HUTCHMED

HUTCHMED (CHINA) LIMITED

DRUG SAFETY INFORMATION REPORTING SUMMARY

Updated December 2022

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1. Definitions

Pharmacovigilance (PV)

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.

Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Special Situation (SS)

All of the following situations associated with the use of a HUTCHMED product should be reported, whether or not there is an associated adverse event:

- Drug exposure during pregnancy, i.e. drug exposure to a fetus in utero (whether the fetus is exposed via the mother taking the product or transmission via semen following paternal exposure)
- Drug exposure during breast-feeding/ lactation
- Occupational exposure
- Overdose
- Drug abuse
- Misuse
- Medication error
- Off-label use
- Lack of therapeutic effect
- Drug-drug or drug-food interactions
- Suspected transmission of an infectious agent

2. HUTCHMED's View

The Company's policy is to comply with all applicable worldwide regulations and laws relating to reporting of Drug Safety Information, i.e. adverse events or special situations associated with Company's products. It is the Company's responsibility to establish and maintain the pharmacovigilance system to monitor, identify, assess and manage drug safety information to safeguard the safety of our patients and subjects to the utmost extent. The Company has detailed internal policies on good pharmacovigilance systems.

All employees are responsible for reporting adverse events or special situations to the Drug Safety and Pharmacovigilance Department within Twenty-four (24) hours from the date of first awareness.

Employees in managerial positions must supervise their direct reports with respect to compliance requirements and activities.

3. What to report

- An identifiable reporter
- An identifiable patient
- A suspect Company product
- At least an adverse event or special situation

4. When to Report

It does not matter whether the adverse event is thought to be caused, or not thought to be caused, by taking an HUTCHMED product or whether an adverse event is listed in the approved Company prescribing information as a possible side effect, employees are expected to report all adverse events or special situations to the Drug Safety and Pharmacovigilance Department within Twenty-four (24) hours from the date of first awareness.

5. How to Report

Employees can report information on adverse event or special situations via any of the following channels:

Product Hotline (within mainland China): 400-658-6360

Group Mailbox: safety@hutch-med.com