



newsletter

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Transparency register

On 1 January 2012, the Code of Conduct for the Disclosure of Financial Relations (further referred to as 'the code of conduct') came into force. This newsletter provides further information about the current status regarding the establishment of the transparency register and how those affected can prepare themselves.

The code of conduct requires that arrangements be made for the disclosure of service and sponsorship relationships agreed between pharmaceutical companies and healthcare professionals, partnerships of healthcare professionals and institutions which employ healthcare professionals.

Disclosure is compulsory if the healthcare professional, partnership or institution in question receives more than € 500 (in money or in kind) from a pharmaceutical company in any calendar year.

The code of conduct stipulates that disclosure is to take place each year following the year-end by means of a single centrally held transparency register. In principle, the pharmaceutical companies are responsible for reporting financial relationships to the transparency register. If a healthcare professional has entered into a financial relationship with a pharmaceutical company based abroad, the obligation to register it lies with the healthcare professional. Financial relationships effectuated in 2012 and which exceed the € 500 limit in total must be entered in the central register at the start of 2013.

Status of the transparency register

The establishment of the transparency register has been delayed by legal complications. It is expected that the transparency register will be operational in early October 2012. The transparency register is being set up by the Foundation for the Code for Pharmaceutical Advertising (CGR), in collaboration with the Ministry of Health, Welfare and Sport, the Royal Dutch Medical Association (KNMG), the Association for Innovative Medicines in the Netherlands (Nefarma) and the Association for the Generic Drugs Industry in the Netherlands (BOGIN). Management will be entrusted to a new independent foundation.

The public will be able to consult the transparency register through the internet. The data will be searchable by the name of the recipient, i.e. the name of the healthcare professional, partnership or institution. Entering the name will produce a summary of the reported financial relationships which the party in question has had with pharmaceutical companies in 2012.

For the sake of clarity of registration and accurate linking of data, a reliable database is crucial. It is more efficient to make use of an existing infrastructure for such a database than to develop and manage one in-house.

The Netherlands has a database of healthcare professionals of this kind in the form of the Individual Healthcare Professions (BIG) register, which provides a guarantee of

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accuracy in registering personal data and compiling the central register. A complication is that the BIG number is a so-called "article 24 Data Protection Act number". Such numbers may only be used for the implementation of the act in question or for purposes laid down by law.

The Individual Healthcare Professions Act does not currently provide scope for using the BIG number for the disclosure of financial relationships between healthcare professionals and pharmaceuticals companies. An agreement was recently reached with the Ministry of Health, Welfare and Sport that this legal obstacle will be removed by means of an amendment to the Individual Healthcare Professions Act or by making a provision under the Data Protection Act.

Preparing for early 2013

At the start of 2013, the financial relationships of 2012 will have to be entered in the central transparency register.

The register has the following reporting structure:

1. The name of the healthcare professional, partnership or institution concerned;
2. The name of the pharmaceutical company concerned;
3. The nature of the financial relationship;
4. The amount;
5. The year to which the relationship relates.

Name of the recipient: in order to be able to "match" the names of healthcare professionals, a unique number must be used. As indicated above, the BIG number will be used for healthcare professionals. The legal basis for doing so will be created. For partnerships and institutions (legal persons), their registration numbers with the Chamber of Commerce will be used.

Name of the pharmaceutical company: the name of the pharmaceutical company which registers as a sponsor. If a professional has entered into a financial relationship with a pharmaceutical company abroad and reports the relationship him/herself, the company name submitted by him/her will be entered.

Nature of the relationship: the reporting party will be asked to classify the financial relationship in question according to one of the following categories:

- **Consultancy services**
- **Advisory board services**
- **Speaker services**

- **Services for non-interventional research outside the scope of the Dutch law on medical research in humans**
- **Other services**
- **Sponsorship of meeting**
- **Other sponsorship**

The amount Amounts are to be submitted in whole euros. In the case of service provision by a healthcare professional, only the fee (excluding VAT and expenses) is to be registered. In case of sponsorship agreements, the full sponsorship amount is to be submitted. If as part of an agreement with a partnership or institution, personal services are rendered by a healthcare professional, this relationship must be registered separately, stating the fee received for these services. In such a case, therefore, certain sums of money must be submitted twice: the total contract value in the name of the partnership or institution and the fee for the personal service provision in the name of the healthcare professional concerned.

The transparency rules apply not only to monetary reimbursements but also to reimbursements in kind. Reimbursements in kind must be submitted at their equivalent monetary market value.

The year: 2012 submissions relate to payments made in 2012 and/or payments for which the service or sponsored activity was performed in 2012. If the service was not completed in 2012 or if the sponsorship continues after 2012, these relationships should not yet be reported. Reporting takes place after completion of the service and/or sponsorship.

Method of delivery

Reporting must take place in automated form from the registration systems of the pharmaceutical companies. To this end, a conversion will need to be made from the registration systems to the format of the transparency register. As soon as this format is known, it will be communicated to the companies. Additionally, expertise will be available to support the execution of the conversion. The companies concerned will be approached on this matter in the months of October - December 2012. ■

For more information

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