

## TO ALL HOLDERS OF CERTIFICATE OF REGISTRATION AND APPLICANTS

### ELECTRONIC SUBMISSION OF ADVERSE DRUG REACTION (ADR) REPORTS - E2B REPORTING

For over a decade, ADR reports have been submitted to the National Adverse Drug Events Monitoring Centre (NADEMC) via fax. These reports were previously captured on the ADRI database. The ADRI database restricted electronic reporting by both applicants and healthcare professionals, and direct uploading of information onto the international database of the WHO Uppsala Monitoring Centre' VigiBase®. This feature forms part of the VigiFlow® software used to record ADR reports received.

SAHPRA obtained the VigiFlow® license and has since initiated capturing of ADR reports onto this database since 2016. During 2017, a pilot for electronic submission of ADR reports (E2B) by interested applicants was conducted. The outcome of the pilot was positive and confirmations to submit ADR reports via e2b format from the 01 of November 2017 were issued to all applicants who participated in the pilot.

To date, more applicants are approved to submit reports via the e2b format. All other applicants are encouraged to join the e2b reporting since this method of reporting will be a requirement in the near future, more details will be provided. In order to join, applicants need the following technical information regarding e2b:

1. Technical specifications - ICH guidelines downloadable from <http://estri.ich.org/e2br22/index.htm>
2. The preferred encoding is ISO-8859-1 but UTF8 is also acceptable
3. Each xml file can contain up to 100 ICSRs.
4. Organisation identifier – SAHPRA

#### Important information to note:

- Testing of cases is no longer required.
- Reports can be uploaded in either E2B R2 or E2B R3 formats.

Applicants joining the e2b reporting portal are advised to refrain from sending ADR reports in both paper and e2b formats simultaneously, as this results in duplication of reports on the system. That is, once an applicant has started sending reports in e2b format, they must immediately stop sending ADRs in paper formats. Applicants are not required to inform the Authority before they begin with e2b submissions. A response message will be forwarded to the email address used together with acknowledgement letter/s, therefore “no reply” email addresses should not be used. All ADR reports in e2b format must be submitted to [e2b@sahpra.org.za](mailto:e2b@sahpra.org.za)

#### Contact Details

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