

DIRECTORATE GENERAL OF DRUG ADMINISTRATION MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure-2

	Document Title: Format of functional Oorganogram					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-RS-027/F02-00	00	DEC'2021	DEC'2026			01 of 01

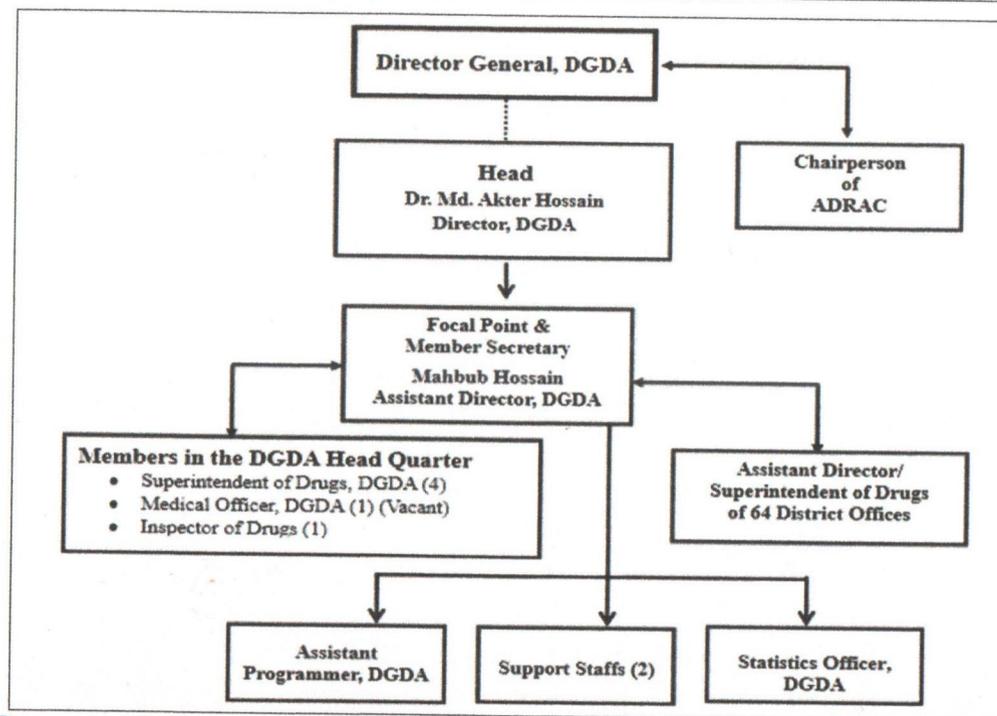
Function/Department: Pharmacovigilance System (PV)

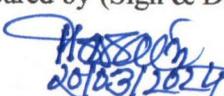
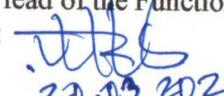
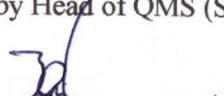
Version No: 03

Page No. 01 of 01

Terms and Reference/Activities:

- Collection, analyzing and archiving suspected ADE and AEFI reports.
- Investigation of the serious ADE and AEFI reports.
- Monitoring PV activities of the MAH through GVP inspection.
- To arrange meetings for causality assessment of the suspected ADE and AEFI reports of the PV committees (ADRM Cell, TSC & ADRAC).
- Communication with the other departments of DGDA and the national stakeholders to inform the regulatory recommendations from the ADRAC and other purposes.
- Communication with international stakeholders, such as WHO and development partners.
- To conduct training and awareness program for the PV stakeholders (like MAH, Health facilities, PHP etc.) and NPC Staffs and visit to in the health facilities, PHP etc.
- Publishing PV newsletter/ bulletin or awareness materials.
- Evaluation of the Risk Minimization Plan (RMP) & Periodic Safety Update report (PSUR) to assess the benefit risk assessment of the products.
- Monitoring of the risk minimization activities.
- Safety data evaluation including clinical trials.
- Emergency safety communications with the relevant stakeholders.
- Keeping records of the PV activities and ensuring Quality Management System (QMS).
- Working as the National Pharmacovigilance Centre (NPC) of Bangladesh.



Prepared by (Sign & Date):  Name: Mahbub Hossain Designation: Assistant Director Directorate General of Drug Administration Mohakhali Dhaka	Reviewed by Head of the Function (Sign & Date):  Name: Dr. Md. Akter Hossain Designation: Director Directorate General of Drug Administration	Approved by Head of QMS (Sign & Date):  Name: Hossain Mohammad Imran Designation: Assistant Director	Authorized by Directorate General (Sign & Date):  Name: Major General Mohammad Yousuf Designation: Director General Directorate General of Drug Administration Government of the People's Republic of Bangladesh 24 MAR 2024
---	---	--	--

IF THIS DOCUMENT IS SIGNED BY BLUE INK, IT IS A MASTER DOCUMENT AND CANNOT BE USED.