**Report on changes on occurrence rate of medical device defects**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Management information** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1) Control number | | Identification number | | | |  | | | | | Registration number | | | |  | | | | | |  | | | | |
| Location of Event | | | | | | ①Domestic | | | | | | | ② Foreign | | | | | |  | | | | |
| 2) Report Category | | Type | | ① Initial report | | | | ② Additional report | | | | | | | Receipt number of the previous report:  (　　　　　) | | | | | |  | | | | |
| 3) Device Approval /Certification /Notification date | | | | |  | | | | | | | | | | 4) Analysis date | | | | | |  | | | | |
| 5) Report date | | | | |  | | | | | | | | | | 6) Date designated by the Minister | | | | | |  | | | | |
| 7) Reporting period | | | |  | | | | | | | | | | | | | | | | | | | | | |
| 8) Next report date | | | |  | | | | | | | | | | |  | | | | | | | | | | |
| 9) Contact person | | | Name | | | |  | | | | | | | | Company | | | | |  | | | | | |
| Department | | | | |  | | | | | |
| Address | | |  | | | | | | | | | | | | | | | | | | | |
| Tel | | |  | | | | Fax | | | |  | E-mail | | |  | | | | | | | |
| **2. Medical device information** | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1) Product name | | | | | | | | |  | | | | | | | | | | | | | | | | |
| 2) Generic name | | | | | | | | |  | | | | | | | | | | | | | | | | |
| 3) Details of the device | | | | | | | | |  | | | | | | | | | | | | | | | | |
| 4) Approval/certification number, etc. | | | | | | | | |  | | | | | | | | | | | | | | | | |
| 5) Medical device classification | | | | | | | | | ① Highly controlled medical device | | | | | | ② Controlled medical device | | | | | | ③ General medical device | | | | |
| ① Biological medical equipment | | | | | | ② Specified biological medical device | | | | | | | | | ③ Other | |
| 6) Remarks | | | | | | | | |  | | | | | | | | | | | | | | | | | |
| **3. Malfunction information** | | | | | | | | | | | | | | | | | | | | | | | |
| 1) Title | | | | |  | | | | | | | | | | | | | | | | | | |
| 2) Occurrence mechanism | | | | |  | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | |
| 3) Current Occurrence rate | | | | |  | | | | | | | 4) Updated Occurrence rate | | | | | |  | | | | | |
| 5) Analysis method | | | | |  | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | |
| 6) Actions taken so far | | | | | ① Recall | | | | | ② Request for suspension of use | | | | | | ③ Provide information | | | | | | ④ Other | |
|  | | | | | | | | | | | | | | | | | | | | | | | |
| 7) Future actions | | | | | ① Recall | | | | | | ② Request for suspension of use | | | | ③ Provide information | | | | | | ④ Other | | |
|  | | | | | | | | | | | | | | | | | | | | | | | |

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| --- | --- | --- | --- | --- |
| **4. List of health hazards** | | | | |
| 1) Number | 2) Health hazard status | 3) Outcome | 4) Number of cases | 5) Measures taken |
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Dear Chairman of Pharmaceutical and Medical Device Agency,

We report the investigation result related to the medical device.

Date :

Address:

Name :