

(i) a draft reference document on the exception regarding extemporaneous preparation of medicines. The input may relate, for example, to relevant court cases, challenges faced by Member States in implementing the exception and the results of the national/regional implementation;

Exception regarding extemporaneous preparation of medicines

Under Japanese Patent Law, the extemporaneous preparation of medicines is not within the scope of patent rights. Article 69 (3) of the Japan patent Act provides as follows, stipulating that patent right effects do not cover the extemporaneous preparation of medicines, or medicines provided by extemporaneous preparation.

Article 69 (3)

“A patent right for a medical invention (whereby medicine refers to a product used in the diagnosis, therapy, treatment or prevention of human diseases; hereinafter the same applies in this paragraph) that is to be manufactured by two or more medicines being mixed together, or for the invention of a process by which a medicine is manufactured by two or more medicines being mixed together has not effect against the act of preparation of a medicine as per a physician's or dentist's prescription, nor against medicine prepared as per a physician's or a dentist's prescription.”

In Japan, the above provision is established in view of the following circumstances:

- (A) Persons who engage in the extemporaneous preparation of medicines cannot avoid obeying the prescriptions.
- (B) It is difficult for doctors and others to judge whether or not the method of mixing conflicts with patent rights.
- (C) The extemporaneous preparation of medicines by doctors and others is related to their special social mission of restoring the health of patients.