# Embracing Technology in the Kenya National Pharmacovigilance Reporting System... *"Kenya Goes Green"*

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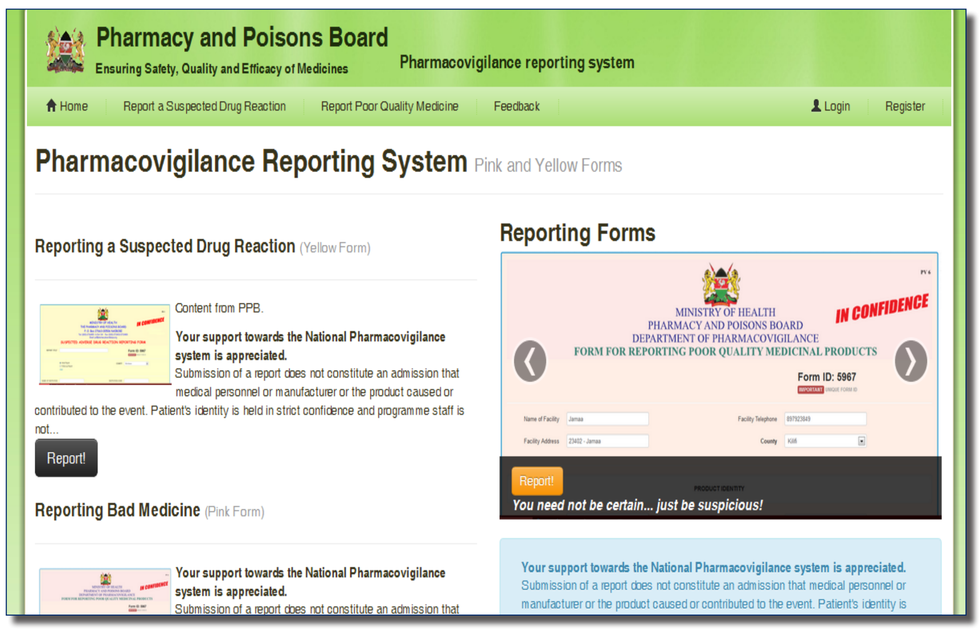
## Background

- Enhancing patient safety remains the core activity for any healthcare provider and the core mandate of any Medicines Regulatory Authority such as the Pharmacy and Poisons Board (PPB).
- Pharmacovigilance is one such system that helps ensure and enhance patient safety.
- The Kenya National Pharmacovigilance System was launched in June 2009
- Since then, the National Pharmacovigilance Centre at the PPB has received over 6300 suspected Adverse Drug Reactions (ADRs) and over 375 Poor Quality Medicines reports, all **paper-based.**
- However routine challenges continue to increase because of:
  - **time** for reporting, providing feedback and documenting in various institutional files
  - the **cost incurred** for printing, dissemination, making multiple copies and data entry for the received reports
  - need for proper filing and storage.
- Therefore appropriate and adequate use of Information, Communications and Technology (ICT) is necessary to improve collection and management of data on the safety and quality of medicines and medicinal products

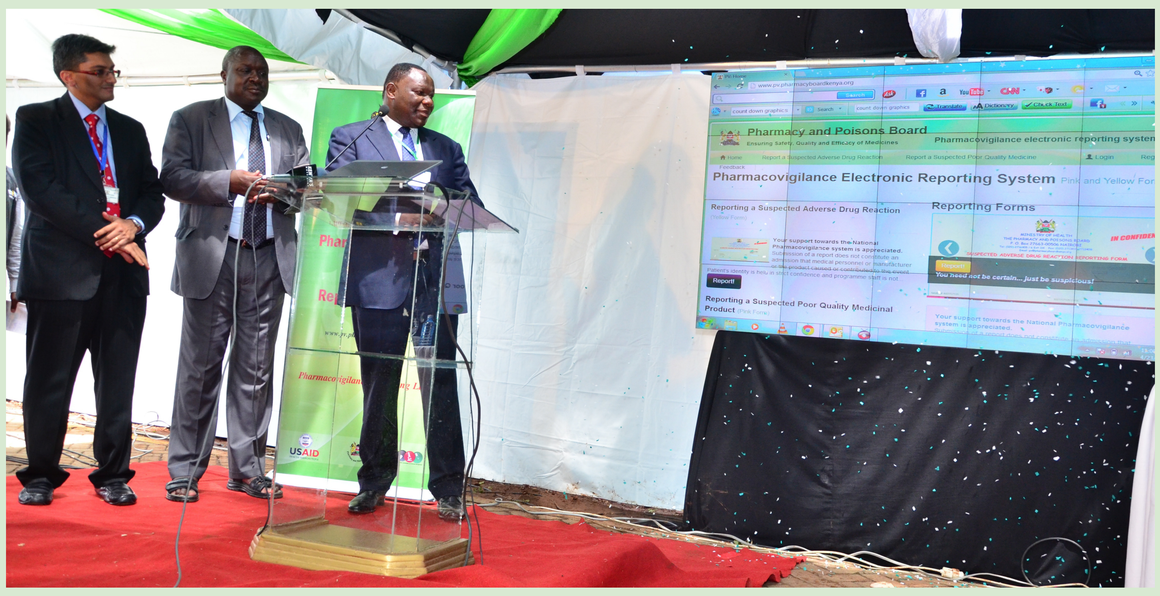
## Approach

- From several pharmacovigilance related trainings and stakeholder fora carried out in Kenya, **the need for a more efficient electronic reporting system (ERS)** for healthcare workers to report directly to the PPB became more apparent.
- The PPB with support from USAID through Management Sciences for Health / Health Commodities and Services Management (MSH/HCSM) program and working with IntelliSOFT Consulting, a local IT firm developed the Pharmacovigilance ERS (PV-ERS).
  - This is a suite of four software applications enabling anyone to report suspected ADRs and poor quality medicinal products through online and offline access via mobile and fixed devices.
  - The system is based on an open-share Linux software platform




## Results

- On 23rd April 2013, with support from MSH/HCSM, the PPB launched the Pharmacovigilance Electronic Reporting System (PV-ERS for reporting suspected ADRs and poor quality medicinal products through:
  - online and offline access via mobile and fixed devices
- The launch was attended by key stakeholders in health, top officials from the Health Ministries and was officially launched by the Permanent Secretary, Ministry of Information and Communication, Dr. Bitange Ndemo.




*The Permanent Secretary in the Ministry of Information and Communication, Dr.Bitange Ndemo, said that he will ensure that Kenyans access this digital pharmacovigilance reporting system and report from their mobile phones free of charge*

- The application can be downloaded either on a computer or accessed on a smart phone, or the report can be made directly to the PPB on their website (http://www.pv.pharmacyboardkenya.org).
- The innovative digital system has made **reporting easier, more cost effective, and prompt, and will serve to build its own database for future reference.**
- The PV-ERS has increased the visibility of the support of USAID and MSH/HCSM to the Kenya pharmacovigilance system strengthening:
  - The launch was covered in several international and local channels including print and audio media.
  - USAID and PPB participated in a live-radio show linking the PV-ERS to innovation, sustainability and patient safety
- This influx of pharmacovigilance information to PPB has resulted in:
  - quarantining, recalling, or withdrawing some medicines; changes in labeling; line inspections for continuous Good Manufacturing Practices; and, in one case, the closure of a pharmaceutical company that was not meeting regulatory requirements.

### Pharmaceutical Company Closed Down Due to Poor Quality of Products

Gesto Pharmaceuticals Ltd was closed down in July 2011 following repeated complaints on poor quality of its products from the field and subsequent confirmatory quality assurance testing reports. PPB has since recalled two products manufactured and distributed by the company as detailed below. All healthcare providers are urged to be on the lookout for these products as they are a risk to patients. For more details of other poor quality products that have been withdrawn and recalled from the Kenyan market, please refer to the Pharmacovigilance Newsletter Volume 1 Issue 2.

| Brand Name | Active Ingredient | Manufacturer | Batch No. | Reason for Recall |
|---|---|---|---|---|
| Benzyl Penicillin 1 MU | Benzyl penicillin 5ml 1 MU | Nestor Pharmaceuticals Ltd | All batches | Corrosion on caps |
| Gestamol Tablets | Paracetamol BP 500mg | Gesto Pharmaceuticals Ltd | All batches | Change of colour, growing mould |

*Source: `The Lifesaver: MIPV newsletter, 1st edition, September 2011*

## Lessons Learned

- The PV-ERS is a locally developed ICT solution tailored to provide information for decision making by policy makers, public health programs and health care workers.
- Development of PV-ERS demonstrates that it is possible to develop **cost-effective home-grown solutions** that address specific priorities through **collaboration and partnerships**

## Conclusion

- The PV-ERS is expected to boost reporting and tracking of suspected ADRs and poor quality medicinal products.
- The PV-ERS will ultimately improve assessment and communication of safety and quality information of medicines in the market.
- The PV-ERS will promote patient safety and health outcomes

## Next Steps

- This will involve sensitizing health care providers on its use and roll out of the system along side integrating the same with other existing electronic medical record systems in Kenya.
  - **"Digital Kenya, here we come".**

## Acknowledgements

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- MSH/Health Commodities and Services Management Program

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