



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

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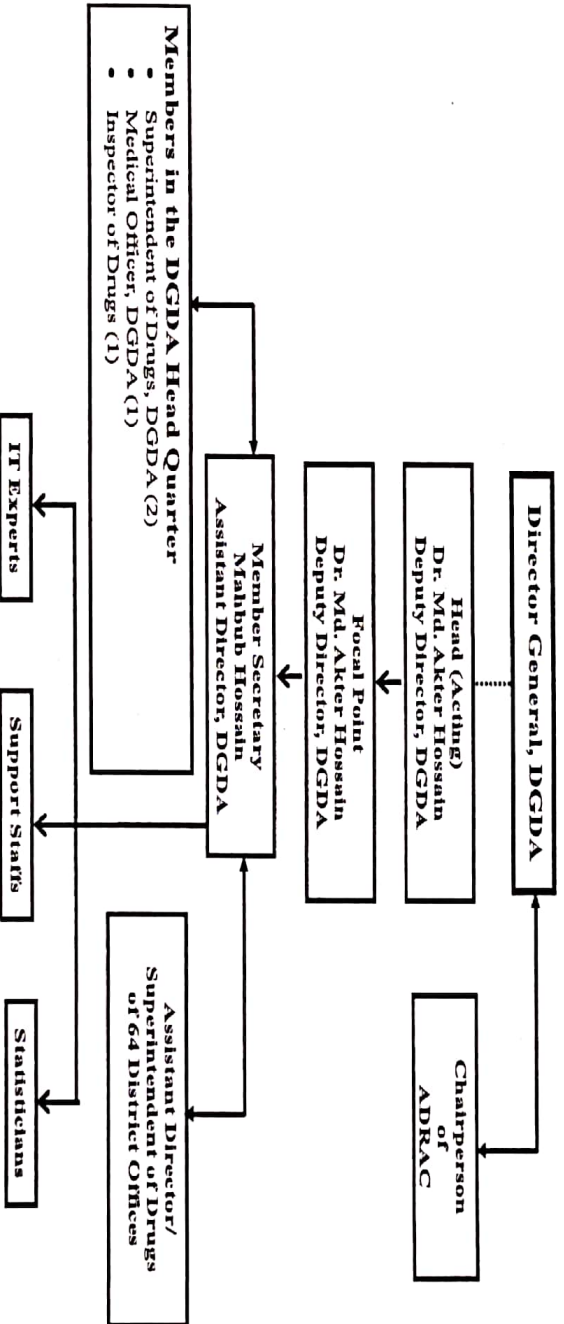
Annexure-2




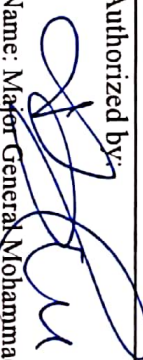
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Organogram of Pharmacovigilance Department

Terms and Reference/Activities:

- ToR of the VL Department attached herewith.



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NRA-RS-027/F02-00	00	DEC'2021	DEC'2026			02 of 02

Terms of Reference (TOR) of Pharmacovigilance Department

- Act as the National Pharmacovigilance Centre (NPC) of Bangladesh
- Collection, analyzing and archiving suspected ADE and AEFI reports.
- Investigation of the serious ADE and AEFI reports.
- To arrange meetings for causality assessment of the suspected ADE and AEFI reports.
- Implement regulatory recommendation from the ADDRAC.
- GVP inspection in the PV stakeholder's facility (such as MAH) and visit to in the health facilities, PHP etc.
- To conduct training and awareness program for PV stakeholders (like MAH, Health facilities, PHP etc.) and NPC Staffs.
- Communicate with international stakeholders, such as WHO, Regulatory Authority/agency and development partners.
- Publishing PV newsletter/ bulletin or awareness materials in regular basis.
- To ensure vigilance data are shared with regional office and international organization/ agencies as appropriate
- Keeping records of the pharmacovigilance activities.
- Implementation risk communication plan of the MAH and evaluation of the PSUR.
- To Follow and Comply the Quality Management System (QMS) in every step of the Vigilance Department.

Revision History:

SL No.	Version No	Causes for Revisions
1.	01	Newly Prepared
2.	02	New member included

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