

1. Member States and Regional Patent Offices are kindly invited to send the following information:

(a) any additional inputs for the preparation of the draft reference document on the exception regarding acts for obtaining regulatory approval from authorities. Specifically, the inputs may relate to: (i) the description of the exception; (ii) its objectives and goals; (iii) national/regional implementation; (iv) challenges faced by Member States in its implementation; and (v) results of its implementation

*The DIP has no further information on this matter. The Regulatory approval is authorized by the Food and Drug Administration which will not include the consideration of patent registration information. This exclusion will be used as a defense of the defendant in the case of alleged patent infringement.*

(b) input with respect to the constraints faced by developing countries and least developed countries (LDCs) in making full use of patent flexibilities and their impacts on the access to affordable especially essential medicines for public health purposes in those countries.

*There is no such information available.*

2. Member States and Regional Patent Offices are kindly invited to send updated information concerning their applicable laws on the following subjects:

(a) certain aspects of the applicable national or regional patent law, available at [http://www.wipo.int/scp/en/annex\\_ii.html](http://www.wipo.int/scp/en/annex_ii.html)

*Add more information under "Novelty" as the text below:*

*"A disclosure which was due to, or made in consequence of, the subject matter having been obtained unlawfully, or a disclosure of the subject matter by the inventor including display of the inventor's work at an international exhibition or an official exhibition and such disclosure was done within twelve months before the application for patent, shall not be deemed to be a disclosure."*

(b) national and regional laws on opposition systems and other administrative revocation and invalidation mechanisms, available at [http://www.wipo.int/scp/en/revocation\\_mechanisms/](http://www.wipo.int/scp/en/revocation_mechanisms/)

*There is no such information available. However, it is currently in the process of amending the Patent Law. If the legal process is completed and in effect, DIP will inform WIPO later.*