



AIPM®

Кодекс
надлежащей
практики
Code
of Practice

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SPECIAL PANEL DECISIONS DISCLOSURE OF VIOLATIONS

Procedure for Review of Complaints and Disputes
Regarding Violations of the AIPM Code of Practice

2020

ASSOCIATION OF INTERNATIONAL
PHARMACEUTICAL MANUFACTURERS

АССОЦИАЦИЯ МЕЖДУНАРОДНЫХ
ФАРМАЦЕВТИЧЕСКИХ ПРОИЗВОДИТЕЛЕЙ

Case summary

- Journal article reprint in the complex with advertising module used by Company can mislead an HCP regarding the possibility of using these medicines beyond the registered indications for the medical use;
- At scientific and educational events for HCPs Company systematically used statements exceeding the registered indications for the medical use, as well as not meeting data of the approved leaflet for the medical use;
- Incorrect extrapolation and presentation of data on the side effects of the medicinal product as its advantage;
- Within the lectures and speeches at events for HCPs, including webinars, information on medicine wasn't provided based on an up-to-date evaluation of all relevant factual evidence and that evidence was not reflected clearly. Special Panel pointed out that information shall not be designed at encouraging the prescription of pharmaceutical products;
- Statements used by Company in promotional brochures do not correspond to the medical use leaflet, mislead HCPs, including without limitation, through the use of exaggeration, create a guarantee of the positive effect and effectiveness of the medicinal products of the Company.

Decision of the Special Panel

The Special Panel acknowledged violation of cl. 2.2.1, 2.3.1–2.3.6 of the AIPM Code of Practice.

Recommendations & Sanctions of the Special Panel

- ☑ Bring information and advertising materials, including within the speakers' speeches at scientific and/or educational events for HCPs, in accordance with the Code and Special Panel recommendations. The requirements for providing information about pharmaceutical products within the Company's events should be explained to the lecturers before the event and monitored during the event;
- ☑ Stop distributing to HCPs and patients information containing violations of the Code;
- ☑ Inform Company HQ about the violation;
- ☑ Oblige Company employees to complete online training on the Code.



Association of
International
Pharmaceutical
Manufacturers

Ассоциация
международных
фармацевтических
производителей

Special Panel Decision dated of August 03, 2020

Case summary

- Statements of an absolute and all-encompassing nature used by company in promotional materials for medicine—namely, "unsurpassed glycemic control," "ideal therapy," "unrivalled efficacy," "a new analog of GLP-1 saves patients' hearts," "excellent and sustainable weight loss," "proven cardiovascular benefits"—may indicate a guarantee of the positive effect, efficacy, and safety and don't present data about the medicine objectively;
- Inaccurate statements of absolute nature are not supported by the corresponding scientific evidence: "Unrivalled "medicine"—new heights in reducing cardiovascular risks in type 2 diabetes." The wording "Medicine is the only GLP-1 receptor antagonist to be administered once a week with proven CV benefits and unsurpassed efficacy" is incorrect and may mislead HCPs by lacking essential information in the material, including, inter alia, an indication of the comparison criteria, given that other medicines are registered in the GLP-1 receptor antagonist class in Russia;
- Statement presented by company at the online conference that medicine is indicated for patients with CVD risk factors and ensures control of cardiovascular risks does not comply with the medical use leaflet and may mislead HCPs, due to the fact that according to the medical use leaflet medicine is indicated to reduce the risk of cardiovascular events as a supplement to the standard of care for CVD;
- Incorrect extrapolation of properties of the medicine in terms of reducing HbA1c level and body weight to its advantages in comparison with other medicines by selective use of comparative study data.

Decision of the Special Panel

The Special Panel acknowledged the violation by company of cl. 2.1.1, 2.3.1–2.3.6 of the AIPM Code.

Recommendations & Sanctions of the Special Panel

- ✓ Take measures to ensure that materials on medicine for HCPs, including as part of speeches at scientific and/or educational events for HCPs, are in accordance with the Code and the recommendations of the Special Panel.
- ✓ Stop distributing information to HCPs containing violations of the Code established by the Special Panel.
- ✓ Provide confirmation of the withdrawal and subsequent nondistribution of information and advertising materials containing violations of the Code established by the Special Panel.
- ✓ Inform the HQ of the company about the violation.
- ✓ Make the fact of the violation public, including, but not limited to, the identity of the offending company.
- ✓ Oblige employees of the company to undergo an online training session on the Code.

Case summary

- Since the beginning of 2020Y, Company has planned a series of scientific events for the HCPs of various profiles at the Areal Congress Hotel at the address: Moscow region, Bogorodsky urban district, village. Novaya Kupavna, Rodinki, st. Sirenevaya, 21, bldg. 1.
- According to the information posted on the website of the Congress-hotel, accommodation of the event participants at the Areal hotel may be accompanied by the provision of entertainment services.
- In addition, the information provided on the hotel's website contributes to the creation of a strong impression among the population that the Areal hotel is a place for country recreation, family recreation, as well as a venue for various kinds of banquets and celebrations.
- The Special panel suspect a violation, expressed in the organization of scientific events for the HCPs in the venue, which does not meet the requirements of cl. 3.3.4. of the AIPM Code and cl. 13 of Annex 3 of the Code (Q&A).

Decision of the Special Panel

The Special Panel acknowledged the violation by the Company of cl. 3.3.4 of the AIPM Code and cl. 13 of Annex 3 of the Code.

Recommendations & Sanctions of the Special Panel

- ☑ Take measures to cancel and/or change the venue of the Company's events, the venue of which is the Areal Congress Hotel.
- ☑ Provide confirmation of the cancellation and/or change of the location of the events, the venue of which is the Areal Congress Hotel.
- ☑ In the future, refrain from organizing and/or supporting scientific events for the HCPs, the venue of which is the Areal Congress Hotel.
- ☑ Oblige the Company's employees responsible for organizing and/or conducting scientific events for the HCPs to complete online training on the AIPM Code;