



Pub. Ref. C190509
Complaint Relating to an Alleged Off-label Promotion

Background

In May 2019, IFPMA received a complaint from an employee of a pharmaceutical company relating to alleged off-label promotion for a prescription medicine in Japan. Apart from referring to previous activities in connection with the use of an erroneous treatment guideline recommending off-label use of a product, the complainant alleged against the presentation of research results related to the same product at a forthcoming scientific society's congress. The complainant considered such activity as "disguised promotion" rather than "an exchange of scientific information".

Prior to submitting this complaint to IFPMA, the complainant had sought action through JPMA's complaint reporting procedure. JPMA processed and investigated the complaint and could not corroborate the alleged activities. The complainant then turned to IFPMA as he concerned that JPMA may not have fully implemented IFPMA's Code provisions and therefore IFPMA may be responsible to rule the complaint, as described in Principle 1.2 of the Code Operating Procedure in Appendix 1 of the IFPMA Code of Practice:

"The IFPMA Code is also applicable if and as far as the code adopted by the respective member association is not fully compliant with the IFPMA Code (unless required by national laws and regulations)."¹

IFPMA Adjudication and Appeal

IFPMA handles all complaints according to the procedures defined in Annexes 1 and 2 of the IFPMA Code of Practice. A complaint is forwarded by the IFPMA Secretariat to an independent Adjudication Group if a complaint is "validated." A complaint is valid when it:

appears to be a genuine matter and submitted in good faith and in a timely manner, provides sufficient information to enable the complaint to be processed, concerns a country where this operating procedure applies, and is not already under investigation by one of the member associations (or relevant body thereof or equivalent regulatory body).²

The goal of this validation step is to ensure that a complaint is not frivolous or predatory.

The complaint was forwarded to all relevant parties because it met the baseline requirements outlined above. The Adjudication Group determined that administration of national codes and local laws and regulations is a national responsibility and it is important to bear in mind that national cultures are different. The Adjudication Group decided that it could not confirm that the relevant sections of the JPMA Code were not fully compliant with the IFPMA Code. Its decision therefore was that Principle 1.2 of the IFPMA Code Operating Procedure does not apply and, as a consequence, IFPMA is not required to consider the complaint under its Code.

The complainant disagreed with the first ruling and requested an appeal. The IFPMA Appeal Group confirmed the ruling issued by the Adjudication Group and considered that no additional actions should be taken under the IFPMA Code.

Published: 15 January 2020

¹ See principle 1.2 in Appendix 1 of IFPMA Code of Practice, 2019, available at <https://www.ifpma.org/subtopics/new-ifpma-code-of-practice-2019/?parentid=264>