

Medicines Safety *and* Strengthening Pharmacovigilance *in* Senegal:

Improving Adverse Drug Event Reporting by Involving the Bajenu Gox

TECHNICAL BRIEF

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Members of the Bajenu Gox who were trained on pharmacovigilance, September 2023, Dakar. Photo credit: Touré, Elhadji Ibrahima, MSH/Global Fund

Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as “the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems.”¹ The scope of pharmacovigilance has grown remarkably in recent years and is now considered, in addition to adverse drug reactions (ADRs) or adverse events (AE), to address counterfeit or substandard medicines, lack of medicine efficacy, misuse and/or abuse of medicines, and interactions between medicines.² The goals of pharmacovigilance systems are to increase consumer safety, improve public health, and support the evaluation, effectiveness, and understanding of medicines.³ PV centers’ spontaneous reporting systems form the basis for global pharmacovigilance as they systematically collect, collate, and analyze ADR reports, thereby enabling the detection and communication of signals—i.e., information suggesting a potential causal relationship between an AE and a medicine—and the management of risks.⁴ Spontaneous reporting has been defined as “an unsolicited communication by a health care professional or consumer to a pharmaceutical company, regulatory authority, or other organization (e.g., WHO, Regional Center, Poison Control Center) that describes one or more adverse drug reactions encountered by a patient who was given one or more medicinal products and that does not derive from a study or any organized data collection scheme.”⁵

Initially, the use of spontaneous reporting systems (SRSs) generally was restricted to physicians, since it was believed that only a doctor could offer high-quality information about ADRs. But access to those systems was later expanded to additional health care professionals (HCPs) such as pharmacists and nurses. In some European countries, ADRs can now be reported directly to the authorities by patients, suggesting a recognition that a wider range of stakeholders needs to be involved in the monitoring of medicines safety.⁶

PROBLEM STATEMENT

The National Pharmacovigilance Center (NPC) for Senegal historically was housed in the Poison Control Center, which itself was a part of the Department of Pharmacy and Laboratory. In 2022, however, the Senegalese authorities shifted responsibility for pharmacovigilance-related regulatory activities to the newly created *Agence Sénégalaise de Réglementation Pharmaceutique* (ARP).

For a pharmacovigilance system to effectively monitor ADRs for both existing and newly introduced drugs, WHO recommends that the level of spontaneous reporting of adverse effects be greater than 200 reported cases per 1 million in population. By 2015, the NPC had recorded a total of 181 individual case safety reports, representing about 2.44 per 1 million in population, since it joined the WHO Program for International Drug Monitoring in 2009.⁷

Although the number of reported cases has increased some in recent years, the reporting rate for the past three years (3,000 cases in total) has remained consistently below the WHO standard. This shows that in countries such as Senegal that mainly use a spontaneous or voluntary ADR reporting system, underreporting remains a big problem. Underreporting in turn severely limits the ability of the regulatory authority to monitor the safety of medicines that are marketed in the country.

TECHNICAL APPROACH

Management Sciences for Health (MSH) is a global nonprofit organization that provides governments, health organizations, and the private sector with the strategies, tools, and management support to deliver high-functioning health systems effectively and efficiently. MSH, through funding from The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), supports increasing the PV capacity in some pilot countries, including Senegal. The approach of the project is to implement change tailored to the specificities and needs of the country. Thus, MSH provided technical assistance to strengthen the pharmacovigilance system in Senegal in the context of the changing pharmaceutical landscape brought about by the creation of the ARP.

The approach used by MSH aligned with the Global Fund objective to strengthen the pharmacovigilance system by helping the country achieve Maturity Level 3 of WHO's Global Benchmarking Tool (GBT) for the evaluation of health regulatory systems. Specifically, this activity aimed to implement the recommendations provided by WHO/GBT sub indicator VL02.02, which states that "documented procedures and mechanisms are implemented to ensure the involvement, coordination and communication among all stakeholders relevant to vigilance activities."

Based on these recommendations, the ARP is in the process of revitalizing the PV system, which will allow for the optimal and efficient monitoring of the safety of medicines and other health products. Focus has been placed on building the capacity of stakeholders involved in the reporting of ADRs so they have the knowledge and skills they need to use the various ADR reporting tools. This activity could enable them to provide notification to the pharmacovigilance center that further investigation and analysis are needed, and the information that results from that investigation and analysis could then be used as evidence for better decision-making by the ARP.

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THE BAJENU GOX

The Global Fund supported the ARP in designing a training program on pharmacovigilance for country stakeholders who have unique and vital roles and responsibilities in promoting health in Senegal. The program focused specifically on certain community health actors (CHAs) who already serve as vital links with respect to the appropriate use of medicines and promotion of health: the Bajenu Gox.

The Bajenu Gox (which means "aunt of the neighborhood" in Wolof) is an organization of CHAs made up exclusively of women who help reduce infant and maternal morbidity and mortality within communities by acting as counsellors and educators and leading community-based health activities. Members of the Bajenu Gox are actively involved in community development through supportive supervision and social mobilization and by encouraging behavioral change. In particular, they help families with reproductive health issues, especially with respect to referrals to health facilities, counselling for pregnant women, and obtaining medicines. Their leadership fosters a strong capacity for mobilization and awareness-raising that can contribute to the success of the ARP's mission as it pertains to community reporting of ADRs and strengthening the monitoring of the safety of medicines.

STRENGTHENING THE CAPACITY OF CHAs

On September 20, 2023, 28 Bajenu Gox members and one community health worker participated in a training facilitated by the ARP. The following presentations were provided, and related discussions were conducted among ARP staff and the Bajenu Gox members:

- Presentation on the role and mission of the ARP
- Presentation on the new law of pharmacy (N. 06-2023)
- Orientation on the ARP website (www.arp.sn)
- Presentation on pharmacovigilance and discussions on information, education, and communication (IEC) materials developed for creating awareness on medicine safety monitoring



Head of the ARP and MSH technical advisor leading the training for the Bajenu Gox, September 2023, Dakar. Photo credit: Touré, Elhadji Ibrahima, MSH/Global Fund

PRESENTATION ON THE ROLE AND MISSION OF THE ARP

ARP staff sought to increase participants' awareness of the agency and described its responsibility for implementing pharmaceutical regulations throughout the country.

PRESENTATION ON THE NEW LAW OF PHARMACY

Bajenu Gox members were introduced to the new law of pharmacy, which recently replaced a law adopted in 1954 and was developed to address the many challenges that arise with respect to pharmaceutical sovereignty—a major goal of the Senegalese government that has gained particular urgency in light of the global COVID-19 pandemic. It was therefore important to share with the Bajenu Gox the provisions of this new law so they can disseminate that information to their communities and to health professionals with whom they work.

PRESENTATION ON PHARMACOVIGILANCE AND DISCUSSIONS ON THE IEC MATERIALS DEVELOPED

Participants in the training learned about the importance of the ARP putting into place procedures and strategies for communicating with the population about pharmacovigilance, which is a vital function of the agency. Among those procedures, the reporting of adverse reactions related to the use of medicines and health products is of paramount significance. Indeed, without notification, the ARP would have no information about potential ADRs and would be unable to make informed regulatory decisions about products that may pose risks. The presentation, therefore, stressed the importance of the Bajenu Gox raising awareness among the population and professionals about reporting adverse reactions using the tools provided by the ARP.

The presentation also detailed the two methods for reporting adverse reactions: through notification sheets and via the website provided by the ARP. The Bajenu Gox can help raise awareness about both methods by encouraging patients to either go to a health professional to report how they felt after taking a medication or by advising them to provide notification of an AE directly through the ARP website.

To help the Bajenu Gox understand the concept of pharmacovigilance, IEC materials developed with the support of MSH were used as training materials. These materials helped ARP technical staff explain what pharmacovigilance is, the role the Bajenu Gox can play in pharmacovigilance, the ARP's expectations with respect to this collaboration, how notification about AEs can be provided through the ARP website, and other important information that will enable the CHAs to contribute to the monitoring of and reporting on medicines safety in Senegal.

ACHIEVEMENTS

- The Bajenu Gox members came to understand and appreciate the ARP's role and mission and the law of pharmacy.
- The Bajenu Gox members came to recognize the significance of pharmacovigilance in protecting the public from unnecessary drug-related harms, thereby enabling them to disseminate the information to patients and other consumers.
- The Bajenu Gox members came to realize the practical application of the pharmacovigilance detection and notification tools, thereby enabling them to implement those tools themselves or support others who want to report AEs.

RECOMMENDATIONS

At the end of the training, the Bajenu Gox made the following recommendations to the ARP:

- ✓ Define a framework for collaboration and communication between the ARP and the Bajenu Gox.
- ✓ Organize similar meetings on pharmacovigilance with the Bajenu Gox from other regions of Senegal, as only those from Dakar and Thies were invited to this event.
- ✓ Involve other community stakeholders, such as community relays (another community organization), in the pharmacovigilance activities of the ARP.
- ✓ Conduct a follow-up on the implementation of PV awareness-creation activities undertaken by the Bajenu Gox.

LESSONS LEARNED

- Monitoring the safety of medicines in a country requires collaboration and the coordination of pharmacovigilance activities through the active engagement of, and sharing of responsibilities by, each stakeholder. If utilized appropriately, Bajenu Gox members can play a vital role in pharmacovigilance because of their special presence in the communities and their existing active role in health promotion and communication. Hence, the lessons learned from this unique experience could be exploited to further strengthen pharmacovigilance in other African countries that have similar organizations in their communities.
- The establishment of a framework for collaboration and communication between the ARP and the Bajenu Gox is necessary for the sustainability of the joint activity on pharmacovigilance.

CONCLUSION

Senegal can now use the Bajenu Gox members who were trained on pharmacovigilance and the different tools of AE notification to further its goals with respect to medicines safety. As a result, the pharmacovigilance center at the ARP can increase the amount of AE data collected, both directly from patients and through reporting by health care professionals. The collected data then can be verified for completeness by the pharmacovigilance center staff and analyzed to provide meaningful evidence for action on medicines that may be harmful to public health. It also can contribute to the global monitoring of medicines safety for the international audience. Additionally, the Bajenu Gox members can use the communications and awareness-raising materials on adverse drug reactions to further promote the ARP's pharmacovigilance function by sharing them with other CHAs, which will help disseminate the knowledge and skills provided through the training to a wider audience.

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To learn more about MSH's work in pharmaceutical systems strengthening, please contact **Kate Kikule**, Senior Principal Technical Advisor, at kkikule@mtapsprogram.org.
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