RWANDA FDA
Rwanda Food and Drugs Authority
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**Kigali on 11/05/2021**

**Ref Nº: DIS/ /FDA/2021**

## LIST OF STAKEHOLDERS IN VIGILANCE

| STAKEHOLDERS | Specific contract with Rwanda FDA /Collaboration | Specific Area/Project | Agreements/MOU |
|---|---|---|---|
| **Ministry of Health** | - | -Integration of vigilance activities in Health system<br>- Training for health professionals<br>-Strengthening of DTCs | |
| **RBC/Public Health Program** | **HIV, TB, Malaria** | -Specific safety monitoring on DTG bases regimen<br><br>-Training of HCP in HIV services | |
| **Health Facilities** | | -Training of HCP in PV<br>-Strengthening of DTC<br>-Reporting of ADR/AEFI<br>- Investigation od Serious AEFI | |
| **WHO/UMC** | **UMC** | -Reporting of ADR/AEFI in vigiflow<br>- Reference to signal detected | |
| **Universities** | **University of Rwanda** | -Seminars in PV<br>-Integration of PV in curriculum of health related sciences | |

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| **Development Partners** | **USAID/MTaPS, PSM** | -Provide Technical support for vigilance activities including capacity building<br>-Active surveillance<br>- Awareness for vigilance activities | |
| **Regional and International organization and regulatory bodies** | **EAC** | -Joint Pharmacovigilance inspections<br>-Information sharing with other NRA on safety of the medical products | **Cooperation agreement** |
| **National Pharmacovigilance advisory committee** | | -Technical support for the Causality assessment for the reported ADR<br>-Advise the authority on regulatory action to be taken due to safety issues of medical products<br>- | |
| **National AEFI committee** | | - Technical support for causality assessment of the reported AEFI | |
| **Research Institutions** | | -Joint study on safety of medical products | |
| **Manufacturers and Marketing Authorization Holders** | **e.g Serum Institute of India Lvt** | -Sharing of information on medical products<br>-Conduct the required PASS/PAES<br>-Submit to Rwanda FDA PSUR/PBRER<br>-Submit the update on the safety profile of the medical products | Contract signed 21st April 2021 |
| **Health professional councils (** | **-NPC**<br>**-RMDA**<br>**-Allied health professionals** | -Enforcement of existing regulations<br>-Sensitizing for the involvement of health professionals in vigilance activities | |
| **Media** | | -Communicate the vigilance decision and communication | |

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| **Consumers** | | -Report any suspected safety issued (ADR, AEFI)<br>-Implement the regulatory decision on vigilance | |

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