Suggested evaluation of biological drugs role for WHO – Editor's response

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The Editor-in-Chief expresses his concerns about the proposal of a WHO run system to approve copy biologicals in the Milani and Gaspani paper [1].

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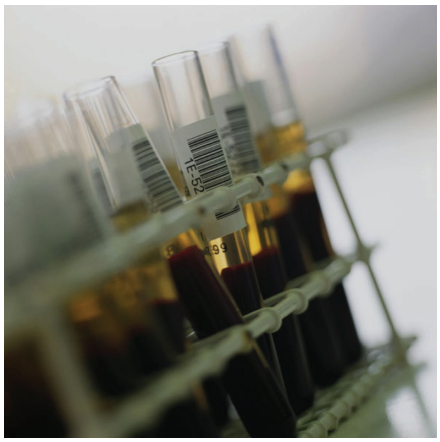
The paper by Milani and Gaspani [1] suggests that the World Health Organization (WHO) sets up a programme to approve follow-on pegylated interferons and similar biological medications, that is biological product meant to mimic approved, effective and tolerated drugs but which are subjected to less restrictive testing that are true biosimilar products. I have problems with this suggestion that require comment and concerns about the ability of WHO to do what is proposed.

The title of their paper suggests that WHO can approve/recommend such products that are 'quality assured' yet they offer little to no evidence that such products will be 'quality assured'. The authors suggest that such products should be approved by a less rigorous approval system than that required by either the European Medicines Agency (EMA) or US Food and Drug Administration (FDA) [1].

WHO is not a regulatory agency. The authors provide no evidence that WHO would be capable of adequately (or even cost-effectively) evaluating, approving or performing post-approval monitoring of such products. They provide some data suggesting that the use of pegylated interferon copies can lower access costs but no data on either comparative efficacy or toxicity. Acquisition costs are only part of overall healthcare costs. The costs associated with the administration, storage, possible differences in efficacy or adverse events from such copies must also be considered.

The authors do not discuss how WHO or any country using such products would monitor the use or efficacy of such products or how they would identify any problems that might occur after approval. There is also no mention of how lower efficacy or adverse events that occur in patients who were given more than one such biological copy could or would be evaluated.

Access of non-wealthy patients in resource-poor countries to expensive medications such as pegylated interferons is certainly an important topic worthy of new solutions. However, there are reasons beyond patent laws and profits that have prevented the marketing of adequate 'follow-on biologics'. Biological products and non-biological complex drugs are much more complex than small molecule generics. There are many examples of 'follow-on biologics' which failed to be marketed because of inadequate efficacy, greater adverse events, or both. Without access to data from both adequate pre-approval testing as well as from post-marketing efficacy



and adverse event surveillance data it is impossible to know whether the examples of increased access provided by the authors represent inferior efficacy, more toxicity or even truly decreased healthcare costs.

The authors' suggestion that a single organization or entity can take on a global regulatory function for a number if not all resource-poor countries definitely has merit, but it is not clear that this should or even could be adequately done by WHO. Perhaps this could be done better by one of the major pharmacopoeas, i.e. *United States Pharmacopeia* or *British Pharmacopoeia*.

The authors suggest both that WHO can develop methods to adequately evaluate and approve 'follow-on biologic' copies such as those being used in Iran and imply that such copies are the same as biosimilars. Both may be true but data to adequately support these suggestions were in my view not adequately presented.

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Reference

1. Milani B, Gaspani S. Pathway to affordable, quality-assured sources of pegylated interferon alpha for treating hepatitis C. Generics and Biosimilars Initiative Journal (GaBI Journal). 2013;2(4):194-203. doi:10.5639/gabij.2013.0204.053

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