be transparent be building transparency in healthcare relationships

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°, 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).

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):
- healthcare professional (see below)
- healthcare organisation (see below)
- 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, farmer, etc.

Some examples that should not be considered as a healthcare professional: dental technician, secretary, 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, wholesaler receiving a premium or benefit from a company subject to notification, PCO (Professional Congress Organiser) who organises a scientific event at its own initiative, etc.

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

j) Patient organisation: 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 witch 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).

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.*

The first reference year is 2017. 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 NOMINATIVELY
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.

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

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).