



Association
of International
Pharmaceutical
Manufacturers

Ассоциация
международных
фармацевтических
производителей

ETHICAL DISPUTES 2014

Disclosure of violations

Special Panel decisions without disclosing the identity of the violating company

I. Violating company distributed advertising materials based on “in vitro” preclinical experimental studies data extrapolated to clinical efficacy.

Special Panel considered these materials as misleading because of the lack of essential information on methodology and design of “in vitro” studies in the materials. Violating company made an attempt to transfer “in vitro” studies results to the usage of medicine in clinical practice and to draw an analogy between “in vitro” activity and clinical efficacy of compared medicines. Special Panel emphasized that “in vitro” studies results should not be used in advertising materials as an argument for comparison between clinical efficacy of two medicines.

Special Panel unanimously admitted by open vote the fact of violation of the clause 2.3.4, 2.3.5 and 2.3.6 of the AIPM Code by the company.

II. Violating company conducted advertising campaign of medicine accompanied with comparative assertions, whereunder comparison is made without comparison object. Special Panel considered that such assertions might be understood by consumer as assertions comparative with other treatment modes.

There was no data on comparative studies results on the medicine of violating company in comparison with other treatment modes / medicines in the materials in the case, whereupon the assertions in advertising materials might create an incorrect impression of medicine properties. Comparative studies of the medicine are related only to comparison with placebo.

Reference to clinical studies publication in advertising materials are difficult to absorb due to the way of submission (short term of presence on screen in video advertising of medicine).

Special Panel unanimously admitted by open vote the fact of violation of the clause 2.3.4 and 2.3.6 of the AIPM Code by the company.

Special Panel decision was confirmed on appeal.



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III. Advertising materials of violating company's medicine contained graph of economic advantage of medicine without any reference to studies and publications data.

Assertions contained in advertising materials went beyond the scope of registered indications for use. Special Panel considered that usage of package design in English in advertising materials is inconsistent with information on medicine approved in the established procedure (including the labeling and package leaflet).

Advertising materials contain assertions in superlative degree.

Special Panel unanimously admitted by open vote the fact of violation of the clause 2.2.1, 2.3.2, 2.3.4, 2.3.5 and 2.3.6 of the AIPM Code by the company.

IV. Violating company organized program to award in-kind prizes to pharmacy organizations for the attainment of certain sales.

Special Panel unanimously admitted by open vote the fact of violation of the clause 6.4.3 of the AIPM Code by the company.

V. Violating company conducted advertising campaign of medicine accompanied with absolute slogan which created the impression of a guaranteed positive effect and efficacy of the medicine.

Special Panel unanimously admitted the fact of violation of the clause 2.3.1 and 4.3 of the AIPM Code by the company.

Special Panel decision was confirmed on appeal.



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VI. Violating company conducted advertising campaign of medicine accompanied with statement not corresponding with the medicine package leaflet and not proved by evidentiary material provided by violating company.

Special Panel unanimously admitted the fact of violation of the clause 2.3.2 and 2.3.4 of the AIPM Code by the company.

Special Panel decision was confirmed on appeal.