Policy Brief – Regulations on Adverse Event Reporting for Medical Devices in China

Global Project Quality Infrastructure, Country Component China, GIZ

Background

On 1 January 2019, the **Provisions for Adverse Event Monitoring and Re-Evaluation of Medical Devices** (SAMR Order No 1) have entered into force. The Provisions were first published by the State Administration for Market Regulation (SAMR) on 31 August 2018 and replace the previous regulations on adverse event (AE) for medical devices from 2008 (SFDA Order No 766).

The purported aim of the new regulations is to **improve the regulatory framework for AE** for medical devices by placing wide-ranging responsibilities and obligations on market authorization holders (MAH), improving the effectiveness to discover and evaluate risks, and linking pre- and post-market surveillance.

The contents of the Provisions are rather general; more detailed requirements will be specified in **8 guideline documents on**:

1) AE monitoring;
2) AE reporting scope;
3) Collecting and reporting on individual AE by the MAH;
4) Focused AE monitoring;
5) Inspections of AE monitoring;
6) Risk evaluation by the MAH;
7) Re-evaluation;
8) Specifications for the compilation of Periodical Risk Evaluation Reports by the MAH.

So far, only drafts versions of the 8 guidelines are available. Public comments have been solicited from 20 September to 20 October 2018 for guidelines 1-5 and from 27 November to 27 December 2018 for guidelines 6-8. Final versions of the guidelines are expected to be published within the first half of 2019.

Main changes / additions in the new regulations

The Provisions specifically include requirements on several topics not part of the previous regulations, including focused monitoring, risk control, supervision and administration, legal responsibilities (listing specific penalties), and periodic risk assessment.

This creates a wide range of new obligations for MAH, including:

- To actively collect and report AE (less reliance on user-generated reports; new reporting method through online system);
- To continuously evaluate risks with regards to marketed MDs and submit Periodical Risk Evaluation Reports (new format replacing general annual AE report; required yearly for initial registration; overall higher frequency; for each license not only for each type of product);

- To conduct re-evaluation of MD following AE (new requirement).

It also includes specific obligations for overseas MAH (all new):

- To designate an authorized representative to take responsibility for AE monitoring of imported MD within China;
- To establish information transmission mechanism with designated authorized representatives regarding AE monitoring and re-evaluation;
- To monitor AE outside of China.

Further changes include:

- Shortening reporting timelines; switch from counting work days to counting calendar days;
- Launch of new monitoring system to collect AE reports from different sources to establish an AE data base.

Preliminary assessment

Potential concerns from an industry perspective include the following:

- Many uncertainties remain as implementation guidelines are still unpublished; despite Provisions already being in force since 1 January 2019, in particular:
  - scope of AE reporting (discrepancies exist regarding accepted exemptions between Provisions and current version of relevant guideline);
  - final format of Periodic Risk Evaluation Report (report for each type of product preferred over report for each license).
- More emphasis could be placed on a risk-based approach to AE monitoring;
- To conduct risk evaluations on AE, manufacturers often require information from hospitals that is not readily being made available to them (e.g. third-party maintenance records or training information on hospital employees);
- Hospitals being required to fulfill arbitrary AE reporting quota;
- Unclear, who will get access to database with AE reports;
- New online AE monitoring systems is not yet fully functional.