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LETTER TO THE EDITOR

Comment on: "Adverse Drug Reaction Reporting by Patients: An Overview of Fifty Countries"

Syed Rizwanuddin Ahmad

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I read with great interest the survey conducted by the authors of the study on patient reporting of adverse drug reactions in 50 countries [1]. The authors have done a commendable job in describing the status of adverse drug reaction reporting by patients in selected countries from five continents. This study adds to the body of literature that highlights the important role played by ADR reports submitted by patients and their contribution to signal detection in addition to those reported by health care professionals. I agree with the study authors that there is a need to harmonize the different reporting forms that exist around the world with consideration of the strengths and weaknesses of the existing forms.

I noted a few issues in the publication that need clarification or elaboration.

The authors state that "Australia was the first" and that "patients are the most involved" in the pharmacovigilance system of the USA.

It is true that Australia was among the first countries to accept reporting of ADRs submitted by patients, along with the US, Canada, and New Zealand. The US Food and Drug Administration (FDA)'s postmarketing surveillance program that was piloted in 1956 [2] has accepted ADR reports from all reporters since its inception.

Another point to mention here is that the US FDA launched a specific patient reporting form in June 2013 to make reporting easier for consumers. Until then, a single voluntary MedWatch reporting form existed for all reporters, and there is a separate mandatory MedWatch reporting form for use by those who are required to report by law, such as user facilities, importers, distributors, and manufacturers. In the US, ADR reports submitted by patients or consumers contribute to the bulk of reports in the FDA Adverse Events Reporting System (FAERS), and their reporting has increased substantially over the years (see Table 1), surpassing reports submitted by either physicians or pharmacists individually. In fact, since 2006 consumers have consistently submitted more reports to the FDA compared to physicians and pharmacists. However, it needs to be emphasized that the majority of ADR reports by patients/consumers are not submitted directly to the FDA but received indirectly via the marketing authorization holders. In 2013, the last full year for which data are available, only about 2.5 % or 28,501 of the total 1.17 million reports submitted to the FDA were received directly (Fig. 1).

A point that needs clarification is that in their study the authors mention "direct patient reporting systems exist in

S. R. Ahmad (✉)
Lanham, MD, USA
e-mail: drugsafetyconsultant@gmail.com

Table 1 Number of reports by reporter type in the US FAERS (2004–2013)

Year	Consumers	Physicians	Pharmacists	Other HCP	Total HCP
2004	74,647	92,705	20,320	45,951	158,976
2005	105,172	106,150	21,492	43,585	171,227
2006	126,915	113,116	21,468	49,652	184,236
2007	174,015	120,700	21,316	60,184	202,200
2008	226,265	153,641	27,027	88,239	268,907
2009	273,033	177,924	29,213	110,777	317,914
2010	403,843	229,394	36,447	161,213	427,054
2011	492,118	278,311	48,283	197,694	524,288
2012	562,474	352,847	54,496	228,098	635,441
2013	664,842	381,808	67,528	265,995	715,331

FAERS FDA Adverses Event Reporting System, *HCP* health care professional

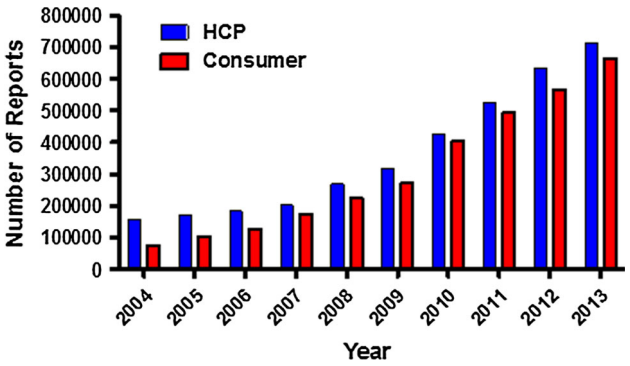

Fig. 1 Number of reports by reporter type in the FAERS (2004–2013). *FAERS* FDA Adverse Events Reporting System, *HCP* health care professional

44 countries" out of the 50 surveyed countries. Can the authors clarify whether they mean that in 44 of the surveyed countries reporting of ADRs by the patients is accepted or they mean there is a separate direct reporting system exclusively for patients?

Syed Rizwanuddin Ahmad, MD, MPH, FISPE, FCP

From 1998–2013, I worked for the US Food and Drug Administration's Center for Drug Evaluation and Research (CDER). Currently, I consult for primarily national medicine regulatory authorities in resource-limited countries and have an adjunct teaching appointment at Georgetown University School of Medicine, Washington, DC, USA.

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