Standard Workflow for the Revision of Drug Product Package Inserts <Part 1>

Safety Evaluation Teams

Primary screening

Use of data mining

No

Extraction of noteworthy adverse drug reactions

Secondary screening (team meeting)
Assessment of necessity of safety measures

YES

Information sharing with the MHLW

Inquiry to MAH
Standard Workflow for the Revision of Drug Product Package Inserts
< Continued >

Inquiry to MAH

Emergent Safety Communication

Rapid Safety Communication

Emergent issue

MAH response

(1 week)

Consultation with MAH concerning revisions

No (action pending)

Yes (intention to revise package insert)

Proceed to primary screening as a noteworthy matter

In-person interview (Discussion of measures to be taken)

No

(1 week)

Yes

(Necessity of Expert Discussion)

(1 week)

(Rapid Safety Communication)

Publication of risk information under assessment

(Within 2 weeks after all required documents are sent)

Revision of package insert

(1 week)

Publication of investigation result

Expert Discussion (Generally every 5 weeks)

No

Yes

(1 week)

Notification to the MHLW concerning proposed measures

(1 week)

Notice of required revision to package insert (generally every 5 weeks)