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CORRESPONDENCE

Author's Reply to Bompart: "Artesunate- and Amodiaquine-Associated Extrapyramidal Reactions: Information Gained from an African-Based Risk Management Plan"

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To restrict postmarketing surveillance to a "Potential risk: to be quantified in large-scale studies" [1] is unusual as it excludes routine pharmacovigilance, no matter how limited that may be perceived. My study [2] showed that a less-dismissive attitude to Sub-Saharan pharmacovigilance is warranted.

It appears that until late 2011, Sanofi did not give weight to the published Anglophone (from 1976) and Francophone (2004) case reports referenced in my paper associating extrapyramidal reactions with amodiaquine and the repeated advice (2010 and 2011) of the WHO's Advisory Committee on Safety of Medicinal Products (ACSoMP) that reporting to the Uppsala Monitoring Centre supported a clear association with artesunate amodiaquine combination products [3, 4]. These followed progress reports to ACSoMP of my ongoing analysis. ACSoMP recommended that the details be published and shared with the manufacturer for a possible update of the Summary of Product Characteristics [3].

It is unclear whether any of the notifications mentioned by Dr Bompart [5] that led to Sanofi's acceptance of the association came from the large-scale studies. If some did, details should be published and an estimate of incidence disclosed.

Acknowledgments The views in this reply are strictly the personal views of the author. His conflicts of interest disclosed in the published paper [2] remain unchanged.

References

1. Sanofi aventis. The artesunate amodiaquine fixed-dose combination (ASAQ) risk management plan, February, 2011. http://www.who.int/selection_medicines/committees/expert/18/applications/RiskManagementPlan.pdf. Accessed 24 Nov 2012.
2. McEwen J. Artesunate- and amodiaquine-associated extrapyramidal reactions: a series of 49 cases in VigiBase™. Drug Saf. 2012;35(8):667–75.
3. WHO Pharmaceuticals. Newsletter. 2010;4:20. http://www.who.int/medicines/publications/newsletter/2010news_4.pdf. Accessed 2012 Nov 29.
4. WHO Pharmaceuticals. Newsletter. 2011;3:12. http://www.who.int/medicines/publications/PharmNew3_2011.pdf. Accessed 2012 Nov 29.
5. Bompart F. Artesunate- and amodiaquine-associated extrapyramidal reactions: information gained from an African-based risk management plan [letter]. Drug Saf. 2013. doi:10.1007/s40264-012-0010-x

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