RWANDA FDA
Rwanda Food and Drugs Authority

# MEDECINE SAFETY BULLETIN

ISSUE Nº4

June, 2026

# Table of Contents



## Editorial *Team*

# FOREWORD

**The Rwanda FDA is mandated by Law N° 003/2018 to protect public health by making sure that medicines and health products in Rwanda are safe, effective, and of good quality. This bulletin shows our ongoing commitment to openness, teamwork and continuous improvement in how we monitor medicine Safety.**

Prof. Emile BIENVENU
Director General

Healthcare is changing fast, with new medicines, vaccines, and technologies arriving every day. While this brings great benefits, it also creates new challenges in managing risks. Our job as a regulatory authority is to stay ahead of these challenges and act early to protect the health of every person in Rwanda.

Over the past years, Rwanda FDA has worked hard to strengthen our medicine safety systems. We have trained hundreds of health workers across the country on how to detect and report side effects from medicines and vaccines. We have also introduced VigiMobile, a phone app that allows health facilities to report safety concerns in real time, making our data faster and more reliable.

None of this would have been possible without the support of our partners, the World Health Organization (WHO), Africa CDC, Akros Research, and the European Union Twinning Programme. Together, we have aligned our work with international standards and contributed to stronger medicine safety systems across Africa.

This bulletin highlights key results from our work. Between January 2024 and July 2025, Rwanda FDA received 1,678 safety reports, 692 about medicine side effects and 986 about vaccine reactions. Most reported events were not serious, confirming the overall safety of medicines and vaccines currently in use. During this period, 528 health workers were trained, and 220 health centres were supervised. We also recalled 38 batches of medical products due to quality concerns. A few serious cases still need follow-up, reminding us that vigilance must never stop.

Looking ahead, we will continue to expand digital reporting, improve data analysis, and work closely with health workers and the public. We will also pay close attention to the safety of new malaria treatments as Rwanda tackles drug resistance.

I sincerely thank all healthcare workers, partners, and Rwanda FDA staff for their dedication to our shared mission. Every safety report, every training, and every partnership brings us closer to a healthier Rwanda.

**Prof. Emile BIENVENU**

**Director General**

# KEY HIGHLIGHTS

Rwanda FDA is proud to share the key findings from its fourth Medicine Safety Bulletin, covering the period from January 2024 to July 2025. This bulletin reflects our ongoing commitment to keeping medicines and vaccines safe for everyone in Rwanda.

Reporting is growing. Between January 2024 and July 2025, Rwanda FDA received 1,678 safety reports, 692 about medicine side effects and 986 about vaccine reactions. Reports came from hospitals, health centres, and vaccination sites across all districts and provinces of Rwanda. In 2024 alone, 880 reports were received, followed by 798 in just the first seven months of 2025, showing that health workers are reporting consistently and actively.

Most reactions were not serious. About 85% of medicine side effect reports and 80% of vaccine reaction reports were classified as not serious. The most commonly reported symptoms were headache, fever, and injection site pain, reactions that are well known, usually mild, and resolve on their own without treatment. A small number of serious cases are being followed up to ensure patient safety.

Health workers are better equipped. Rwanda FDA trained 528 health workers on medicine safety monitoring and the use of the VigiMobile app, a phone-based tool that allows real-time reporting of safety concerns directly from health facilities. Rwanda FDA also supervised 220 health centres across the country to strengthen reporting systems and ensure guidelines are being followed.

New malaria treatments are showing encouraging results. Rwanda introduced two new malaria treatments, DHAP and ASPY, to address growing resistance to Coartem. Of 146 patients reviewed, all were successfully cured with no cases of malaria returning. No severe side effects were recorded, though monitoring continues.

Product quality is being actively enforced. Rwanda FDA recalled 38 batches of medical products due to quality concerns, covering medicines, medical devices, and diagnostic test kits. About 74% of recalls were initiated voluntarily by manufacturers and distributors, reflecting a growing sense of responsibility within the industry. Only one recall involved a serious health risk.

Rwanda is investing in stronger safety systems. Through partnerships with WHO, Africa CDC, the European Union Twinning Programme, and continental programmes such as the AU-3S, Rwanda FDA is continuously building faster, more reliable, and internationally aligned medicine safety systems for the benefit of all people in Rwanda.

# PART I: MEDICINE AND VACCINE SAFETY MONITORING

## 1. Capacity building of healthcare professionals

### 1.1. Training of healthcare professionals from health centers on Pharmacovigilance and vaccine safety surveillance

*Rwanda FDA*, in partnership with the WHO Country Office, Africa CDC, and the Akros project, conducted a series of training sessions for health workers across Rwanda to strengthen medicine and vaccine safety monitoring.

The trainings focused on the basics of safety surveillance and how to report suspected side effects and reactions. A total of 217 health workers were trained, funded by Africa CDC through the Akros project. As a result, health workers now have stronger practical skills to detect, report, and respond to safety concerns quickly, helping to protect patients and build public trust in vaccines. This initiative demonstrates the value of strong partnerships in improving healthcare quality and ensuring that medicines and vaccines are used safely across Rwanda.


*Photo 1: Training of Nurses from health centers on pharmacovigilance and vaccine safety surveillance (Kigali, June 2025)*

### 1.2. Official Launch of the VigiMobile Application

Rwanda FDA, with financial and technical support from the WHO country office, organised training on medicine safety reporting and the use of the VigiMobile application. A total of 528 health workers from health centres across the country were trained on how to use the app, which allows health workers to report medicine side effects and vaccine reactions quickly and directly from their health facility in real time.

The training aimed to make reporting easier, reduce underreporting, and improve the quality and timeliness of safety data submitted to Rwanda FDA. Since its introduction, VigiMobile has noticeably improved the number and quality of reports received, supporting better regulatory decisions and stronger patient protection. The app also reduces errors by capturing information electronically. This initiative reflects Rwanda FDA's commitment to building a stronger medicine safety system through technology and international partnership with WHO.

*Photo 2: Launch of the VigiMobile application during training with health professionals (Musanze, December 2024)*

*Photo 3: Training for health professionals on the importance of reporting adverse drug events using the VigiMobile application (Musanze, December 2024)*

### 1.3 Supportive supervision of health centers

Rwanda FDA, in collaboration with Akros Research/Africa CDC and the WHO country office, carried out supportive supervision visits to health centres across Rwanda to strengthen medicine safety monitoring. The visits aimed to raise awareness, build the capacity of health workers to identify and report medicine side effects, and ensure compliance with national medicine safety guidelines. During the visits, Rwanda FDA provided training and tools, including the VigiMobile app, to make reporting easier and faster. Rwanda FDA also collected previously unreported reactions during the visits. Health centres were encouraged to share feedback, helping Rwanda FDA develop practical solutions to address challenges at the facility level. A total of 220 health centres were visited. This initiative reflects Rwanda FDA's commitment to protecting patients, improving healthcare quality, and building a stronger medicine safety system through active collaboration with health workers, facilities, and international partners.

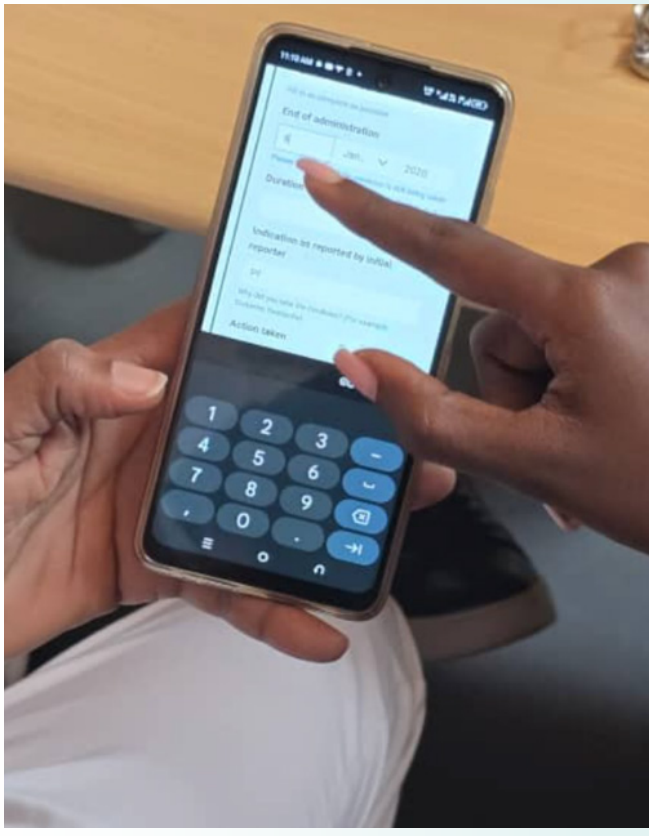


*Photo 4: Practical session on the use of the VigiMobile application (Kigali, August 2025)*


*Photo 5: Supportive supervision at Kinyinya Health Center (August 2025)*

## 2. Collaboration with partners to strengthen Pharmacovigilance across the continent

### 2.1. Technology Onboarding Workshop for Wave 2 Member States and the AfriVigilance Technical Working Group (TWG) in Lusaka /Zambia

Rwanda FDA is part of the African Union Smart Safety Surveillance programme, which works to improve medicine safety monitoring across Africa. Rwanda FDA staff took part in a Technology Onboarding Workshop alongside other African member countries, focused on migrating medicine safety data onto a shared digital platform called Safety Connect. Participants built skills in data entry, validation, and analysis on the platform, and began sharing safety data across borders to support more consistent regional monitoring. This collaboration strengthens Rwanda FDA's ability to detect and respond to safety concerns more quickly, contributing to better patient protection not only in Rwanda but across the continent.

*Photo 6: AfriVigilance Technical Working Group (TWG) in Lusaka, Zambia (August 2025)*

### 2.2. Strengthening Regional and International Medicine Safety Collaboration

Rwanda FDA joined the African Union Smart Safety Surveillance Programme, which brings together African regulatory authorities to share knowledge, methods, and real-time safety data, enabling faster detection of and response to medicine safety concerns across the region.

The programme also provides targeted training and capacity building to help regulatory authorities improve reporting systems and data analysis. As part of this work, an orientation workshop was held in Nairobi to build technical skills for running a shared regional signal validation system, helping African regulatory systems stay proactive and aligned with global safety standards.

Additionally, under the European Union Twinning programme, Rwanda FDA staff received specialised training from highly

experienced experts from Lithuania on reviewing Risk Management Plans and Periodic Safety Update Reports submitted by medicine manufacturers.

This training strengthens Rwanda FDA's capacity to make well-informed regulatory decisions, protect patients, and meet internationally recognised standards, reflecting the authority's ongoing commitment to building a world-class regulatory system.

*Photo 7: Signal Validation Hub (SVH) workshop in Nairobi, Kenya (September 2025)*


*Photo 8: Training of Rwanda FDA staff on assessment of RMPs and PSURs (Kigali/Rwanda, March 2025)*

## 3. Immunization safety report: January 2024 – July 2025

### 3.1. Safety Reporting Overview

Between January 2024 and July 2025, Rwanda FDA received 1,678 safety reports — 692 reports of suspected medicine side effects and 986 reports of reactions following vaccination. Reports came from hospitals, health centres, and vaccination sites across all districts and provinces of Rwanda, submitted mainly by nurses, doctors, and pharmacists. In 2024, 880 reports were received, followed by 798 in the first seven months of 2025, reflecting growing engagement among health workers and steady progress in medicine and vaccine safety monitoring.

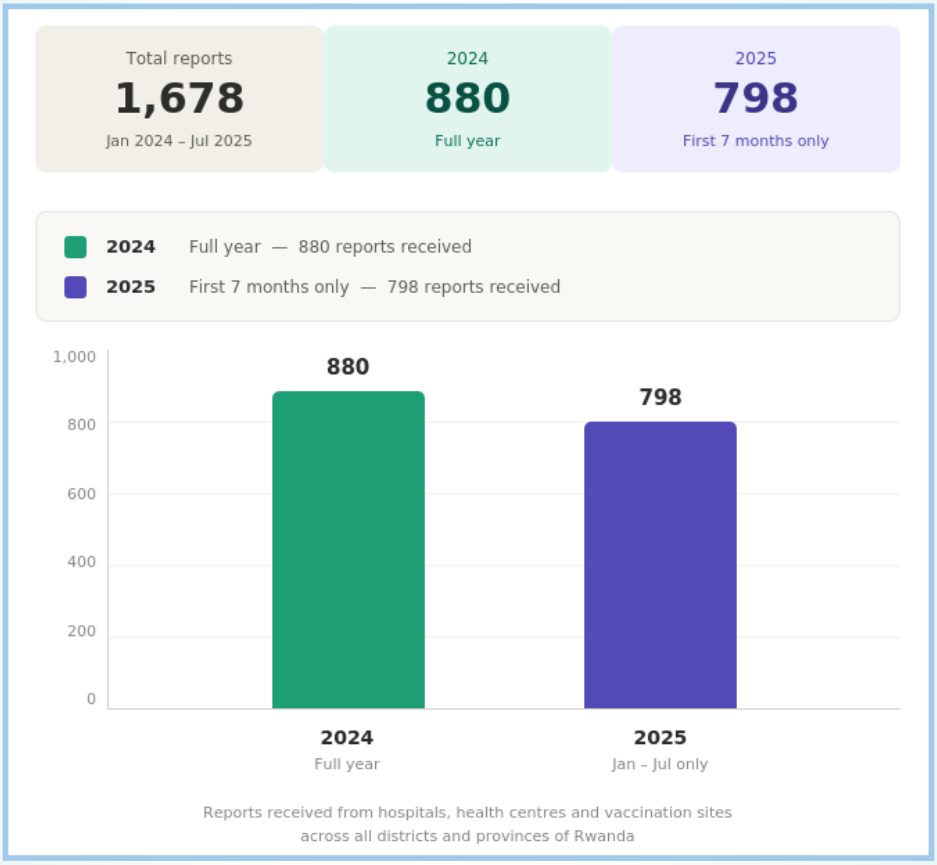
### 3.2. Patient Demographics

Looking at the age of people in the reports, most reactions were reported in people aged 18 to 44 years, making up about 60% of all cases (1,005 people). The next largest group was adults aged 45 to 64 years, who accounted for about 19% of cases (323 people).

This pattern likely reflects the fact that younger adults tend to use health services more frequently and are more likely to receive vaccinations and treatments.

**Figure 1. Safety reports per year**

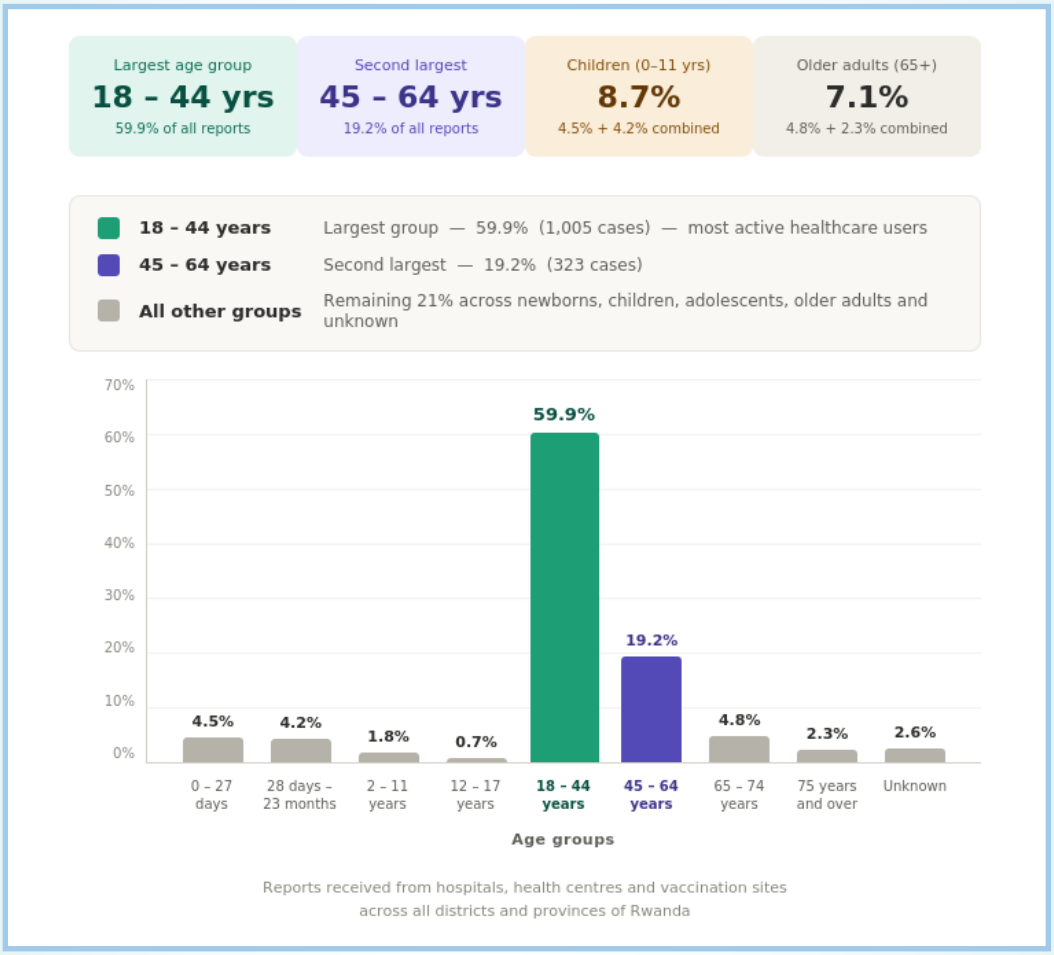
January 2024 - July 2025 | Rwanda FDA | N = 1,678



When looking at gender, women made up the majority of reports in both categories. For vaccine reactions, 71% of reports were from women and 27% from men, with the remaining cases having no gender recorded. For medicine side effects, 63% of reports were from women and 26% from men, with 11% having no gender information recorded. This pattern is seen in many countries around the world, where women tend to report health concerns more often than men, which may be linked to differences in biology, health-seeking behaviour, or greater involvement in public health programmes such as vaccination.

**Figure 2. Age categories of reported cases**

January 2024 - July 2025 | Rwanda FDA | N = 1,678



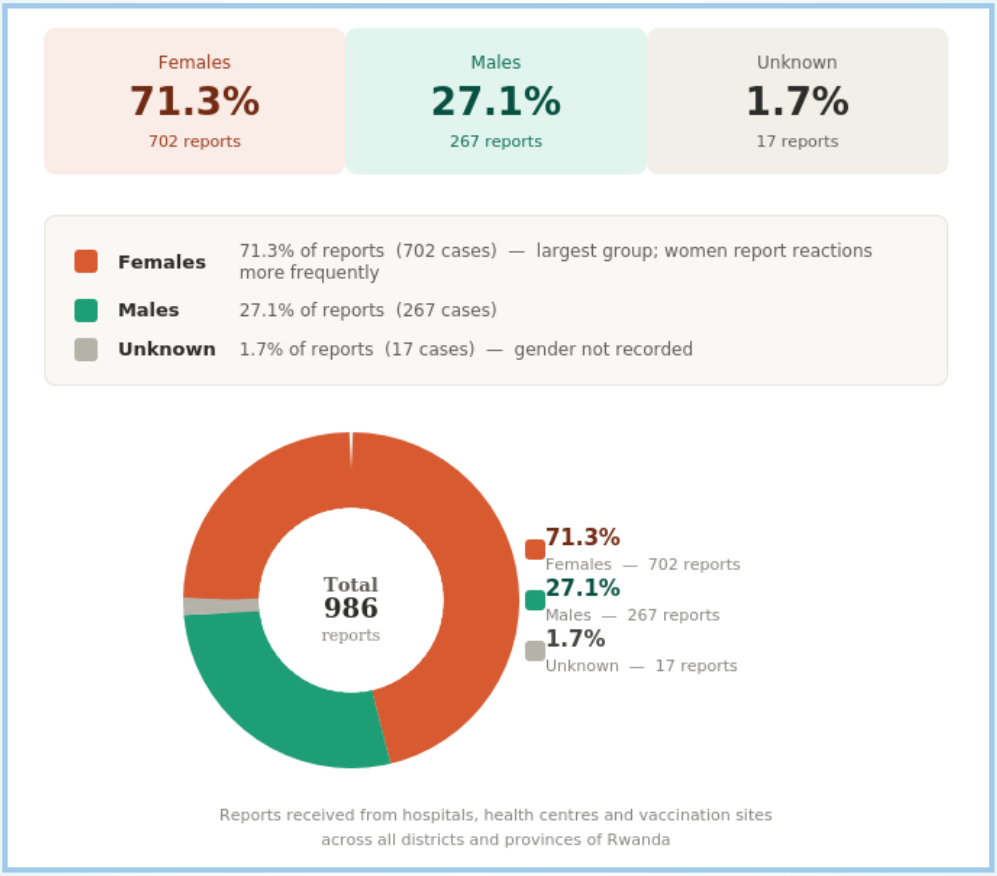

### 3.3. Characterization of Reported Events

Looking at how serious the reported reactions were, the majority were not serious in both the vaccine reaction and medicine side effect reports. Specifically, about 80% of vaccine reaction reports (785 cases) were not serious, while about 20% (192 cases) were serious, including 15 deaths. Similarly, for medicine side effects, about 85% of reports (587 cases) were not serious

and about 15% (105 cases) were serious. This data shows that serious reactions made up only a small proportion of all reports, which is reassuring and suggests that the medicines and vaccines currently in use in Rwanda have a generally good safety profile.

**Figure 3. Gender distribution - Vaccine reactions (AEFI)**

January 2024 - July 2025 | Rwanda FDA | N = 986



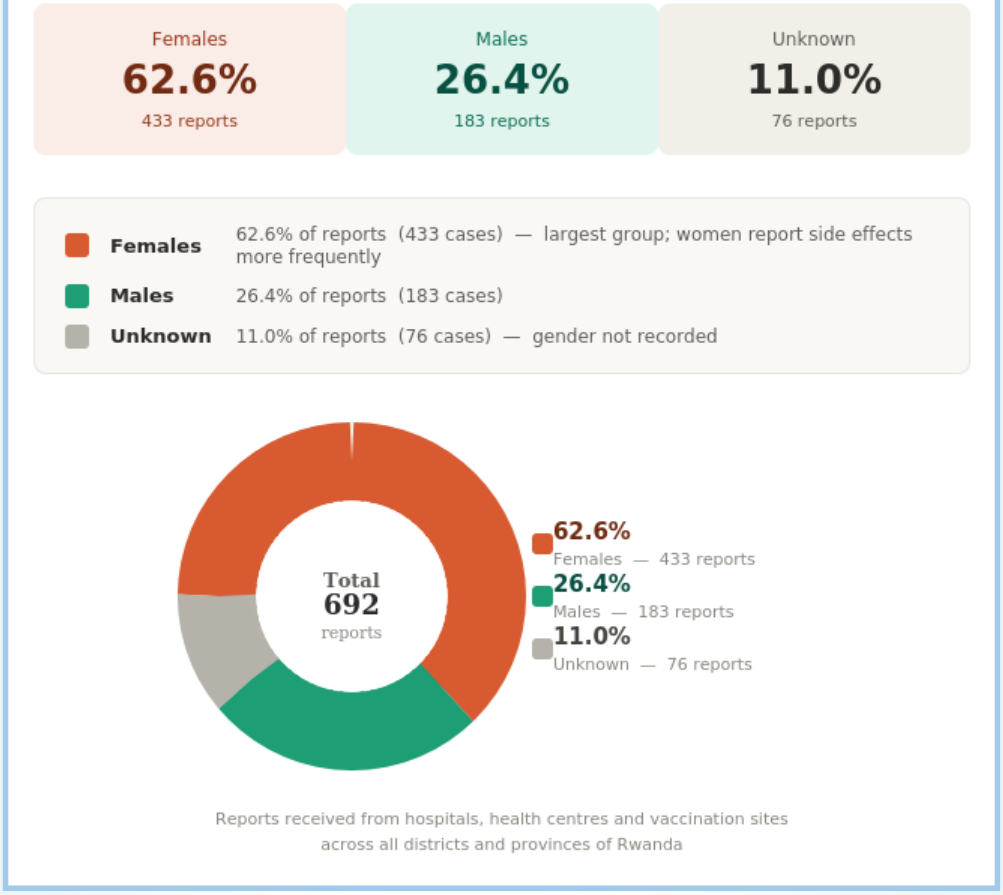

Looking at the most commonly reported symptoms across both vaccine reactions and medicine side effects, the top three were headache (12%), fever (11%), and pain at the injection site (11%). These are well-known reactions that are commonly expected after receiving a vaccine or taking certain medicines, and they usually get better on their own without any treatment. Continued reporting by health workers and patients remains essential to catching any unexpected safety concerns early and maintaining public confidence in vaccines and medicines.

### 3.4. Drug/Vaccine Characteristics

Most vaccine reaction reports were linked to vaccines used in mass vaccination campaigns, particularly the Mpox vaccine (Jynneos). Most medicine side effect reports were linked to medicines used to treat high blood pressure, particularly a medicine called Nifedipine.

**Figure 4. Gender distribution - medicine side effects (ADR)**

January 2024 - July 2025 | Rwanda FDA | N = 692

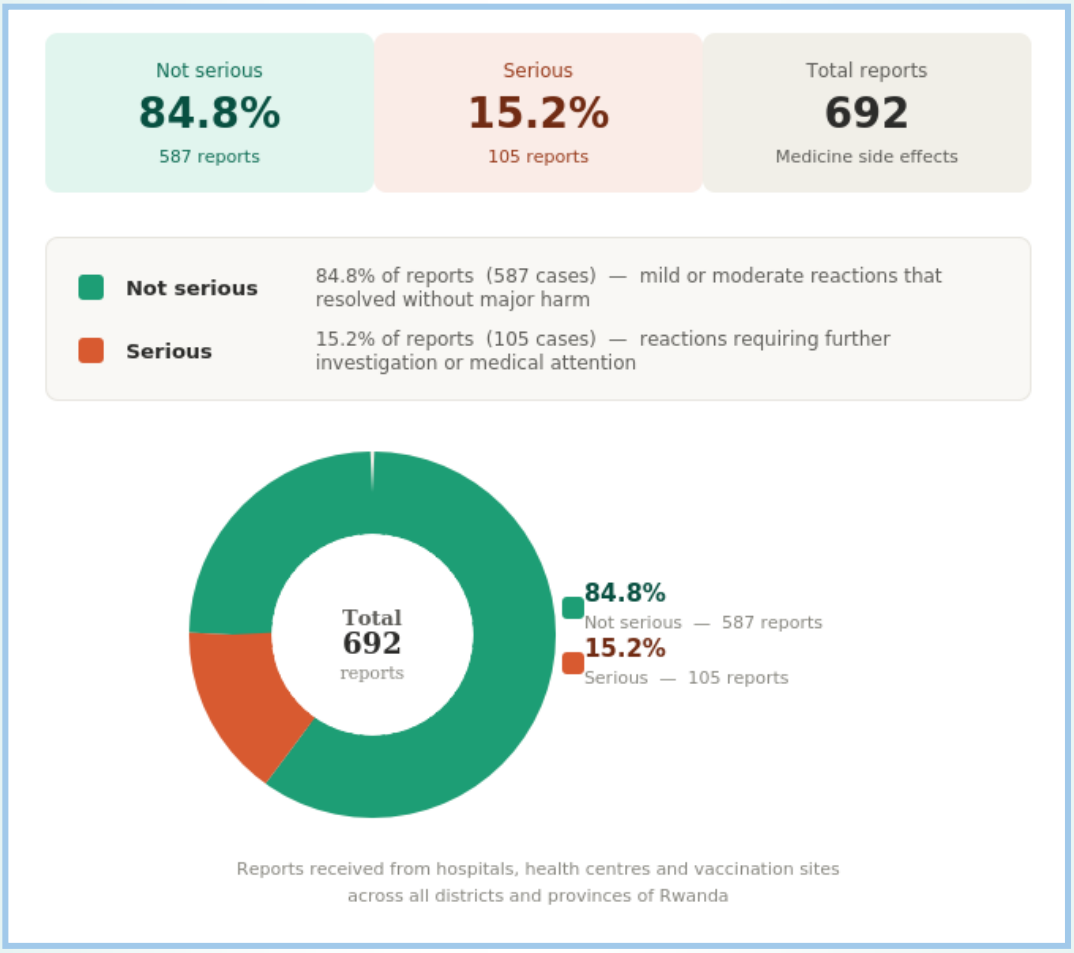



### 3.5. Recommendations

1. Continue training health workers and involve community health workers in detecting and reporting medicine side effects and vaccine reactions promptly.
2. Encourage health workers to record product details carefully, including batch numbers, manufacturing dates, and expiry dates, to help trace products if a safety concern arises.
3. Conduct refresher training sessions on how to report medicine and vaccine reactions to improve the quality and completeness of the reports submitted.

**Figure 5. Seriousness of medicine side effects (ADR)**

January 2024 - July 2025 | Rwanda FDA | N = 692




### 3.6. Conclusion

A small number of serious cases require further investigation, but these do not indicate that the overall benefits of the medicines and vaccines in use are outweighed by the risks. Continued monitoring, prompt follow-up of reported cases, and ongoing strengthening of medicine safety systems remain key priorities.

**Figure 6. Seriousness of Vaccine reaction (AEFI)**

January 2024 - July 2025 | Rwanda FDA | N = 986

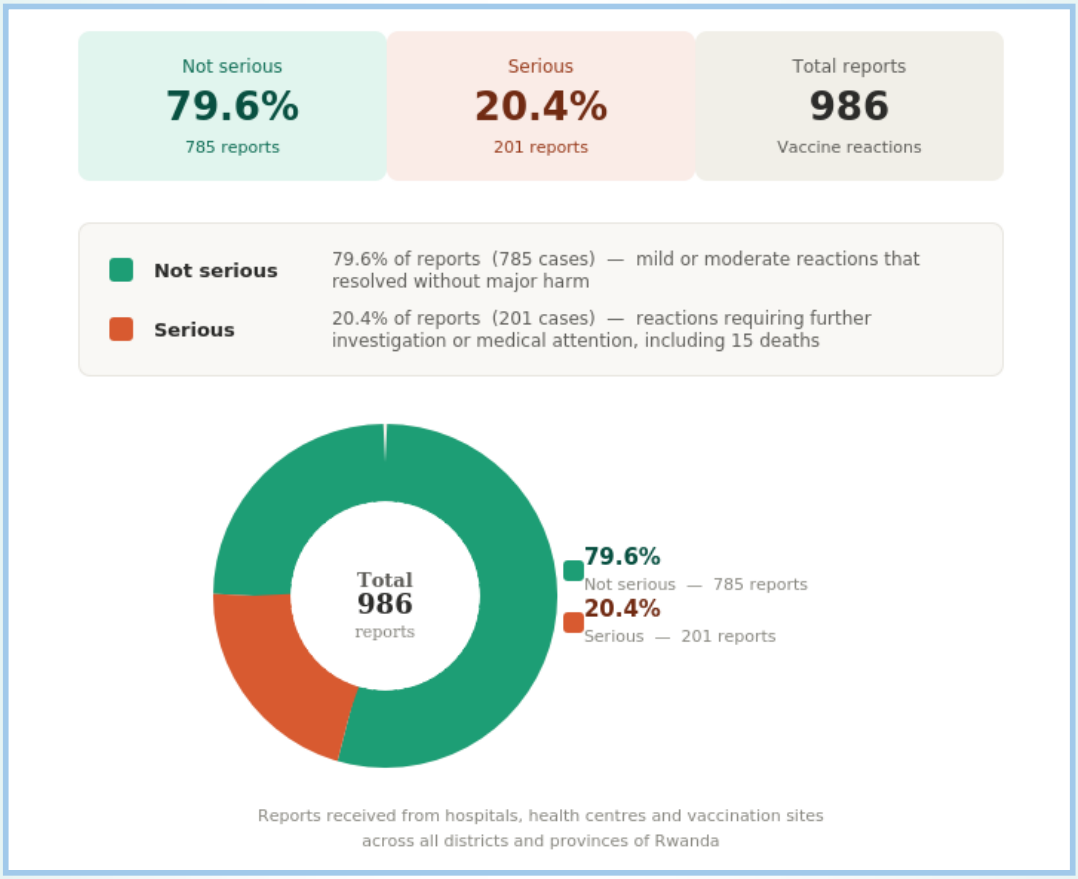


**Figure 7. Most commonly reported adverse events by symptom**

January 2024 - July 2025 | Rwanda FDA | N = 1,678

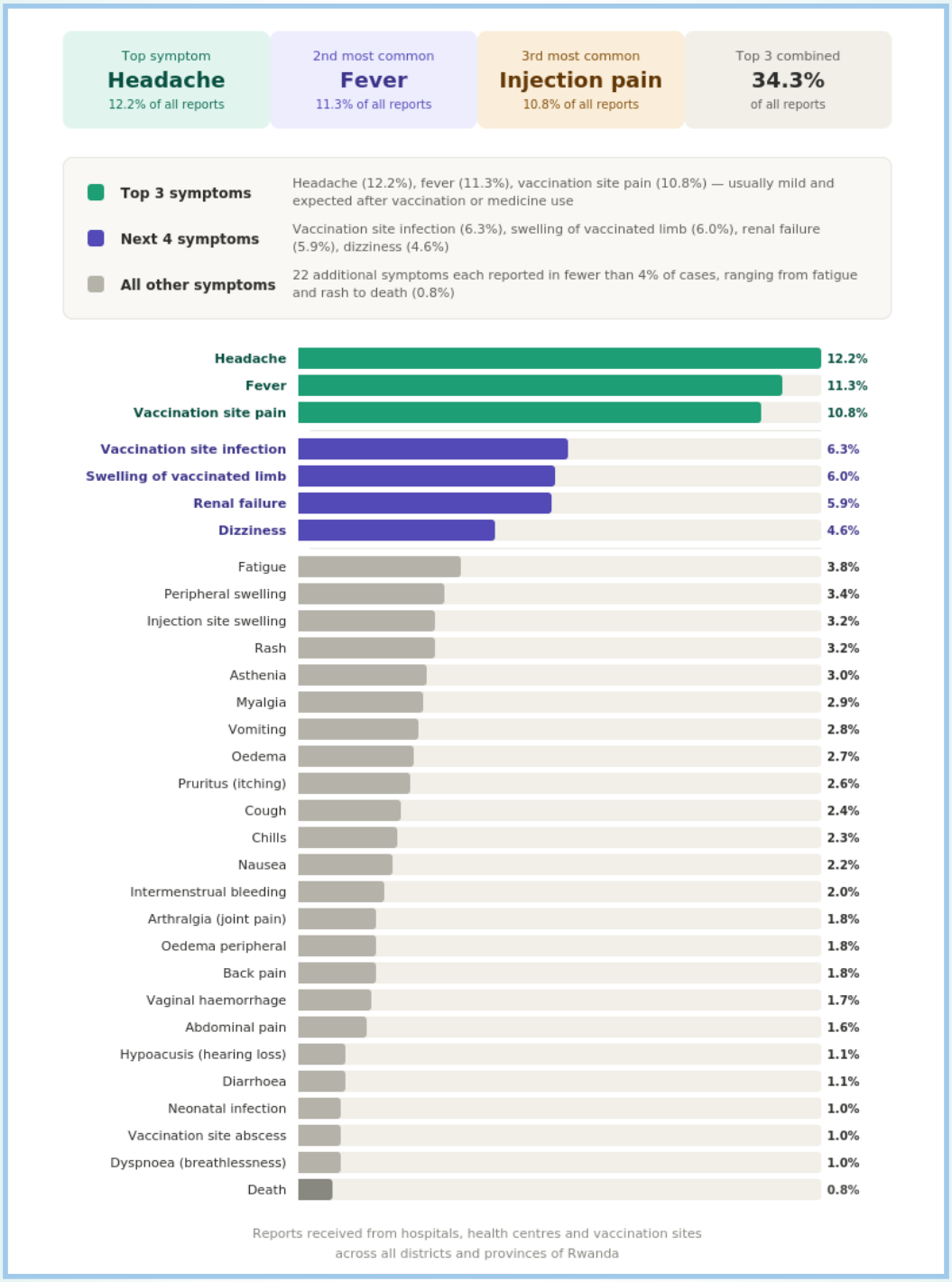


**Figure 8. Most commonly reported vaccines associated with reactions**

January 2024 - July 2025 | Rwanda FDA | N = 986 Vaccine reaction reports

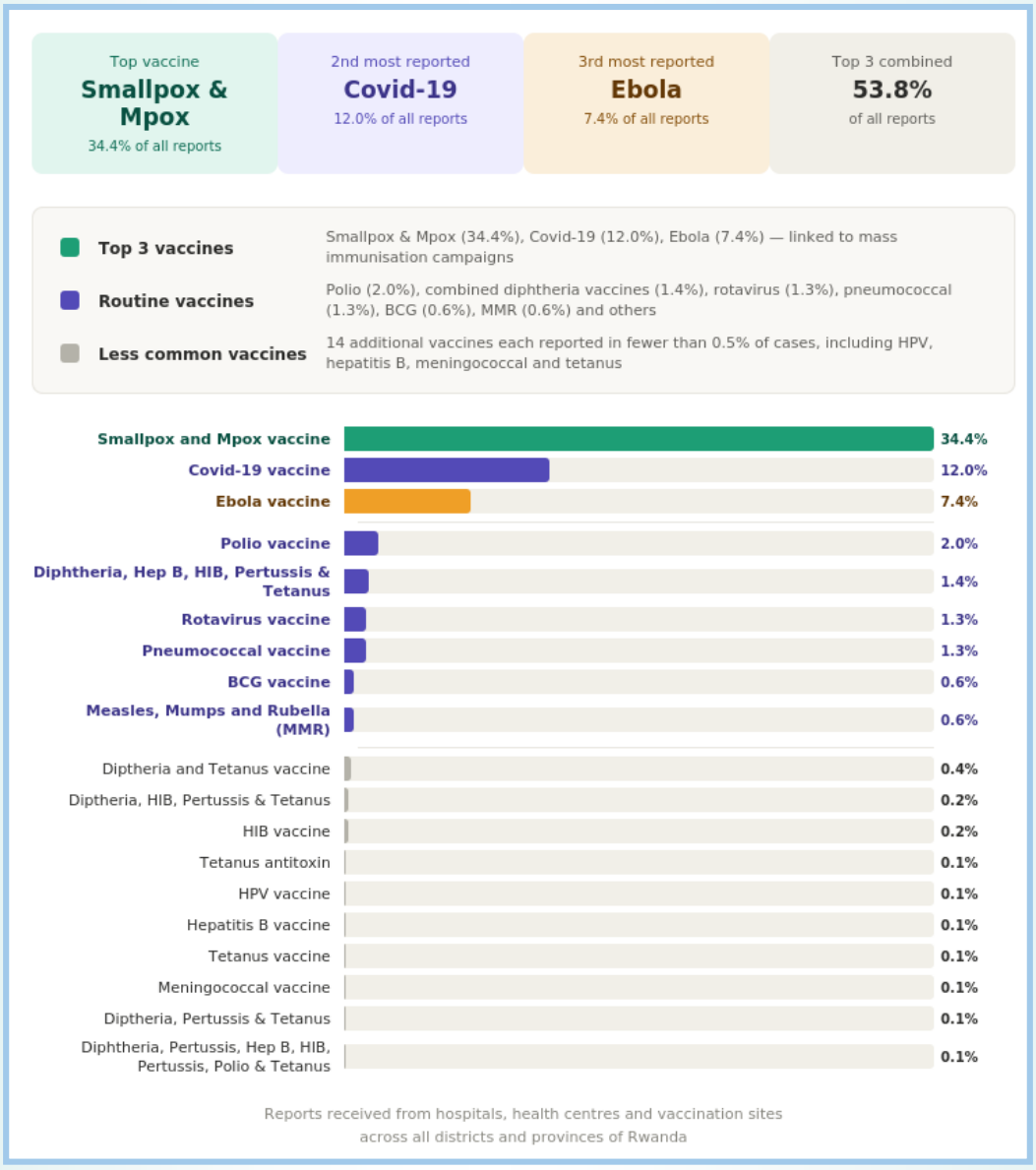
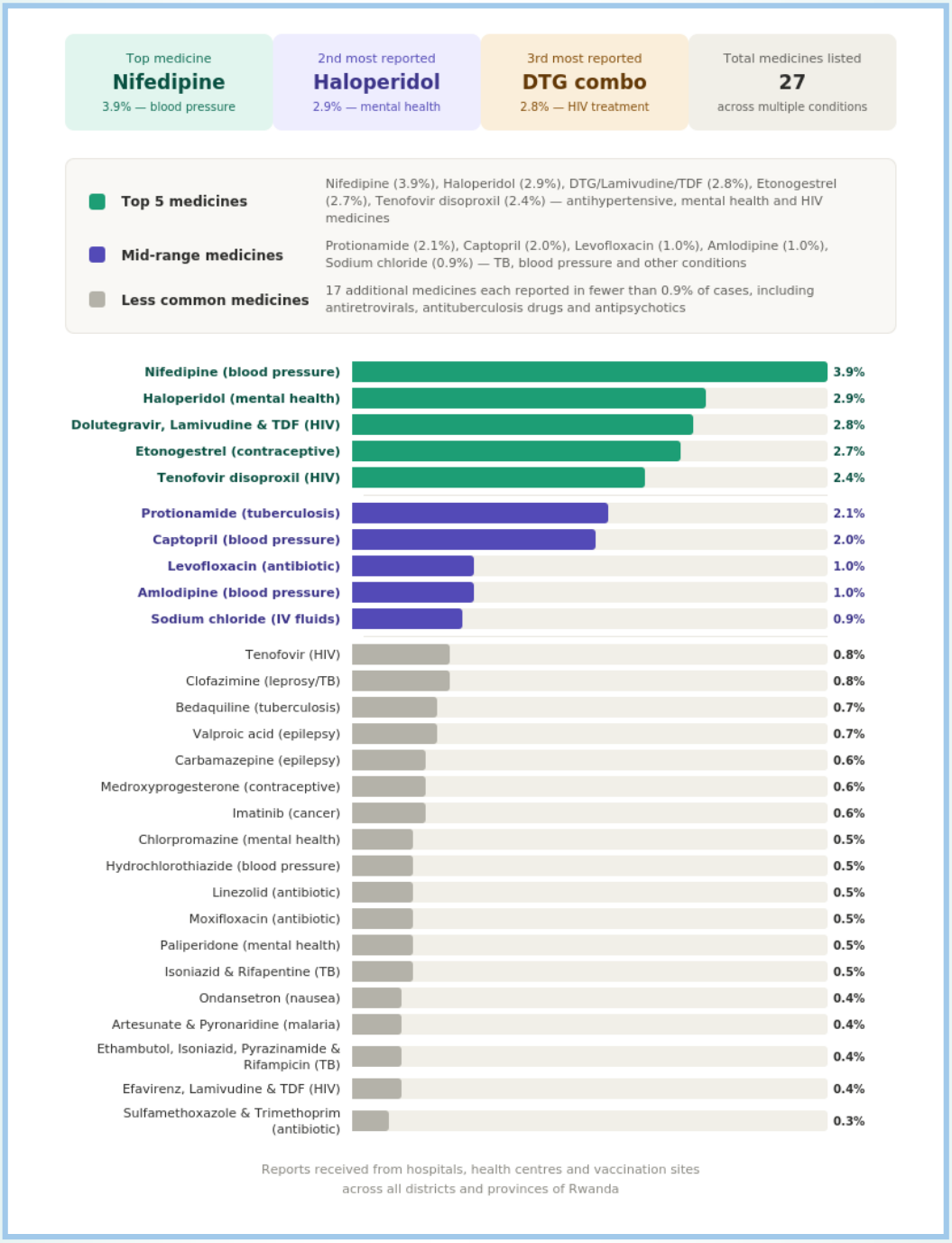


**Figure 9. Most commonly reported reported medicines associated with side effects**

January 2024 - July 2025 | Rwanda FDA | N = 692 Vaccine side effect reports



## 4. Safety monitoring of novel malaria treatments in Rwanda

### 4.1. Adverse events on Dihydroartemisinin-Piperaquine (DHAP) and Artesunate Pyronaridine (ASPY)

Rwanda has been facing a growing problem with its main malaria medicine, Coartem, becoming less effective as the malaria parasite develops resistance to it. To address this, Rwanda introduced two new WHO-recommended malaria treatments: Dihydroartemisinin-Piperaquine (DHAP) and Artesunate Pyronaridine (ASPY). While malaria cases had dropped significantly to around 200,000 in 2023/24, a worrying increase of nearly 46% was recorded in 2024, making it urgent to bring in these new treatments.

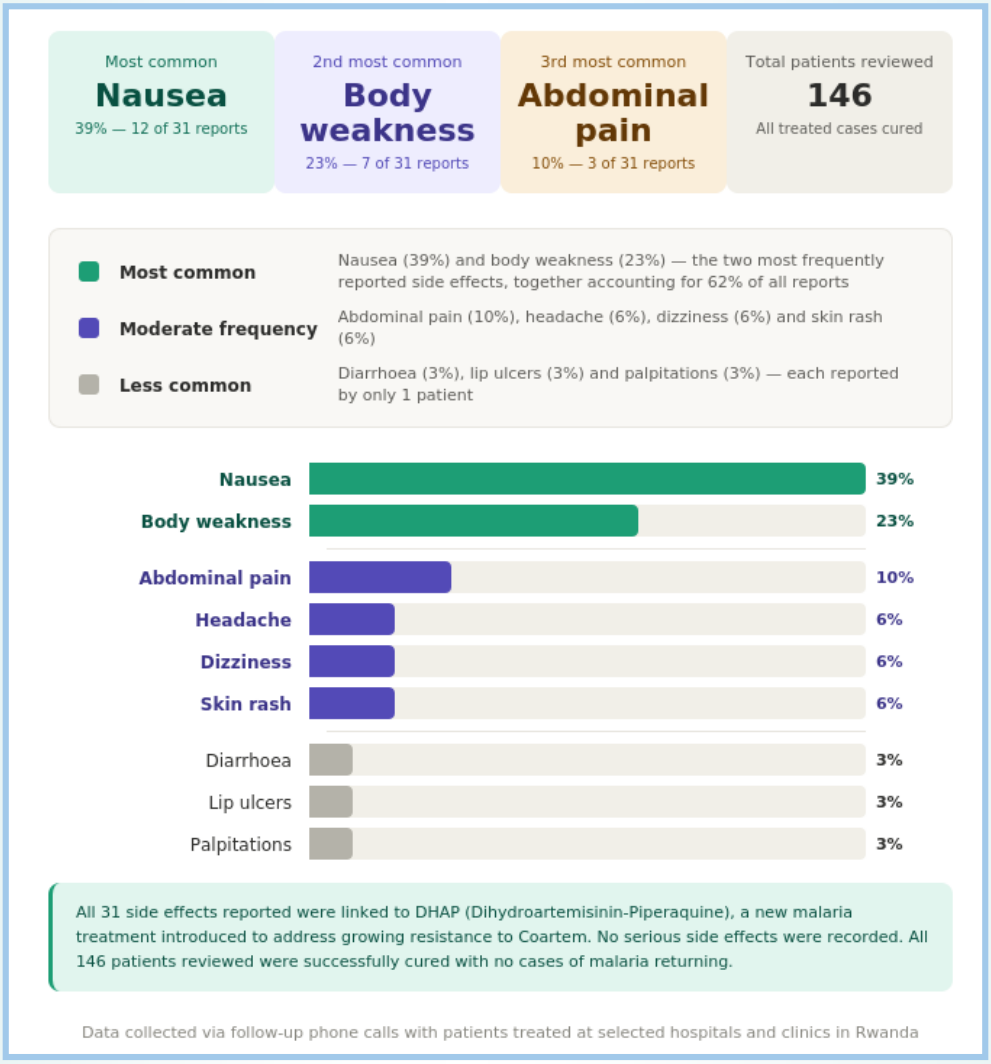
To ensure patient safety, Rwanda FDA began actively monitoring side effects at selected hospitals and clinics. Health workers followed up with patients by phone after malaria treatment, recording and reporting any side effects using the VigiMobile app. A total of 146 patients have been reviewed so far. Women made up 57% of cases, and the age group most commonly affected was 22 to 31 years old.

All 31 reported side effects were linked to DHAP. The most common were nausea, reported by 39% of affected patients, and body weakness, reported by 23%. No side effects were reported for ASPY, most likely because it was used in fewer health facilities. Masaka District Hospital recorded the highest number of malaria cases at 47%, the most resistance to Coartem at 49%, and the most reported side effects at 55%. Encouragingly, all treated patients were cured with no cases of malaria returning.

Overall, DHAP appears well tolerated, and the safety results so far are encouraging with no severe side effects reported. Continued monitoring, wider use of ASPY, and involvement of more health facilities will build a fuller safety picture. Rwanda FDA encourages all health workers to report side effects promptly, reinforcing public confidence in these new treatments and supporting Rwanda's long-term malaria control strategy.

**Figure 10. Side effects reported for new malaria treatments (DHAP)**

Active safety monitoring | Rwanda FDA | N = 31 side effect reports from 146 patients reveiwed




## 5. Medicine safety information communication

Medicine safety communication is a cornerstone of pharmacovigilance, ensuring that accurate and timely information reaches all stakeholders to support informed decision-making and risk minimization. This communication spans product leaflets, alerts notification, and public safety reports, enabling healthcare professionals and patients to adopt safe practices.

Guided by established safety and vigilance guidelines, Rwanda FDA regularly prepares and disseminates safety updates to health professionals, patients, and marketing authorization holders. These updates highlight newly identified risks associated with medicines or vaccines and recommend appropriate risk mitigation measures.

Effective communication goes beyond issuing notices, it requires that messages are clearly understood by the intended audience and prompt appropriate action. When safety information is received, understood, and acted upon as intended, it strengthens patient safety and fosters trust in the healthcare system.

**Table 1. Medicine safety information for health workers**

Rwanda FDA | Important safety alerts for five medicines and medicine groups

| Skin reaction risk | Bleeding risk | Pregnancy risk | Birth defect risk |
|---|---|---|---|
| DRESS<br>Phenobarbital & Acyclovir | Warfarin + Tramadol<br>Dangerous interaction | Multiple medicines<br>5 safety categories | Valproate<br>Risk to unborn children |

| | |
|---|---|
| ☐ DRESS (skin reaction) | A rare but life-threatening skin and organ reaction. Symptoms include widespread rash, fever, and swollen lymph nodes. Requires immediate stopping of the medicine. |
| ☐ Drug interaction | When two medicines are taken together and one affects how the other works — in this case causing dangerous bleeding when Warfarin and Tramadol are used at the same time. |
| ☐ Pregnancy risk categories | A grading system (A to X) showing how safe a medicine is to use during pregnancy — from Category A (safe) to Category X (must not be used in pregnancy). |
| ☐ Neurodevelopmental risk | Risk that children born to fathers taking Valproate may be affected in their brain development. Applies to men of reproductive age taking this medicine. |

| Medicine | Safety concern | What health workers should do |
|---|---|---|
| **Phenobarbital**<br>Used for epilepsy and seizures<br>DRESS skin reaction risk | Risk of a rare but serious skin and organ reaction called DRESS — which causes widespread rash, fever, swollen lymph nodes, and organ damage | • Watch closely for signs of DRESS in all patients taking this medicine<br>• Stop the medicine immediately if DRESS is suspected<br>• Teach patients the warning signs and tell them to seek urgent medical care if they appear<br>• Do not restart this medicine or use a similar medicine after a DRESS reaction<br>• Look beyond the skin rash to assess how severe the reaction is<br>• Detect drug reactions early so treatment can be adjusted in time<br>• Pharmacists: give patients full information about risks and report any reactions to Rwanda FDA<br>• Report suspected DRESS cases to Rwanda FDA |
| **Warfarin and Tramadol**<br>Blood thinner + painkiller<br>Risk of severe bleeding | Taking Warfarin and Tramadol together can cause dangerously heavy bleeding. Warfarin is a blood-thinning medicine that requires careful dosing — adding Tramadol raises the risk further. | • Use extra caution when prescribing Tramadol to any patient already taking Warfarin<br>• Be aware that this combination raises the risk of serious bruising and life-threatening bleeding<br>• The same caution applies if Tramadol is given with other similar blood thinners<br>• Check whether additional INR blood tests are needed when adding Tramadol or any new medicine<br>• Always ask patients what other medicines they are taking before prescribing Warfarin<br>• Check the medicine information leaflet of any new medicine being added for patients on Warfarin<br>• Tell patients to go to hospital immediately if they notice signs of unusual or heavy bleeding<br>• Report suspected side effects or reactions to Rwanda FDA |

| Medicine | Safety concern | What health workers should do |
|---|---|---|
| **Acyclovir**<br>Used for viral infections (herpes, chickenpox)<br>**DRESS skin reaction risk** | Risk of a rare but potentially life-threatening skin and organ reaction called DRESS following Acyclovir treatment | • Be alert to the risk of DRESS — a serious skin and organ reaction — in patients taking Acyclovir<br>• Tell patients to watch for severe skin reactions and seek urgent care immediately if they occur<br>• If DRESS is suspected, stop Acyclovir immediately and refer the patient to a skin specialist<br>• Never restart Acyclovir in a patient who has had a DRESS reaction — use an alternative medicine instead<br>• Report all suspected side effects linked to Acyclovir to Rwanda FDA |
| **Medicines during pregnancy**<br>All medicines used by pregnant women<br>**Pregnancy safety categories** | The risk a medicine poses to an unborn baby is graded from Category A (safest) to Category X (must never be used in pregnancy). Health workers must know these categories before prescribing. | A Safe — studies in pregnant women show no risk to the baby at any stage<br>*e.g. vitamins, levothyroxine*<br>B Probably safe — animal studies show no risk, and limited human data suggests no concern<br>*e.g. paracetamol, amoxicillin*<br>C Use with caution — animal studies show possible harm but human studies are lacking<br>*e.g. diltiazem, spironolactone*<br>D Risk confirmed — evidence of harm to unborn baby exists, but benefits to the mother may still justify use<br>*e.g. phenytoin, valproic acid*<br>X Must NOT be used — the risk to the unborn baby clearly outweighs any benefit to the mother<br>*e.g. thalidomide, warfarin* |
| **Valproate-containing medicines**<br>Used for epilepsy, bipolar disorder, migraine<br>**Risk to children of male patients** | New evidence suggests that children born to fathers who were taking Valproate in the 3 months before conception may have a higher risk of developmental problems affecting the brain and behaviour | • Valproate treatment in male patients should be started and supervised by a specialist<br>• Inform male patients about the potential risk to children they may father while taking Valproate<br>• Discuss the need for effective contraception — for the patient and their female partner — during treatment and for at least 3 months after stopping<br>• Regularly review whether Valproate remains the most suitable treatment and discuss alternatives<br>• Advise male patients not to donate sperm during treatment or for at least 3 months after stopping<br>• If the patient's partner becomes pregnant while he was taking Valproate, advise them to speak to a health worker<br>• Patients must not stop taking Valproate without speaking to their health worker first |

All health workers are encouraged to report any suspected side effects or safety concerns related to these or any other medicines to Rwanda FDA using the VigiMobile app or through your nearest health facility pharmacovigilance contact.

Source: Rwanda FDA medicine safety communications | For use by healthcare professionals

# PART II: RECALLS AND SUSPENSION: MOVING FROM REACTION TO PREVENTION

## 1. Purpose and approach of product recalls and import suspension

Recalling medicines and suspending imports are two important tools Rwanda FDA uses to protect public health by quickly removing unsafe, poor quality, or fake products from the market. Beyond their immediate protective role, recalls also help identify weaknesses in manufacturing, distribution, and regulation, creating opportunities to improve systems and prevent problems from recurring.

To tackle recurring issues more proactively, Rwanda FDA is shifting from reacting to problems after they occur toward preventing risks before they reach patients. This includes using digital tracking systems to follow every medicine pack from manufacturer to patient, enabling precise identification of affected products during recalls. Rwanda FDA also works closely with regional and global partners to align standards and respond more quickly, and has introduced a risk-based approach to market monitoring; directing resources where they are most needed and ensuring decisions are based on solid evidence.

## 2. Recall Statistics and Key Findings

Between April 2024 and October 2025, Rwanda FDA carried out 38 product recalls covering human and veterinary medicines, medical devices, and diagnostic test kits. Of these, 28 recalls (74%) were initiated voluntarily by manufacturers or a distributor, reflecting growing industry accountability, while 10 recalls (26%) were ordered by Rwanda FDA through regulatory enforcement. Only 1 recall (3%) was classified as a serious health risk, while the remaining 37 (97%) involved moderate risks requiring timely corrective action. Rwanda FDA also suspended the Relief tablet after an unauthorised version was found on the market, with further investigation revealing five different versions claiming different manufacturers, a serious finding pointing to possible fake products.

These results highlight the importance of continuous market monitoring and strong collaboration between Rwanda FDA, manufacturers, distributors, and health workers to maintain a safe medicine supply for all patients.

**Table 2: Recalled medical products from April 2024 and October 2025**

| NO | Date of recall | Medecine incriminated | BATCH NO. & EXPIRY DATE | Types and Class of Recall | Manufacturer | Safety/Quality issue |
|---|---|---|---|---|---|---|
| 1 | 12/04/2024 | Benylin Pediatrics Syrup | BN:329304 Exp:April 2024 | Statutory Recall, Class I | Johnson & Johnson, South Africa | The medicine contained unacceptable high level of diethylene glycol |
| 2 | 26/05/2024 | Warfarin 1mg tablets | BN:T220237 | Statutory Recall, Class II | | The medicine does not meet quality standards with regards to uniformity of contents. |
| 3 | 30/06/2024 | Efferalgan vitamine c 500mg/200mg | I | Statutory Recall, Class II | UPSA SAS, France | The medicine had Color change from white to brown color |
| 4 | 30/06/2024 | Tetracycline eye ointment | BN:23038 | Statutory Recall, Class II | Curis Lifescience Pvt Ltd, India | Discloration |
| 5 | 03/01/2025 | Captopril 12.5 mg tablets USP | BN 85181 | Voluntary recall, Class II | Lab & Allied Ltd, Kenya | Medicine failed dissolution rate test, uniformity of content |
| 6 | 03/01/2025 | Omiren (Omeprazole Capsules BP 20 mg) | BN: 00124 Exp. 3/2026 | Voluntary recall, Class II | RENE INDUSTRIES LTD, Kampala/ Uganda | Medicine failed to comply with dissolution test specifications |
| 7 | 27/01/ 2025 | Chlorpheniramine (Chaleate) 4 mg tablets | BN: 84936 Exp. 10/ 2026 | Voluntary recall, Class II | Lab & Allied Ltd, Kenya | The product failed to comply with uniformity of content and assay test specifications. |
| 8 | 03/01/ 2025 | Dix (Digoxin Tablets 0.25 mg) | BN:T36028 Exp.10/2026 | Voluntary recall, Class II | Agog Pharma Ltd | The product failed to comply with uniformity of content and assay (overdosed) test specifications |
| 9 | 10/10/2024 | Efferalgan Vitamine C | BN: A6091 | Voluntary recall, Class II | UPSA SAS, France | Color change from white to brown color |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10 | 02/09/2024 | Methyldopa 250 mg tablets | BN:211371, 211372, 211373 | Voluntary recall, Class II | Sevatto Pharma 303, Gujarat, India | Physical appearance ( Change of color) |
| 13 | 23/04/2025 | Aspirine vitammin C 330MG/200 mg | BN: B6224, Exp. 08/2026 | Voluntary recall, Class II | UPSA SAS, France | Color change from white to brown color |
| 14 | 15/07/2025 | Blood grouping sera ABD 4 X 10ml Kit BN:All | All | Voluntary recall, Class II | Med Source Ozoclone Biomedicals Pvt Ltd | Issues of weak agglutination reactions / potential false negative |
| 15 | 20/08/2025 | Lidocaine 2% injection 30ml | I02158, I02159, I02160, I02161, I02162, I02163, I02164, I02165, I02167, I02168, I02169, I02170, I02171, I02172, I02173, I02174, I02175 | Voluntary recall, Class II | Merit Organic Ltd (India) | The Medicine had particulate matter within solution for injection |
| 33 | 25/08/2025 | PROSTREP 20/20 INJ 100ml (Procaine Benzyl Penicillin 200mg, Dihydrostreptomycin Sulphate 200mg) | BN:MV32-002, MV32-003, MV32-004, MV32-005 | Statutory recall, Class II | ModHike Private Limited | Precipitates in solution and color change from white to yellow |
| 37 | 24/09/2025 | Adhesive perforated plaster, | all Batches | Statutory recall, Class II | JINHUA JINGDI MEDICAL SUPPLIES Co. Ltd / China | The plaster leaves color stains on patients' linens and on the applied areas of the skin |
| 38 | 24/09/2025 | IV Catheter G24, all batches | all Batches | Statutory recall, Class II | ANJI SPENQ INDUSTRIAL CO. LTD/China | The catheter are easily broken and causes trauma to the patients during use |

# PRIORITIES FOR MEDICINE SAFETY, MARKET MONITORING

In line with the Rwanda FDA Strategic Plan 2024–2029, Rwanda's regulatory priorities for 2026 focus on strengthening medicine safety monitoring and post-market surveillance as essential parts of a modern and internationally aligned regulatory system. These priorities support Rwanda FDA's goal of meeting globally recognised standards for regulatory quality, while also delivering on national health commitments. Active safety monitoring has already been carried out on newer products including medicines for HIV, Mpox, malaria, and COVID-19, and regulatory decisions have been taken based on the findings.

Improving medicine safety monitoring is at the heart of the 2026 agenda. Rwanda FDA plans to fully roll out the national medicine safety plan, including setting up a system that can detect and respond to product-related risks quickly, even in emergencies. Safety monitoring will be extended across medicines, vaccines, medical devices, cosmetics, and food products, backed by stronger inspection and enforcement mechanisms across all product categories.

Post-market surveillance is also expected to improve significantly. By 2026, Rwanda FDA aims for at least 68% of sampled products to meet safety and quality standards, as a stepping stone toward the target of 95% compliance by 2029. Reaching this will require more product testing, better laboratory capacity, and smarter risk-based inspection approaches across all product categories and supply chain levels.

Digital tools are central to all these improvements. By 2026, at least 60% of compliance checks are expected to be automated through centralised digital systems, enabling faster reporting, better data analysis, and stronger real-time safety monitoring. Already, 95% of medicine side effect reports are received electronically through the VigiMobile app, demonstrating what is possible when technology is embraced.

Finally, better use of evidence in decision-making will be supported through the operationalisation of the National Health Research Hub, strengthening regulatory research and collaboration with international partners including AMA, APTF, and IVI.

Together, these priorities are building a safer, more transparent, and globally aligned regulatory system for Rwanda.

# GENERAL CONCLUSION

*Rwanda FDA* remains firmly committed to protecting public health through strong medicine safety work. This bulletin highlights important progress made in strengthening how medicine and vaccine safety is monitored, building a culture of vigilance among health workers, and strengthening the system for monitoring products already on the market. Key achievements include extensive training programmes for health workers, the successful launch of the VigiMobile app for real-time safety reporting, and productive partnerships with international organizations to bring Rwanda's regulatory practices fully in line with global standards.

Data from January 2024 to July 2025 show consistent engagement in safety reporting, with 1,678 reactions documented, the majority of which were not serious. These findings confirm the overall safety of medicines and vaccines currently in use, while reinforcing the importance of keeping up continuous monitoring and acting quickly when any concerns arise. Rwanda FDA's proactive approach to visiting and supporting health facilities, embracing new technologies, and actively participating in regional efforts to harmonize standards reflects its dedication to protecting patients and improving health outcomes across Rwanda.

Looking ahead, Rwanda FDA will continue to expand digital reporting tools, strengthen data analysis capabilities, and build stronger partnerships to respond to emerging health challenges. Through teamwork and sustained vigilance, Rwanda can ensure that medicines and health products remain safe, effective, and of the highest quality for everyone.

RWANDA FDA

Rwanda Food and Drugs Authority

www.rwandafda.gov.rw

@RwandaFDA