Life Sciences and Health Care
Industry News

News regarding sponsorship reporting

The Order of the Health Minister approving the Norms for the evaluation and approval the advertising for human use drugs was published in the Official Gazette no. 168 on 11th March 2015.

This Order brings clarifications with respect to the way the drugs are promoted to the public, but also to medical professionals.

The news brought by this Order is the regulation of the reporting forms for sponsorships and other expenses made by the producers, market authorization holders and distributors for the following beneficiaries:

- medical professionals;
- professional organizations;
- patient organizations;
- any other organizations that perform activities regarding the human health, medical or pharmaceutical assistance.

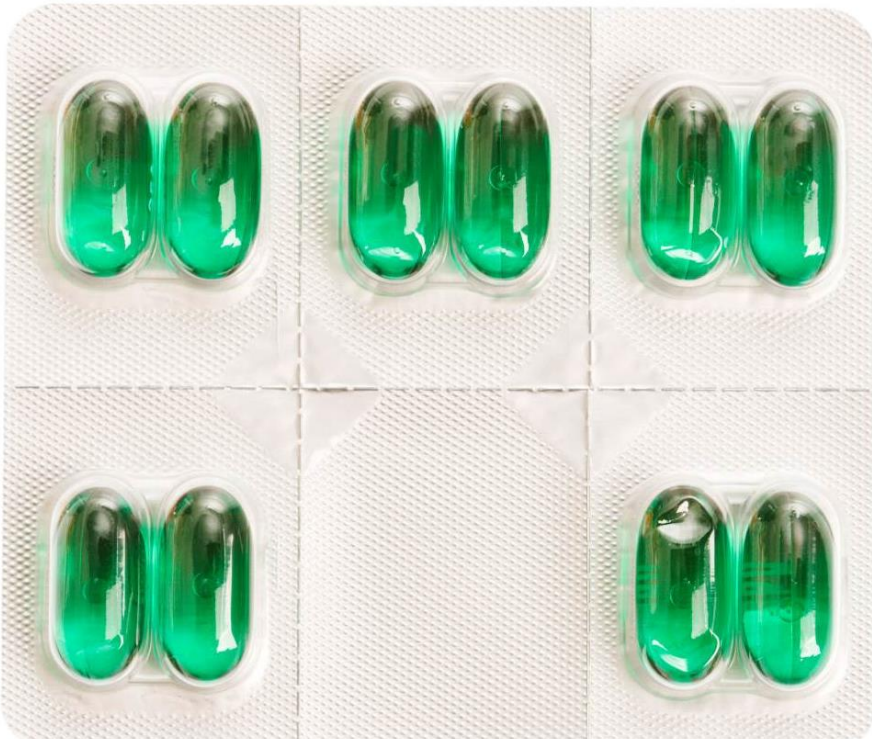
This reporting liability lies with the sponsorship's beneficiaries as well.

The annexes to this Order set out the template of the reporting forms. Based on these templates, each sponsorship/expense should be reported individually, regardless of its nature (i.e. material or financial).

Apart from the sponsorships granted, the service contracts concluded with the above mentioned beneficiaries should be reported as well. Among these contracts, the following are mentioned:

- speakers contracts;
- consultancy contracts (e.g. advisory board, expert opinion, training for employees etc.)
- transfer of IP rights.

The sponsorships/expenses performed during 2014 will be reported to the National Drug and Medical Devices Agency by 30 June 2015. Starting with 2016, the reporting will be done by 31st March of the following year.



News regarding the claw-back tax

Emergency Ordinance no.2 regarding the amendments to Emergency Ordinance 77/2011 in relation to the claw-back tax was published in the Official Gazette no. 176 on 13th March 2015,.

The main amendments brought are:

- it is specifically mentioned that in case of non-resident market authorization holders, the liability to pay the claw-back tax lies with the market authorization holder, through its legal representative;
- it is specified that the consumption of medicines based on which the claw-back tax is computed does not contain those medicines for which cost-volume/cost-volume-result agreements were concluded; the same provision was introduced in the definition of total quarterly consumption (CTt);
- the value of the percentage "p" that can be established in the cost-volume/cost-volume-result agreements takes into consideration its value from the quarter prior to signing the agreement plus from 5 to 70 percentage points (previously, it was added from 5 to 30 percentage points). This percentage is dependent on the number of contractible patients for each therapy, compared to the number of eligible patients;
- for the cost-volume-result agreements the value of the medicines for those patients for which the medical result was not achieved will be paid in full.

Should you have any questions, please do not hesitate to contact us:

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