Health Research Policy and Systems

LETTER TO THE EDITOR Open Access

The Swedish Medical Products Agency's rules of procedure

Catarina Andersson Forsman

The Swedish Medical Products Agency (MPA) is the Swedish national authority responsible for regulation and surveillance of the development, manufacturing and marketing of medicinal products. Relenza, a neuraminidase inhibitor used in the treatment of influenza, has been evaluated by both the Swedish MPA and the United States Food and Drug Administration.

In a paper by Mulinari et al. [1], the divergent conclusions reached by the authorities are discussed. The purpose of this letter is not to discuss the conclusions drawn by Mulinari et al. [1], but to comment on the way they refer to an assessor at the MPA. By naming a specific assessor at the MPA, the reader is given the false impression that a single employee is solely responsible for the benefit–risk evaluation of a drug. We want to emphasize that all assessments at the MPA are the work of a team of assessors with complementary competencies, including a comprehensive standardized quality assessment procedure for each decision. Hence, it is the MPA, as a national regulatory agency, that is responsible for any opinion or decision. Besides giving a misleading description of regulatory procedures, the publication of an individual assessor's name adds no scientific value to the paper and could therefore have been omitted.

Received: 29 June 2018 Accepted: 18 September 2018
Published online: 15 November 2018

Reference

1. Mulinari S, Davis C. Why European and United States drug regulators are not speaking with one voice on anti-influenza drugs: regulatory review methodologies and the importance of 'deep' product reviews. Health Res Policy Syst. 2017;15:93. https://doi.org/10.1186/s12961-017-0259-8.

Author's contributions

CAF wrote the manuscript. The author read and approved the final manuscript.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The author declares that she has no competing interests.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Correspondence: catarina.andersson.forsman@lakemedelsverket.se
Swedish Medical Products Agency, SE -751 03 Uppsala, Sweden