## Supplementary file 1. The Data Collection Form for Evaluation of the Pharmacovigilance System in Iran

| Core structural indicators                                                                 | Yes | No  | Description                                      |
|------------------------------------------------------------------------------------------|-----|-----|-------------------------------------------------|
| 1- Is there a pharmacovigilance center, department, or unit with a standard accommodation? |     |     |                                                 |
| 2- Is there a statutory provision (national policy, legislation) for pharmacovigilance?    |     |     |                                                 |
| 3- Is there a medicines regulatory authority or agency?                                    |     |     |                                                 |
| 4- Is there any regular financial provision (e.g., statutory budget) for the pharmacovigilance center? |     |     |                                                 |
| 5- Have the pharmacovigilance center the human resources to carry out its functions properly? |     |     |                                                 |
| 6- Is there a standard ADR reporting form in the setting?                                  |     |     |                                                 |
| 6a- Was the standard reporting form provided for reporting suspected medication errors?    |     |     |                                                 |
| 6b- Was the standard reporting form provided for reporting suspected counterfeit/substandard medicines? |     |     |                                                 |
| 6c- Was the standard reporting form provided for reporting therapeutic ineffectiveness?    |     |     |                                                 |
| 6d- Was the standard reporting form provided for reporting suspected misuse, abuse of and/or dependence on medicines? |     |     |                                                 |
| 6e- Was the standard reporting form provided for reporting ADRs by the general public?    |     |     |                                                 |
| 7- Is there a process in place for collection, recording and analysis of ADR reports?      |     |     |                                                 |
8- Was pharmacovigilance incorporated into the national curriculum of the various health care professions?
8a- for medical doctors?
8b- for dentists?
8c- for pharmacists?
8d- for nurses or midwives?
8e- for others?
   - to be specified;
9- Is there a newsletter, information bulletin, and/or website as a tool for dissemination of information on pharmacovigilance?
10- Is there a national ADR or pharmacovigilance advisory committee or an expert committee in the setting capable of providing advice on medicine safety?

| Indicators                                                                 | Answer | Description |
|---------------------------------------------------------------------------|--------|-------------|
| **Core process indicators**                                               |        |             |
| 1- How many ADR reports were received by the center in 2017?              |        |             |
| *Definition*: Valid case reports should contain the four core data elements, as per ICH-E2A:                           |        |             |
| 1. Reporter                                                               |        |             |
| 2. Identifiable patient                                                   |        |             |
| 3. Suspected medicines                                                    |        |             |
| 4. Adverse reaction.                                                      |        |             |
| 2- How many reports are there in the national database currently? (Since its inception to 2017) |        |             |
| Question | Answer |
|----------|--------|
| 3- How many reports were acknowledged and/or issued feedback in 2017? | |
| 4- How many reports were subjected to causality assessment in 2017? | |
| 5- How many reports were satisfactorily completed and submitted to the national pharmacovigilance center in 2017? | Definition: Total reports received yearly at the pharmacovigilance center that have all the relevant fields for causality assessment satisfactorily filled in. |
| 5a- Of the reports satisfactorily completed and submitted to the national pharmacovigilance center, how many were submitted to the WHO database? | |
| 6- How many reports of therapeutic ineffectiveness were received in 2017? | Definition: Failed treatments owing to the lack of effectiveness of medicines used in the healthcare system. |
| 7- How many reports on medication errors were reported in 2017? | Definition: Failure in treatment processes that resulted in harm to patients. |
| 8- How many registered pharmaceutical companies are there in Iran? | |
| 9- How many registered pharmaceutical companies have a functional pharmacovigilance system? | |
| 10- How many active surveillance activities were initiated, ongoing, or completed from 2013-2017? | |
### Core process indicators

1- How many signals were detected from 2013 to 2017 by the pharmacovigilance center?

2- How many regulatory actions were taken in 2017 consequent to national pharmacovigilance activities?

2a- Product label changes (variation)?

2b- Safety warnings on medicines?

2c- Drug withdrawals?

2d- Other restrictions on the use of medicines?

3- How many people were admitted to the hospital as a result of events associated with medicines and their use in 2017?

4- How many medicine-related deaths reported to the national pharmacovigilance center?

### Pharmacovigilance indicators for public health programs (PHP)

1- There are pharmacovigilance activities in place within the PHP routinely?

*Definition:* The presence or absence of key pharmacovigilance activities in the PHP: to report suspected ADRs to the pharmacovigilance center, using or adapting the standard ADR form recommended by the pharmacovigilance center; and to have an open communication link with the pharmacovigilance center, to analyze and react to drug-related problems.

2- Was pharmacovigilance systematically considered in all the main treatment guidelines and protocols in use within the public health programme?
| Question                                                                 | Answer |
|-------------------------------------------------------------------------|--------|
| 3- Was the standard reporting form provided for reporting in settings?  |        |
| 3a- suspected medication errors?                                        |        |
| 3b- suspected counterfeit/substandard medicines?                       |        |
| 3c- therapeutic ineffectiveness?                                       |        |
| 3d- suspected misuse, abuse of and/or dependence on medicines?          |        |
| 4- How many ADR reports were collected within the public health programme in 2017? |        |
| 5- How many reports on therapeutic ineffectiveness were received from PHP in 2017? |        |
| 6- How many satisfactorily completed reports were submitted to the national pharmacovigilance center in 2017? |        |
| 6a- Of the reports satisfactorily completed and submitted to the national pharmacovigilance center, how many were submitted to the WHO database? |        |
| 7- How many patients were admitted to the hospital with a medicine-related illness attributable to a PHP's preventive or healing regimen during 2017? |        |
| 8- How many PHP medicine-related deaths reported to the national pharmacovigilance center in 2017? |        |