# ADVISORY

## ADVISORY ON REPORTING OF PHARMACOVIGILANCE DATA DURING COVID-19 PANDEMIC.

**Date:** 27th April, 2020.

### Target Audience:

- Provincial Pharmacovigilance Centres;
- Manufactures and importers of therapeutic goods;
- Healthcare professionals; and
- Patients or relative of patients.

### Purpose:

Although every ADR and AEs report is important yet reporting within timelines defined by Pakistan National Pharmacovigilance guidelines may not be feasible due to the impact of the COVID-19 pandemic on normal business operations. Through this document Pakistan National Pharmacovigilance Centres (PNPC) is clarifying expectations for Provincial Pharmacovigilance Centres and for manufacturers and importers of therapeutic goods regarding requirement to report adverse drugs reactions (ADRs) and adverse events (AEs) during the pandemic.

### Measures to be taken:

1. Regular submission of pharmacovigilance reports should be maintained to the maximum extent possible. However, due to pandemic-related employee and personnel shortages, PNPC accepts if the submission of reports to PNPC does not occur within the time frames stipulated under Pakistan National Pharmacovigilance guidelines, provided that any delayed submissions are sent as soon as feasible. Provincial Pharmacovigilance Centre and manufacturers/ importers of therapeutic goods should maintain records to identify what has been delayed.
2. Reporting timelines will be maintained for some high priority products or those that may be used in a pandemic. These include antivirals, medicines for outbreak symptom management, medical devices i.e. respirators and other used for the diagnosis and management of patients with COVID-19, blood and blood components. Furthermore, all reports of ADRs and AEs associated with death as an outcome should also be treated as priority. Therefore, Provincial Pharmacovigilance Centres and manufactures/ importers of therapeutic goods should prioritize those therapeutic goods which have use in COVID-19 and reporting with these therapeutic goods should be subject to expedite reporting.
3. All ADR and AE reports associated with confirmed or suspected cases of COVID-19 and that meet the requirements for expedited reporting should be identified as priority and submitted in the same manner as outlined in Pakistan National Pharmacovigilance guidelines.
4. Submission of reports in E2Bxml format would be through the same channel i.e. through email address as outlined in Pakistan National Pharmacovigilance Guidelines. However, for manual submission, PNPC would accept the submission of reports through email if manufactures/ importers of therapeutic goods faces problem in manual submission.
5. Healthcare Professionals and patients are also requested to report any ADR or AE with those high priority products that may be used in a pandemic and reports of ADRs and AEs associated with death as an outcome to Pakistan National Pharmacovigilance Centre, Drug Regulatory Authority of Pakistan through DRAP Med Vigilance e-reporting system:
   https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PK
6. It is further to clarify that this is only an interim solution and usual reporting processes should be restored as soon as feasible.

DRAP, Islamabad | 92 51 910 7413 | npc@dra.gov.pk