Ghana's Pharmacovigilance Experience: From Vertical Program Activity to Nationwide System

Huihui Wang
Delese Mimi Darko
Albert Figueras
Patricio V. Marquez
James K. Kumwenda

Korea—World Bank Partnership Facility
China—World Bank Partnership Facility
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# Table of Contents

Acknowledgements.............................................................................................................. iv  

Reports in the Pharmacovigilance and Essential Public Health Services Series ........................................ v  

Abbreviations and Acronyms............................................................................................ vi  

Introduction.............................................................................................................................. 2  

Ghana’s Health System: Organizational Structure and Governance ................................. 3  
  Ministry of Health ................................................................................................................ 3  
  Ghana Health Service .......................................................................................................... 3  
  Health Sector Funding .......................................................................................................... 3  
  Origins of FDA Ghana ......................................................................................................... 4  

Legislative mandate of FDA Ghana.................................................................................... 7  
  Mission .............................................................................................................................................................. 7  
  Provisions on Drugs, Herbal Medicinal Products, Cosmetics, and Medical Devices.............. 8  

Funding of the FDA Ghana and for PV ............................................................................. 9  

Reporting in the Ghana PV System...................................................................................... 10  
  Addressing Underreporting .................................................................................................... 12  
  Toward the Digitalization of Reporting ................................................................................ 13  

Pharmacovigilance in Public Health Programs .................................................................. 14  

COVID-19 Vaccine Surveillance: Organization and Challenges ......................................... 15  
  The Value of Safety Monitoring during a Pandemic and in Normal Times ......................... 15  
  Response to COVID-19 Vaccination Rollout ...................................................................... 16  

The Safety Monitoring Potential of FDA Ghana ................................................................ 17  
  Opportunities to Improve PV in Ghana .................................................................................. 18  
  Potential Areas of International Support .............................................................................. 18  

Lessons Learned.................................................................................................................... 19  

References ............................................................................................................................. 20
Box
Box 1 Description of the Safety Monitoring of Medicines and Medicinal Products, Ghana ................................................................. 8

Figures
Figure 1 FDA Ghana Revenue and Expenditure Performance, 2020–2022 .......... 9
Figure 2 Ghana Pharmacovigilance System ................................................................. 11
Figure 3 Individual Case Safety Reports, by Number and Year, 2016–22 .......... 12
Figure 4 Share of AEFIs Reported by 306 Health Care Workers Surveyed.......... 14

Map
Map 1 Pharmacovigilance in African Countries .............................................................. 6

Tables
Table 1 Development Milestones: The Pharmacovigilance System, Ghana ....... 5
Table 2 Funding for Pharmacovigilance in Ghana from 2018–2022 ................. 10
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- Positioning Report on Pharmacovigilance: The Value of Pharmacovigilance in Building Resilient Health Systems Post-COVID
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- The Caribbean Regulatory System: A Subregional Approach for Efficient Medicine Registration and Vigilance
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- Learning from Best Practices: An Overview of the Republic of Korea Pharmacovigilance System
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- Starting and Strengthening a National Pharmacovigilance System: The Case of Catalan Regional
- Activities that Propelled the Spanish Pharmacovigilance System
- Ghana’s Pharmacovigilance Experience: From Vertical Program Activity to Nationwide System
Abbreviations and Acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADR</td>
<td>Adverse drug reaction</td>
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<tr>
<td>AEFI</td>
<td>Adverse event following immunization</td>
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<td>FDA</td>
<td>Food and Drugs Authority</td>
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<td>GHS</td>
<td>Ghana Health Service</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<td>PV</td>
<td>Pharmacovigilance</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>PIDM</td>
<td>Program for International Drug Monitoring (WHO)</td>
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Abstract

Establishing and consolidating a pharmacovigilance (PV) system in a country requires political opportunity, the involvement of well-trained health professionals, and the activity of engaged individuals who submit the reports. However, the initial spark is produced according to the characteristics of the country, the interests of mindful professionals, and awareness of the opportunity.

This case study analyzes the evolution of this process in Ghana. This experience shows that one way to promote the development of PV capacity in a country is to take advantage of public health programs that are centered on the administration and use of vaccines and medicines for disease control, such as the immunization program or the TB, HIV, or malaria programs. In Ghana, the routine reporting on adverse events began with the monitoring of adverse effects following immunization (AEFIs) under the Expanded Program on Immunization, that was launched in 1978. Similar efforts followed under other public health programs for disease control, such as the National Malaria Eradication Program, the National Tuberculosis Control Program, the National AIDS Control Program, and the Neglected Tropical Diseases Control Program.

The experience generated under these disease control programs served to expand the reporting of adverse drug reactions from other medicines after the establishment of and development of a mature medicine regulatory authority—the Food and Drugs Authority (FDA), Ghana—and a solid PV system that, in 2001, became part of the World Health Organization (WHO) Program for International Drug Monitoring (PIDM). Ghana was among the early adopter countries in Africa, and the lessons from its experience are relevant to other low- and middle-income countries for developing PV as a core public health function in the health system.
Introduction

Safe and effective medicines, vaccines, and medical devices are a key component of health care systems, and their regulation is a core public health function (Nwokike and Eghan 2010; Owusu-Asante et al. 2023). In Ghana, the Food and Drugs Authority (FDA) is the agency mandated to ensure the safety, quality, and efficacy of human and veterinary medicines, food, biological products, cosmetics, medical devices, household chemical substances, clinical trials, and the control of tobacco products through the enforcement of relevant standards to protect public health.¹

The objective of this report is to examine the development of pharmacovigilance (PV) in Ghana, and illustrate the role it plays in the health system, and more recently, during the COVID-19 emergency response. It concludes by offering some relevant lessons for building PV capacity in other low- and middle-income countries.

Ghana Health Service

The Ghana Health Service (GHS) is an MOH public service agency outside the civil service. The GHS governing council is mandated by Act 525 to implement approved national policies on health service delivery in the country, expand access to improved health services, and manage resources. The GHS is the lead service delivery agency in the Secretariat of the Cabinet in the Office of the President. It handles about 60 percent of health service delivery. It supervised a health workforce of 68,132 in 2020 (Awoonor-Williams 2020). The GHS sets technical guidelines, establishes effective mechanisms for the Secretariat of the Cabinet, and collaborates with other recognized health care providers.²

The GHS has 11 divisions and operates at five levels: community, subdistrict, district, region, and nationwide. Under a director-general and a deputy director-general, these divisions are organized into programs, units, and departments. The 16 regional and 260 district health directorates are the subnational structures of the GHS that are responsible for planning and coordinating the delivery of comprehensive primary and secondary health services in their respective jurisdictions in collaboration with other service providers and stakeholders.

Health Sector Funding

The health sector in Ghana is financed by public funds (government revenues), private funds from companies and from households through prepaid voluntary premiums and out-of-pocket payments, and international funds from donors and development partners.³ Government revenues are subdivided into general revenue for the health budget, targeted revenues for the National Health Insurance Scheme, and local government revenue.⁴ The National Health Insurance Authority under the MOH manages the

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³ Brief Introduction to the NHIS (web page), National Health Insurance Authority, Accra, Ghana, https://www.nhis.gov.gh/about.
National Health Insurance Fund, which relies on six main sources of funding to operate the health insurance scheme:

- The national health insurance levy, which largely funds the scheme, is a 2.5 percent levy on goods and services collected under the value added tax
- A 2.5 percent social security deduction among formal sector workers managed by the Social Security and National Insurance Trust
- Premiums and contributions paid by scheme subscribers
- Annual government budgetary allocations proposed and approved by Parliament for the health insurance fund
- Accruals from National Health Insurance Council investments of surplus funds in the health insurance fund
- Grants, gifts, and donations for the health insurance fund

Origins of FDA Ghana

FDA Ghana is an agency under the MOH with an eleven member Governing Board inclusive of the Chief Executive Officer who is responsible for its day to day administration.

FDA Ghana was initially established as the Food and Drugs Board in 1997 by the Food and Drugs Act of 1992, as amended by the Food and Drugs Act of 1996. The food and drugs legislation was revised in 2012 and integrated into the new Public Health ACT, 2012 (Act 851), which created the FDA (Assembly Press 2012). ⁶

In West Africa, FDA Ghana is considered a pioneer among national medicines regulatory authorities. It is respected because of its regulatory standing. It was adjudged maturity level 4 Regulatory Function through the World Health Organization (WHO) global benchmarking tool in 2020 (Owusu-Asante et al. 2023). The tool is used to assess the maturity of national regulatory authorities by classifying them on a scale of 1 to 4. ⁶ Level 3 represents the minimum target for most regulatory authorities: a stable, well-functioning, and integrated regulatory system. Level 4 exceeds this required standard and represents a regulatory system operating at an advanced level of performance and continuous improvement (Khadem Broojerdi et al. 2020).

The FDA serves as the National Pharmacovigilance Center and coordinates pharmacovigilance activities in Ghana. It is also the repository of adverse reaction reports from patients, health care professionals, and the pharmaceutical industry. ⁷ Table 1 lists the key milestones in the development of the pharmacovigilance system in Ghana.

The WHO Program for International Drug Monitoring (PIDM) is a global collaboration that seeks to ensure the timely detection of safety issues in medicinal products. The Safety Monitoring Department of FDA Ghana, which hosts the National Pharmacovigilance Center, joined the WHO-PIDM in November 2001, the 65th member of the program. Membership by African countries may be classified by year according to four waves (Map 1). South Africa and Morocco (1992) and Tanzania and Tunisia (1993) were the innovators, while Zimbabwe (1998) and Ghana (2001) started the second wave of early adopters, together with Egypt (2001), Nigeria (2004), and Mozambique (2005). Most countries joined WHO-PIDM during the third early majority wave between 2006 and 2010. Ghana, however, was the first West African country to undertake PV activities. Public health programs, such as the immunization program and the malaria, HIV, and tuberculosis programs, contributed to instituting and scaling up pharmacovigilance.

Ghana has been actively involved in various PV activities during these two decades. It is a dynamic partner in the WHO-PIDM and a PV model in western

⁵ To ensure structural consistency across regulatory functions and to assist benchmarking on one or more specific themes across the functions, the tool indicators are classed into nine categories: (a) legal provisions, regulations, and guidelines; (b) organization and governance; (c) policy and strategic planning; (d) leadership and crisis management; (e) transparency, accountability, and communication; (f) quality and risk management system; (g) regulatory process; (h) resources (human, financial, infrastructure, equipment, and information management system), and (i) progress monitoring and impact assessment.

Sub-Saharan Africa. Additionally, to strengthen PV in Ghana, Ghana also collaborates with and is mentored by other international organizations, such as the UK Medicines and Healthcare Products Regulatory Agency and the Netherlands Pharmacovigilance Center, in addition to the WHO and the WHO-PIDM. Ghana is also one of the five countries piloting the African Union Smart Safety Surveillance Program. This program is funded by the Bill and Melinda Gates Foundation and has a long-term goal to strengthen the safety surveillance of priority medicinal products across the African continent through efficiencies, such as technological innovation, resource pooling, and work sharing.

Research results of the PV system in Ghana have been shared with colleagues at the international level, such as at International Society of Pharmacovigilance meetings and publications in peer-reviewed journals.

Table 1 Development Milestones: The Pharmacovigilance System, Ghana

<table>
<thead>
<tr>
<th>Year</th>
<th>Milestone</th>
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<tbody>
<tr>
<td>1999</td>
<td>Formal collation of individual case safety reports</td>
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</table>
| 2001 | Ghana joined the WHO Program for International Drug Monitoring (PIDM)  
First collaboration with the Expanded Program on Immunization pentavalent vaccine introduction |
| 2005 | Formation of the technical advisory committee on safety of medicines |
| 2012 | The Food and Drugs Law was revised and renamed the Food and Drugs Act; provisions for pharmacovigilance are now included |
| 2013 | New guidelines developed to align with the new act  
First edition of the drug safety newsletter (DrugLens Newsletter) |
| 2015 | First training of qualified persons for pharmacovigilance  
Designation as regional center of regulatory excellence for pharmacovigilance |
| 2016 | Launch of direct patient reporting  
Formation of the technical advisory committee on safety of vaccines and biological products to focus on the review of safety information from vaccines and biological products |
| 2019 | Launch of the MedSafety App |
| 2020 | Attainment of WHO maturity level 4 |
Map 1  Pharmacovigilance in African Countries

PIDM African Full Member Countries

- **Innovators** 1992–1993
- **Early Adopters** 1998–2005
- **Early Majority** 2006–2010
- **Late Majority** 2011–2023
- **Associate Members**
- **Not PIDM Members**

Legislative mandate of FDA Ghana

Mission

Public Health Act, 2012 (Act 851) provides a legal basis for preventing, promoting, safeguarding, maintaining, and protecting human and animal health and allied matters in Ghana (Assembly Press 2012). Public Health Act, Part 7, Section 81 defines the mission of the FDA. According to Section 82, the functions of the authority are as follows:

- Ensure adequate and effective standards for food, medicines, cosmetics, household chemicals, and medical devices
- Through district assemblies and any other public agency, monitor compliance with the provisions of Parts 6, 7, and 8 of the Public Health Act
- Advise the minister on measures for the protection of the health of consumers
- Advise the minister on the preparation of effective regulations for the implementation of Parts 6, 7, and 8 of the Public Health Act
- Approve the launch and implementation of clinical trials in the country
- Perform any other functions that are ancillary to attaining the objectives of the authority

Section 83 of the Public Health Act provides for the establishment of the Governing Board with the responsibility of ensuring the effective realization of the functions of the FDA. The FDA Governing Board currently has 10 members. FDA Ghana is headed by a chief executive officer, who reports directly to the Governing Board and takes responsibility for daily operational management, service delivery, and strategic issues.

The office of the chief executive officer consists of departments on internal audit, finance, business development, international partnerships, the Center for Import and Export Control, and the Center for Laboratory Services and Research.

FDA Ghana is structured in four divisions, as follows:

- Food
- Health Products and Technologies
- Technical Operations
- Corporate Services

The Center for Laboratory Services and Research manages six testing laboratories and a quality assurance unit that is responsible for the quality management system of the center. The six laboratories are specialized in (1) drug physicochemical properties, (2) food physicochemical properties, (3) pharmaceutical microbiology, (4) food microbiology, (5) cosmetics and household chemical substances, and (6) medical devices. The laboratories hold accreditation according to the International Organization for Standardization–International Electrotechnical Commission ISO/IEC 17025:2017 standard. The quality assurance unit is accredited by both the ISO/IEC 17025:2017 standard and the WHO good practices for pharmaceutical quality control laboratories.

The FDA is assisted by five technical advisory committees made up of experts with diverse scientific backgrounds. The technical advisory committees cover (1) the safety of medicines, (2) the safety of vaccines and biological products, (3) medical devices, (4) clinical trials, and (5) nutrition. The FDA also sets up ad hoc technical advisory committees for specific purposes as needed, for instance, the joint malaria vaccine committee and the joint COVID-19 vaccine safety review committee. These committees are responsible for reviewing safety data from the Malaria Vaccine Implementation Program and COVID-19 vaccines, respectively.

The role of the FDA in the fight against infectious diseases is enshrined in Public Health Act, 2012, Part 7. The divisions, laboratories, and technical advisory committees apply separate approaches in the fight against infectious diseases, including ensuring the safety, efficacy, and quality of medicines, food, herbal medicinal products, vaccines, and other medical products through testing, regulation, and

standard setting. After approval for the manufacture and use of a product, the FDA conducts market surveillance and pharmacovigilance activities continuously to ensure that product quality and safety are maintained. The FDA is also mandated to authorize the launch and implementation of clinical trials, examine the efficacy of vaccines and drugs in the context of infectious disease control and prevention, and evaluate adverse events following immunization (AEFIs) (Assembly Press 2012). It issues clinical trial certificates to researchers, monitors clinical trials, and may stop a trial if the trial infringes on the trial subjects or public safety or if it does not meet required standards.

The functions of the clinical trial technical advisory committee include providing the FDA with the technical support required to conduct investigations to authenticate the safety, efficacy, purity, and quality of drugs, herbal medicinal products, and medical devices. The FDA currently has at least 86 national and 2 international collaborators, including the Food and Agriculture Organization of the United Nations, the US Food and Drug Administration, and the WHO. It therefore plays a key role in quality laboratory testing and assurance not only in Ghana, but in the African region. The FDA has a critical part in COVID-19 vaccine production in Ghana and in other African countries, such as Rwanda (RBC 2022).

The FDA has established risk communication arrangements to guide communication to avert crisis escalation in case of adverse drug events based on country safety data and data of collaborating agencies.

Provisions on Drugs, Herbal Medicinal Products, Cosmetics, and Medical Devices

Public Health Act, 2012 includes provisions on drugs, herbal remedies, medicinal products, cosmetics, and medical devices. It defines standards, what constitutes misleading consumers, who can sell these substances and products, advertisement, and the control of manufacturing processes. It also describes applications, the registration process, conditions for the cancellation of the registration, and import restrictions. Section 125 covers drug safety monitoring (Box 1). These activities are the responsibility of the Safety Monitoring Department.

Box 1

Description of the Safety Monitoring of Medicines and Medicinal Products, Ghana

- A local representative for a regulated product shall be appointed by the relevant body.
- The local representative
  - Shall monitor the safety of the product granted marketing approval
  - Shall report an adverse effect or event to the authority during the period during which the product is registered
- The authority shall continually monitor the safety of the products regulated under this act through analysis of adverse effects or event reports and any other means and take appropriate regulatory action if necessary

Source: Assembly Press 2012.
Funding of the FDA Ghana and for PV

As stipulated in Public Health Act, 2012 (Act 851), the funds of the FDA Ghana include:

- moneys approved by Parliament,
- donations, gifts and grants,
- loans contracted and guaranteed by the Government of Ghana (GoG), subject to article 181 of the Constitution, and
- any other moneys that are approved by the Minister of Finance

FDA Ghana is mandated to retain a percentage of money that accrues to the Authority in the performance of its functions as provided by law. Approved fees and charges include registration application fees, facility inspection fees, good manufacturing practice audit and licensing of manufacturing facilities, clinical trial authorization and monitoring, and laboratory testing services. In terms of medicines, application fees are charged based on the type of marketing authorization application for new active substance and generic medicines.

As shown in Figure 1, FDA Ghana exceeded its revenue target by 13 percent in 2022 and increased revenue collection by 30 percent compared with 2021 figures. The total revenue generated in 2022 amounted to 141.3 million Ghanaian Cedis (USD 12 Million). However, the institution exceeded its expenditure by 12 percent and performed 126 percent over 2021 expenditure figures due to the general increase in the prices of goods and services, increase in exchange rates and upward review of contracts (FDA 2022).

The funding for PV is obtained from GoG/Internal Generated Funds and donor funding as shown in Table 2. The conservative estimated total funding for PV in Ghana over the past 5 years was 17.18 million Ghanaian Cedis (USD 1.56 million).

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*Source: Adapted from FDA Financial Report (2022)*

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### Table 2  Funding for Pharmacovigilance in Ghana from 2018—2022

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<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
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</thead>
<tbody>
<tr>
<td><strong>Revenues from Government (or Internally Generated Funds)</strong> Ghanaian Cedis, million</td>
<td>0.95</td>
<td>1.47</td>
<td>1.54</td>
<td>2.32</td>
<td>1.91</td>
</tr>
<tr>
<td><strong>Non-Government Revenue (Donor funds)</strong> Ghanaian Cedis, million</td>
<td>1.37</td>
<td>0.45</td>
<td>1.24</td>
<td>4.00</td>
<td>1.93</td>
</tr>
<tr>
<td><strong>Total Ghanaian Cedis, million</strong></td>
<td><strong>2.32</strong></td>
<td><strong>1.92</strong></td>
<td><strong>2.78</strong></td>
<td><strong>6.32</strong></td>
<td><strong>3.87</strong></td>
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</table>

Source: Elaboration by FDA Ghana team, September 5, 2023.

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### Reporting in the Ghana PV System

Initially, PV activities in Ghana were centralized. Reporting occurred through a few hospitals in the Greater Accra Region. However, there has been significant decentralization of PV in recent years. Adverse drug events and reaction reports are received from 15 FDA regional offices nationwide. FDA regional pharmacovigilance officers are responsible for collecting the reports submitted by patients and health care professionals. There are also institutional contact persons in almost all health care facilities who serve as links between the FDA and other health care staff in the institutions.

Figure 2 describes the operation of the Ghana PV system. The reporting system for ADRs uses the FDA adverse reaction reporting form, but there are additional forms, including the tuberculosis form and the AEFI form (Amedome and Dadson 2017). In 2016, the FDA launched direct patient reporting, a program that allows patients to report adverse drug reactions (ADRs) directly to the FDA. The Med Safety App was launched in 2019 to encourage reporting on adverse reactions by health care professionals and patients using a mobile app. If a patient experiences an ADR, the FDA Blue Form is filled out through institutional contact persons or any health professional at the facility and submitted to the regional offices of the Ghana FDA (Asiamah et al. 2022). FDA Ghana also collaborates with public health programs to ensure that the medicines used in these programs are safe, efficacious, and good in quality. At the regional offices, designated regional PV officers receive the submitted reports, assess the validity of the reports, and submit the reports to the national FDA Central Database (SPS 2009).

FDA Ghana manages an online database, Safety Watch System, for registering and sharing reports on adverse drug events. The system is compliant with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, which aims to achieve greater harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource efficient manner.

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The council has issued efficacy guidelines. E2B is one of the PV guidelines. It deals with data elements for the transmission of individual case safety reports. In addition, spontaneous reports that are received are sent to VigiBase, the ADR database for the WHO PIDM through an application programming interface (FDA 2016).

Signal detection is typically carried out using qualitative and quantitative methods. The FDA receives assistance from the UK Medicines and Healthcare Products Regulatory Agency in quantitative signal detection. Potential signals detected are presented to the relevant technical advisory committee for review and confirmation. If a signal is confirmed, the committee provides regulatory recommendations to the FDA. These recommendations may encompass label updates, communication with health care professionals, and other appropriate measures. Figure 3 shows the volume of individual case safety reports received by the FDA in 2016–22.

The higher number of reports received in 2021 relative to previous years was primarily attributed to the influx of adverse event reports following the deployment of COVID-19 vaccines.

While patients and health professionals report ADRs voluntarily, reporting is compulsory for manufacturers. Pharmaceutical companies report ADRs associated with their products to FDA Ghana through qualified persons for pharmacovigilance, trained individuals responsible for monitoring the safety of all medicinal products granted authorization for marketing in Ghana (Asiamah et al. 2022).

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Two technical advisory committees—the technical advisory committee on safety of medicines and technical advisory committee on safety of vaccines and biological products—provide expertise to assist FDA Ghana in making appropriate benefit-risk assessments based on the reports received by the Authority.

**Addressing Underreporting**

Spontaneous ADR reporting is the most widely used and cost-effective method of monitoring the safety of drugs. However, the method is heavily affected by the underreporting of ADRs by health care professionals. This is also a problem in Ghana, acknowledged by the program coordinators in the country. In 2015, the FDA received a total of 697 spontaneous reports. The population of Ghana was 27.4 million at that time. The number of reports thus represented 24.4 reports per million inhabitants, far from the WHO–Uppsala Monitoring Center recommendation of 200 reports per million per year (UMC 2000). In 2017, the situation improved as the PV center received 2,715 spontaneous ADR reports, which represented 90 reports per million inhabitants. And, in 2018, the report volume rose again to 3,729 (121 reports per million). Based on the reports received, several timely safety-related regulatory decisions have been taken, including the withdrawal of substandard and unregistered medicines from the Ghanaian market, notices sent to health care professionals, and alerts issued to protect public health and safety.

Efforts to understand why health care professionals identify ADRs, but do not report them, or do not identify ADRs are crucial for a PV system. In 2019, a cross-sectional survey was conducted among 306 health care workers in 176 health facilities in Ghana to understand the factors associated with reporting AEFIs (Gidudu et al. 2020). Of these, 58 percent reported that they had encountered an AEFI; of the 42 percent who had encountered an AEFI in the previous year, only 55 percent indicated they had reported the AEFI (Figure 4). The most common barriers to reporting were fear of personal consequences (44.1 percent), lack of knowledge or training (25.2 percent), and not believing an AEFI was sufficiently serious to report (22.2 percent). The authors conclude that discussing AEFI during supervisory visits with health care workers might improve reporting.

A study among doctors in Ghana that assessed ADR reporting rates, knowledge about the reporting system, and attitudes to spontaneous reporting in Greater Accra showed that only 27.4 percent of doctors participating in the study had received training on drug safety monitoring and ADR reporting. Among the respondents, 59.5 percent had seen a patient with suspected ADRs in the previous year, although only 20 percent of these respondents had reported the ADR by completing the spontaneous ADR reporting form (Sabblah et al. 2014). The most prominent reasons given by the doctors for not reporting were unavailability of the reporting form (43.1 percent)
and lack of knowledge of the reporting procedures (28.5 percent). Because most of the doctors who participated in the study had not previously received training on ADR reporting, the findings suggest that reporting forms should be made readily available to the doctors, training and refresher courses should be organized, and each report submitted by a doctor should be acknowledged and prompt feedback given on the actions taken.

The major strategy for promoting spontaneous reporting in Ghana has been the implementation of awareness creation and training programs for health care professionals (FDA 2016). Since 2015, the FDA has also launched initiatives to increase the ADR reporting rate and improve signal generation. One initiative has involved the identification of qualified persons for pharmacovigilance who are able to ensure mandatory industry reporting. Others are the Patient Reporting Program and the launch of the Patient Safety Center, which has been undertaken in collaboration with community pharmacies. There is also a program in collaboration with the GHS to peer review the pharmacovigilance performance of health facilities using the pharmacovigilance assessment tool adapted from the indicator-based pharmacovigilance assessment tool developed through the Strengthening Pharmaceutical Systems Program (SPS 2009). This is to ensure that pharmacovigilance issues are promoted within these health care facilities by measuring the PV performance of the facilities using established indicators. The National Pharmacovigilance Center has successfully collaborated with the Nursing and Midwifery Council of Ghana to incorporate PV into the curriculum among nurses and midwives in training institutions in Ghana. The center makes presentations to students at pharmacy training schools in Ghana and is working with these institutions to make PV an integral part of the training curriculum. Additional strategies are needed to address the fear of personal consequences as a barrier to reporting AEFI’s (Gidudu et al. 2020).

PV should not be seen as a job for a select few; all health care workers must be involved. Moreover, if the public comes to see their role as a stakeholder, this can lead to improvements in reporting rates.

**Toward the Digitalization of Reporting**

Computer technology, which allows multiple databases to be linked, is helping in investigating drug safety issues. The widespread use of electronic medical record databases enhances patient safety through the automation of signal ADR detections, thereby improving the quality of medical services. Besides reducing printing costs and the use of paper, electronic reporting centralized on a web page allows the receipt of reports without any delay, which is highly relevant in case of serious ADRs or clusters of ADRs that suggest a possible signal.

In 2016, FDA Ghana embarked on an initiative to empower the public to report safety issues involving regulated products to the FDA (FDA 2016). The effort led, in 2019, to the launch of the mobile application **Med Safety App** to enable patients, consumers, and health care professionals to report ADRs associated with medicines, herbal medicines, vaccines, and other health products. The app adds an electronic platform to existing reporting tools to enable consumers, patients, and health care professionals to report safety issues concerning their medicines and other health products to the FDA in real time.

The **Med Safety App** has been developed with support from the Access and Delivery Partnership, the WEB–Recognizing Adverse Drug Reactions Project, and the UK Medicines and Healthcare Products Regulatory Agency. It is downloadable from the App Store or Google Play Store and is a convenient alternative to paper or online reporting tools (FDA 2019). The intended benefits for users are as follows:

- Facilitates the submission of reports on adverse reactions while offline
- Permits the viewing or submission of updates to previously submitted reports
- Allows previous ADR reports submitted through the app to be examined
- Permits the immediate acknowledgment that a report has been received
- The associated medication watchlist may be accompanied by personalized news and alerts
Monitoring medicine safety is an important undertaking for public health programs on disease control within countries. Vaccination programs and other vertical public health programs offer opportunities to enhance reporting and strengthen national pharmacovigilance systems.

This has been the case of PV in Ghana, where the routine reporting of AEFIs began with the launch of the Expanded Program on Immunization in 1978 and was continued by the FDA beginning in 2001 through the establishment of the National Pharmacovigilance Centre. Similar efforts have been undertaken through other programs. An example is the National Malaria Eradication Program, which involves the monitoring of adverse events and administration of seasonal malaria chemoprevention, such as antimalarial drugs or intermittent preventive treatments against malaria aimed at reducing the burden of malaria among certain high-risk groups, namely, pregnant women and children. Other examples are the National Tuberculosis Control Program, the National AIDS Control Program, and the Neglected Tropical Diseases Control Program for monitoring adverse events among patients receiving therapy for neglected tropical diseases, such as lymphatic filariasis, onchocerciasis, trachoma, schistosomiasis, soil-transmitted helminthiasis, Buruli ulcer, yaws, leprosy, and Guinea worm.

In the case of the Expanded Program on Immunization, PV developed in association with the overall aim of promptly detecting and managing AEFIs, real or perceived, and contributing to the credibility of immunization programs by preventing inappropriate responses to reports of AEFI that could lead to crises or vaccine-hesitancy among the population in the absence of a surveillance system (Laryea et al. 2022).
The operation of the AEFI surveillance system is a collaborative effort between the Expanded Program on Immunization of the GHS and the FDA Ghana that involves the collection and collation of routine data using the health structures of the GHS (Laryea et al. 2022). Case reporting is passive, that is, caregivers and vaccinees report adverse events to health facilities. The health facilities then record the reported events using a standard case reporting form to submit the report to the district health directorate, where the data forms are entered into the district health information management system II and transmitted to the national level through an intervening regional focal point. Data are aggregated at the regional and national levels. Some notifications are sent directly from the community or the health facility to FDA Ghana through an electronic reporting system.

In 2018, almost one-third of the spontaneous ADR reports (1,132) were AEFI reports involving stimulated spontaneous reporting during nationwide yellow fever and measles-rubella campaigns. The FDA and other stakeholders involved in PV promote reporting in these situations as part of immunization campaigns that convene thousands of citizens in a short period or other, vertical public health programs. This practice has led to good results in Ghana, contributing to the evolution and strengthening of PV nationwide. Overall, Ghana’s experience shows that involving vertical public health programs that monitor the safety of the medicines administered may represent a quick way to start receiving reports and consolidating PV activities, but also to increase the effectiveness of these programs by understanding the adverse effects of the medicines used and increase patient adherence. The latter also helps reduce drug resistance to medicines administered in such programs as well.

COVID-19 Vaccine Surveillance: Organization and Challenges

In both routine and emergency situations, information on vaccines, which represent a control measure in these situations, is always limited, especially safety data, because of the accelerated product development process and the product reviews carried out on the basis of incomplete information. Yet, safety is key in emergencies and pandemics and cannot be compromised.

Most African countries participate only irregularly in clinical trials, including vaccine trials. South Africa is the only African country that included volunteers in the initial COVID-19 vaccine trials. According to the African Academy of Sciences Clinical Trials Community, only 2 percent of clinical trials globally for any type of vaccine take place in African nations and the WHO Africa Region (Makoni 2020). Some clinical data from trials are thus not representative of the Ghanaian population. For this reason, safety monitoring within the country is important to obtain relevant information. In Ghana, pharmacovigilance is a well-known and long-standing activity that had to be adapted to respond to the rollout of the COVID-19 vaccines.

The Value of Safety Monitoring during a Pandemic and in Normal Times

In Ghana, it is said that the response improves with each pandemic. Because of Ebola, FDA Ghana upgraded the clinical trial system in 2014 (FDA 2015). Because of the COVID-19 pandemic,
PV has been greatly enhanced. The FDA realized that PV helps ensure that risk minimization measures are implemented and that the vaccines administered and the vaccination process are as safe as possible.

According to 2021 data, the National Pharmacovigilance Center received 1,359 ADR reports and 8,325 AEFI reports (FDA 2022). This important increase in the reporting rate paralleled the COVID-19 vaccination campaigns and was the consequence of the resilience of the PV system, which had become well consolidated in the country and was able to adapt to the new situation.

The availability of safety data on Africa also tended to boost confidence and trust in immunization. The results could be used to counteract the fake news on the vaccine that was favoring vaccine hesitancy. PV, which monitors safety, can contribute to the attainment of global herd immunity and more rapid control over COVID-19. In addition to contributing to VigiBase, the global safety database, national safety monitoring programs help inform the public.14

Response to COVID-19 Vaccination Rollout

In response to the COVID-19 vaccination rollout, the government instituted the Joint COVID-19 Vaccine Safety Review Committee, an independent committee with expertise in diverse fields and broad competence to review safety data and make recommendations on safety monitoring of vaccines. The committee met every two weeks and reviewed the reports describing AEFIs. A total of 26,513,553 doses of the five vaccines—Covishield/Vaxzevria, COVID-19 vaccine Janssen, Moderna COVID-19 vaccine, Pfizer BioNTech COVID-19 vaccine, and Sputnik V) that had received emergency use authorization were distributed in Ghana from March 2021 to July 2023.

The committee reviewed the 9,584 AEFI reports and carried out causality assessments on 63 serious AEFI reports. Based on the extensive data collected in Ghana, it concluded that AEFIs associated with COVID-19 vaccinations are rare and that the vaccines are well tolerated. Statistically, the AEFIs reported in association with COVID-19 vaccines occur at about 36 events for every 100,000 doses administered. Most of these reported AEFIs were also identified during clinical trials of the vaccines and were thus not unexpected.

After each meeting, clear and effective information was distributed to the public to build trust in the immunization process and AEFIs, thus reducing vaccine hesitancy. Additionally, a dedicated telephone line was opened to facilitate the reporting of suspected AEFIs by the public. An app was prepared for the PV system to ease the process and as a complement to the web page that was available for health professionals and patients (FDA 2021).

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14 About VigiBase (web page), Uppsala Monitoring Centre, Uppsala, Sweden, [https://who-umc.org/vigibase/](https://who-umc.org/vigibase/).
National medicines regulatory authorities are the gatekeepers of the supply chain of medical products. They are mandated to ensure the quality, safety, and efficacy of medicines, vaccines, blood and blood products, and medical devices, including diagnostics and traditional or herbal medicines. The associated evaluation and assessment process is based on verification of the indicators included in a data collection tool conforming to the recommendations of the WHO for strengthening regulatory bodies. If a national regulatory system is independent, efficient, science-based, transparent, and well-managed, it supports robust and effective medical product regulation. As a result, medicines and other health technologies entering the market are more likely safe, efficacious, and assured in quality. This protects the population from harm arising from unregulated supplies, including substandard and falsified medical products, and thus fosters confidence in the health care delivery system (Khadem Broojerdi et al. 2020).

The COVID-19 pandemic has served as a demonstration of the safety monitoring potential of FDA Ghana as a national regulatory authority.

First, a national regulatory authority must be prepared to review the documentation submitted on COVID-19 vaccine applications, even though some of them may have already been approved by the WHO. According to national policy, all the applications submitted to the regulatory authority must be reviewed, although the reliance approval process can be used in some cases. As of June 2021, FDA Ghana had given emergency use authorization for two COVID-19 vaccines. As of December 2022, six COVID-19 vaccines had received emergency use authorization (Comirnaty, Covishield, Jcovden, Spikevax, Sputnik V, and Vaxzevria).

Health authorities also have a safety monitoring strategy. This has been a key element because it is a prerequisite for emergency authorization. An enhanced vaccination system relies on vaccination reports, which are appropriately followed up on and assessed. Furthermore, health authorities conduct cohort event-monitoring studies to collect information on any rare event occurring at a higher frequency than expected in the target population of 10,000 people enrolled in these cohorts. Additionally, those responsible for marketing authorization conduct formal epidemiological studies (which is also a requirement for authorization). Research centers are performing complementary studies that advance the authorization process, such as gene sequencing to identify available SARS-CoV2 variants in the country.

In Ghana, there are legal mandates regarding PV that apply to anyone marketing a product, and the public and private sectors must monitor the product’s safety. So, there are guidelines for the surveillance of vaccines at various levels, including the unit responsible for marketing authorization, the health care provider, and the public.

Within this framework, the support of several actors and stakeholders should be highlighted. First is the Ghana MOH, which carries out the required PV activities. Second is the strong collaboration with the WHO, the African Vaccines Regulatory Forum, and the Africa Centers for Disease Control and Prevention. The Vaccine Safety Surveillance System available through the Africa Union Smart Safety Surveillance provides a continental view, even though reports are also uploaded to the WHO VigiBase global database.

Opportunities to Improve PV in Ghana

Three main opportunities have been identified for improving PV in Ghana:

• The attainment in 2020 of WHO maturity level 4 for PV in Ghana indicating a regulatory system operating at an advanced level of performance challenges the government to support continuous improvement (WHO 2021), including the funding required to expand and carry out the PV activities across the different regions in the country.

• The introduction of medicines that will be used mainly in Africa and for which the safety monitoring responsibility resides solely with the national regulatory authority provides opportunities for improvement of the PV system, for example, malaria vaccine, COVID-19 therapeutics (generic), and monoclonal antibodies for prevention.

• Because it is a Regional Center of Regulatory Excellence, FDA Ghana is provided with the opportunity to share expertise and knowledge within and beyond the subregion. The designation means that FDA Ghana is in a partnership with other institutions with specific regulatory expertise and training capabilities that has been established by the African Union’s African Medicines Regulatory Harmonization program to fill a gap and address the regulatory capacity challenges experienced by national medicines regulatory authorities and the pharmaceutical industry in Africa.

Potential Areas of International Support

In PV, many planned activities require funding support that is appropriately allocated. These activities, which are important in ensuring complete surveillance of the COVID-19 vaccination deployment, include the following:

• The scaling of cohort event monitoring to COVID-19 vaccines
• Training programs for health care workers and awareness of the importance of AEFI reporting
• Improvement of the dedicated telephone line to a call center that is able to handle many calls simultaneously
• Support for the engagement of short-term employees across various regions

Additionally, the FDA could benefit from the development of its technical capacity and the strengthening of its expert committees to assist in reviewing vaccine safety data and publishing the resulting information to increase the trust of health professionals and the public.

International technical cooperation agencies could also supply assistance. For example, the WHO supports member states in strengthening their regulatory systems for medical products by setting norms and standards, promoting smart regulation, identifying strengths and gaps, providing specialized technical assistance and capacity-building opportunities, and advising on issues related to the quality assurance of medicines for national and international markets. Also, as part of its regulatory system strengthening program, WHO could support in benchmarking and regulatory systems by, for instance, using a set of indicators designed to evaluate regulatory oversight for vaccines (Khadem Broojerdi et al. 2020).
Lessons Learned

Ghana’s PV experience offers some lessons that may be of relevance to other countries, as follows:

- A strong national medicines regulatory authority, such as FDA Ghana, is crucial to defining clear objectives for medicines safety monitoring and to informing key legislation that facilitates the emergence and growth of a national pharmacovigilance system.
- Both local and external stakeholders are needed to build a strong PV system.
- Clearly defined funding arrangements are critical for ensuring the sustainability of PV activities. The judicious use and accountability of donor funds are important to ensuring continuous support.
- One way to promote the development of PV capacity in a country is to take advantage of public health programs that are centered on the administration and use of vaccines and medicines for disease control, such as the immunization program or the TB, HIV, or malaria programs.
- Sharing safety information on specific public health programs is important to ensure continued collaboration.
- Having the right staff strength in terms of knowledge and numbers is important for effective safety monitoring.
- Communication arrangements are crucial to minimizing crisis escalation in the case of adverse drug events based on country safety data and from abroad.
- Good international relations help in remaining up to date on good international practices and in facilitating early engagement with interesting and useful projects.
- Preparing international publications explaining the results of PV activities requires expertise and time, but the potential impact on becoming a reference center will repay all the effort.


RBC (Rwanda Biomedical Center). 2022. "Rwanda FDA and Ghana FDA Sign a Memorandum of Understanding." News and Events, June 27, 2022. https://rbcb.gov.rw/index.php?id=100&tx_news_pi1%5Bnews%5D=646&tx_news_pi1%5Bday%5D=27&tx_news_pi1%5Bmonth%5D=6&tx_news_pi1%5Byear%5D=2022&cHash=274c95697be83c6f7600e670468af0b.


