

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.

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

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>.

Ready to submit your research? Choose BMC and benefit from:

- fast, convenient online submission
- thorough peer review by experienced researchers in your field
- rapid publication on acceptance
- support for research data, including large and complex data types
- gold Open Access which fosters wider collaboration and increased citations
- maximum visibility for your research: over 100M website views per year

At BMC, research is always in progress.

Learn more biomedcentral.com/submissions



© The Author(s). 2018 **Open Access** This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (<http://creativecommons.org/publicdomain/zero/1.0/>) applies to the data made available in this article, unless otherwise stated.