The Belgian Sunshine Act has been published in the Belgian Official Gazette on 27 December 2016. A few months later, a royal decree implementing the Sunshine Act marked the effective entry into force of the Sunshine Act on 23 June 2017, while providing companies with essential clarifications in terms of scope and operation.

Several points deserve special emphasis when comparing the Sunshine Act to the methods found in the deontological or ethical codes of pharma.be and beMedTech to disclose transfers of value.

Firstly, the scope of the Sunshine Act is broader than the ethical rules, both with regard to companies subject to reporting and to the beneficiaries. The transfers of value covered by the new system are, however, largely similar to the existing categories despite small differences. Furthermore, several practical aspects are now expressly regulated by the act and the royal decree, which should put an end to the use of methodological notes that companies were required to submit on www.betransparent.be. The Sunshine Act is also accompanied by specific implementation and control measures in Belgium. Foreign companies are therefore encouraged to pay attention to these specificities and to the rules that concern them directly. Lastly, the Sunshine Act is aligned with the legislation on personal data, the collecting of which will take place under conditions different from the self-regulation system which was applicable until now.

Persons and entities covered by the Sunshine Act

On the one hand, the obligation to notify transfers of value applies to any entities carrying out an economic activity, regardless of their legal form and the manner in which they are financed, within the meaning of Title VII of the TFEU.

This includes, « among others », MA holders of medicinal products for human or veterinary use, importers, manufacturers and distributors of medicinal products for human or veterinary use, persons engaged in brokering activities in medicinal products for human or veterinary use and distributors, retailers and manufacturers of medical devices.

There is, however, a difference here between the French and Dutch texts. The French version refers to the word « notamment » (« among others »), which leads to believe that the aforementioned companies are only a list of examples. The Sunshine Act would therefore apply to « any entity carrying out an economic activity » including, among others, cosmetic, food, or biocidal products companies. The Dutch version uses the term « meer bepaald » (« id est », « that is »), thereby restricting the list of companies to those referred to in the previous paragraph. A correction of the French version should be published shortly in the Belgian Official Gazette, to align the French text with the Dutch text and thus limiting the scope of the transparency obligations.

On the other hand, three types of beneficiaries are distinguished: healthcare professionals ("HCPs"), healthcare organisations ("HCOs") and patient organisations ("POs"). When they are practicing in Belgium or have their seat in Belgium, any transfer of value made to these beneficiaries must be disclosed in the Belgian transparency register.

- The following professionals are considered as HCPs:
  - Individuals acting as medical, dental, pharmaceutical, veterinary or nursing practitioners, and whose practice is established in Belgium, and

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1. Act of 18 December 2016 on various health-related matters (art. 41 and seq.), B.O.G. 27 December 2016.
3. The provision referred to above is article 41, par. 1, 1° of the Act of 18 December 2016 on various health-related matters.
Individuals who, in the course of their professional activities, may prescribe, purchase, deliver, recommend, rent, use or administer medicinal products or medical devices, and whose practice is established in Belgium.

Are included, among other additions, all veterinary healthcare professionals, but also all persons using medicinal products (e.g. medical aides, pharmaceutical-technical assistants) and medical devices (e.g. laboratory scientific officer using in vitro diagnostic devices, laboratory technologists) or renting those products (e.g. professionals renting medicinal products as part of their private practice, or in hospitals). Hospital managers and persons working in medicinal products and medical device purchasing groups also appear to be covered, the intention of the legislature being, clearly, to extend the scope of the transparency requirement.

- The following organisations are considered as HCOs:
  - Associations or organisations active in healthcare, medical or scientific care, regardless of their legal or organisational form, and
  - Legal entities through which one or more HCPs provide services.

  This definition covers, in particular, hospitals, foundations, medical offices, scientific associations of physicians, and scientific congress organisers.

- Lastly, POs are understood as HCOs, as defined above, specifically in charge of patients’ representation. The inclusion of POs is a novelty.

Transfers of value subject to reporting

Details concerning the transfers of value regulated by the Sunshine Act can be found in the table at the bottom of the page. There is, it seems, little change as compared to the transfers of value disclosed to date on www.betransparent.be pursuant to ethical rules.

It is worth noting that all transfers of value, pecuniary or in kind, granted directly or indirectly, from Belgium or elsewhere, are concerned. Therefore:

- In order to publish advantages/benefits in kind, companies subject to reporting will have to evaluate their amount in EUR, based on the market value applicable in Belgium.
- Transfers of value made through an intermediary third party will be considered as indirect transfers.

By way of example, grants provided to HCOs, through which an HCP attends a scientific congress, will be published in the name of the HCP acting as effective beneficiary of the sponsoring. It will therefore become necessary for medical devices companies member of MedTech Europe, which are subject to the ban on direct sponsorship of HCPs, as of 1 January 2018, to know the identity of the HCP to whom transfers of value have been indirectly made. In this respect, the Sunshine Act provides that data relating to final beneficiaries must be provided to companies subject to reporting at the latest by the 31st of December of the reference period.

Financing of event services companies for the organisation of scientific events at the benefit of HCOs, will be published in the name of the HCOs which benefits from the sponsoring in fine.

Lastly, the addition of POs to the list of beneficiaries results in reporting (i) fees, payments and reimbursements of expenses for services and consultancy, as well as (ii) any financial or other support granted to such entities. It seems that this new inclusion has a very extensive reach. Companies are therefore encouraged to keep track of any advantage or benefit granted to POs, to assess their conformity with article 10 of the act of 25 March 1964 on medicinal products, and to agree contractually on any form of support.

Practical aspects

The first reference period to record transfers of value is the calendar year 2017 (i.e. from 1 January 2017 to 31 December 2017). It should be noted that the date of the financial transaction will determine the applicable calendar year, and not the date on which the beneficiary (or beneficiaries) have effectively received an advantage/benefit. An exemption scheme is provided for veterinary companies subject to reporting, but only in respect of their veterinary activities – for these companies, the first reference period is postponed to 1 January 2018.

Companies subject to reporting should ensure that all relevant data are uploaded online for the first time by 31 May 2018 using a .xls or .csv file. These data will be published at the latest by June 30, 2018 on www.betransparent.be. This website should soon receive official recognition via a royal decree certifying the www.betransparent.be for the purposes of transparency reporting.

When they have not granted any gift or advantage/benefit during the reference year, it should be stressed that companies subject to reporting remain bound by a reporting (information) obligation. In this case, companies must report that they have not transferred any values by following the procedure detailed above.
Monitoring and implementation

 Whereas the www.betransparent.be platform should soon be accredited for the purpose of transparency reporting, the Federal Agency for Medicines and Health Products (FAMHP) remains responsible for ensuring compliance with the Sunshine Act. In this context, companies and members of their staff may be subject to hearings, interrogations and inspections. Certain documents may also be required and findings made on this basis.

 In case of infringement, FAMHP officers are entitled to draw up a report and, if necessary, to issue warnings, possibly accompanied by deadlines for complying. The sanctions provided for by the Sunshine Act amount to between EUR 1,600 and EUR 120,000. Settlements can also be proposed, which implies discontinuance of (criminal) court proceedings in case of payment.

 Impact on foreign companies

 Companies outside Belgium (including non-EU companies) which meet the general definition of a “company subject to reporting” are subject to the Sunshine Act as soon as they grant gifts and advantages (transfers of value) to beneficiaries covered by the Sunshine Act.

 The Sunshine Act adds that the place where gifts and advantages have been granted does not matter.

 An additional obligation is placed on companies located outside the EU, which are now required to designate either a related company located in the EU or (in the absence of a related company) a legal representative within the EU. The designated European company will be responsible to proceed with the notification imposed by the Sunshine Act.

 As this takes place, it should be remembered that any company subject to reporting remains responsible to inform the Belgian authorities via www.betransparent.be, even if no transfer of value has taken place during a given calendar year. One question which remains is does it mean that the Sunshine Act imposes such reporting (information) obligation on all foreign companies which meet the definition of “company subject to reporting”?

 Practically speaking, it is difficult to envisage how foreign companies could be required to proceed to such transparency notifications, and how compliance with this requirement will be effectively monitored by the FAMHP, in particular when there is no subsidiary or mother company on the EU territory.

 Processing of personal data

 Many personal data relating to HCPs are collected by companies subject to reporting to comply with the requirements of the Sunshine Act: name, first name, occupation and/or unique identifiers (i.e. as the case may be: company numbers, NIHDI numbers, national registry numbers and other identifiers).

 While it was previously mandatory to obtain the HCPs’ consent prior processing their personal data under self-regulation codes developed by industry associations, it turns out that the binding nature of the Sunshine Act provides as such sufficient legal grounds to be able to stop obtaining HCPs’ consent for that purpose.

 Therefore, the absence of consent, or the refusal to consent, which some HCPs may have expressed before the Sunshine Act entered into force does no longer constitute an obstacle for data collection and publication on www.betransparent.be.

 Companies should nonetheless pay close attention to informing beneficiary HCPs correctly about the publication when collecting all necessary data, in accordance with Belgian (act of 8 December 1992 regarding the protection of privacy) and European (including the general data protection regulation, “GDPR”) laws.

 It should be noted that the www.betransparent.be platform provided Belgian companies with a 12-page document titled « frequently asked questions » in July 2017 to guide them towards compliance with the new legal obligations.
In closing, the following table relates certain changes brought by the Sunshine Act, as compared to self-regulation provisions enacted by the two industry associations listed hereunder:

<table>
<thead>
<tr>
<th>Companies subject to reporting</th>
<th>pharma.be member companies</th>
<th>beMedTech member companies</th>
<th>Any entities carrying out an economic activity, regardless of their legal form and the manner in which they are financed, within the meaning of Title VII of the TFEU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Published transfers of value (HCPs)</td>
<td>Contributions to costs relating to scientific events (such as: registration, travel and accommodation costs)</td>
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<td>Contributions to costs relating to scientific events (such as: registration, travel and accommodation costs)</td>
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<tr>
<td></td>
<td>Fees for services and consultancy</td>
<td>Fees for services and consultancy</td>
<td>Fees, payments and reimbursements of expenses for services and consultancy</td>
</tr>
<tr>
<td>Published transfers of value (HCOs)</td>
<td>Donations and funding which support healthcare</td>
<td>Donations and funding which support healthcare</td>
<td>Donations and funding which support healthcare</td>
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<td></td>
<td>Contributions to costs relating to scientific events, including sponsoring offered to HCOs to participate in such events (such as: registration, travel and accommodation costs, and sponsoring agreements with HCOs or third parties selected by HCOs to manage a scientific event)</td>
<td>Contributions to costs relating to scientific events, including sponsoring offered to HCOs to participate in such events (such as: registration, travel and accommodation costs, and sponsoring agreements with HCOs or third parties selected by HCOs to manage a scientific event)</td>
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<tr>
<td>Published transfers of value (PAs)</td>
<td>Not included</td>
<td>Not included</td>
<td>Fees, payments and reimbursements of expenses for services and consultancy</td>
</tr>
<tr>
<td>Published transfers of value (R&amp;D)</td>
<td>Transfers of value to HCPs or HCOs in connection with the planning or performance of non-clinical studies, clinical trials and non-interventional studies)</td>
<td>Transfers of value to HCPs or HCOs in connection with the planning or performance of non-clinical studies, clinical trials and non-interventional studies)</td>
<td>Gifts and advantages granted in the context of scientific research (experimentations on the human person, non-clinical studies and clinical trials)</td>
</tr>
<tr>
<td>First publication on betransparent.be (deadline)</td>
<td>30 June 2016</td>
<td>30 June 2017</td>
<td>30 June 2018 30 June 2019 (one-year transition period for companies in the veterinary sector)</td>
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</tbody>
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