and I am looking for a pharmaceutical or medical devices company but I do not find it in the Transparency Register:

There may be several reasons, but the most common ones are the following:

- Regarding premiums and benefits granted in 2015: the company concerned is not a member of pharma.be: the premiums and benefits published by the platform in 2016 are only those voluntary made in 2015 by pharmaceutical companies members of pharma.be (click [here](#) to see the list of members).
- Regarding premiums and benefits granted in 2016: the company concerned is not a member of pharma.be (click [here](#)), beMedTech (click [here](#)) or FeBelGen (click [here](#)). The legal obligation of transparency applicable to all companies applies as from calendar year 2017.

8. I am a healthcare professional and do not agree with my published data. What can I do?

A. My data are incorrect

There is a procedure for correcting your incorrect data. On the website of the platform, where your data are published (see "*Consult the register*"), you can click a button to report a possible error. A form will open that you must fill in to identify yourself and describe the error encountered. When you click "Send", the form will be sent directly to the pharmaceutical or medical device company that has published the data. This company will contact you to make the necessary corrections. This procedure proceeds directly between the company and you, and not via the platform.

B. I do not want my data to be visible in the transparency register

As the publication of your personal data takes place according to a legal basis in the Sunshine Act, you cannot object to the publication of the data mentioned in the law. Companies subject to notification should therefore not have your consent to be able to publish this data in the Transparency Register. However, they must first inform you of this publication in accordance with the Law of Privacy ("Law of 8 December 1992 on the protection of privacy with regard to the processing of personal data"). This information is often provided by a clause included in the contract you have entered into with the company subject to notification.

9. What is an Explanatory note?

An Explanatory note is a document that the companies subject to notification can publish to provide more information about the premiums and benefits they have granted. The Explanatory note appears in the Transparency Register.

The publication of an Explanatory Note is purely optional and therefore not mandatory, except in the case of a grouped notification when an enterprise is part of a group with different entities (see FAQ 2 for the concept of "company subject to notification").

In addition, companies subject to notification are advised, when disclosing premiums and benefits relating to patient associations, to clarify or explain in an Explanatory note what the disclosed premiums and benefits exactly are.

10. Sanctions

A. Competent authority

The Federal Agency for Medicines and Health Products (FAMHP) is responsible for monitoring compliance with the legislation.

Infringements may be punished by fines of 1.600 to 120.000 euro (Art. 47 Sunshine Act).

B. What if the beneficiaries do not cooperate and do not communicate certain data?

Article 42, §3, Sunshine Act provides that beneficiaries must communicate to the companies subject to notification the necessary information in order to enable them to comply with the Sunshine Act. In addition, Art. 3, paragraph 1, 8°, Royal Decree Sunshine Act provides that this obligation to collaborate applies to both the beneficiaries who have

directly received a premium or benefit, and to the beneficiaries who have received funds in order to transfer them entirely or partly to one or more other beneficiaries. In the latter case, the beneficiary who has received the funds from the company subject to notification must inform this company, inter alia, of the identity of the final beneficiaries, as well as of the amount of the premiums or benefits received by them. The information to be notified to the companies subject to notification in view of the implementation of Article 42 of the Act must be done by 31 December of the concerned reference year at the latest.

However, if the beneficiary does not do so, the company subject to notification must inform the FAMHP or the platform betransparent.be thereof (which in turn will notify the FAMHP).