

Standing Committee on the Law of Patents

Twenty-Eighth Session
Geneva, July 9 to 12, 2018

**ADDENDUM: REFERENCE DOCUMENT ON EXCEPTION REGARDING ACTS FOR
OBTAINING REGULATORY APPROVAL FROM AUTHORITIES (SECOND DRAFT)**

Document prepared by the Secretariat

1. In the Annex of document SCP/28/3, the word “Romania” should be introduced after the word “Poland” in Table 1. Consequently, number “65” in paragraph 25 should be replaced by number “70”.

2. In the Appendix of document SCP/28/3:

- (i) the word “Romania” should be added in the table of contents after the “Republic of Korea”; and
- (ii) the following text should be introduced after the provision of the law of the Republic of Korea:

“ROMANIA

*Article 80 of the Implementing Regulations to the Patent Law No.64/1991
(Official Gazette of Romania, Part I, NO.456/18.VI.2008).*

Exceptions concerning the infringements of rights

(1) In the application of Art. 34 paragraph (1) letter e) of the Law, the following shall not constitute an infringement of the rights provided for in Art. 32 and 33 of the Law:

a) the carrying out of the tests and studies necessary for obtaining the authorization for placing a medicament on the market, as well as the practical requirements resulting therefrom;

[...]"

[End of document]