

1. Grants the request for a compulsory license for non-commercial public use over the patent number PI-2016-2142, titled HYDROXYPYRIMIDINONE CARBOZAMIDE N-SUBSTITUTE HIV INTEGRASE INHIBITORS, which covers the RALTEGRAVIR active ingredient, valid until October 21, 2022, assigned to MSD ITALIA S.r.l.

2. Grant as term of the compulsory license the time remaining to the term of protection of the granted patent, as long as the public interest grounds provided with the entry into force of Executive Decree No. 118 remain.

3. Orders the company SOULPHARMA CIA. LTD., annual payments as economic compensation following the TRM2 calculation, in favor of MSD ITALIA S.r.l.:

FACTOR	CALCULATION in USD (\$)
Price in ITALY of the drug ISENTRESS (raltegravir 400 mg) 60 tablets bottle. Source: https://medisoc.it/scheda-raltegravir/#:~:text=Prezzo%20al%20pubblico%20(IVA%20inclusa)%3A%20%E2%82%AC%20341%2C07 (February, 2021)	900,40 € (USD \$1096.37)
Price in ITALY per table	15,00 € (USD \$18.27)
Base royalty 5% in relation to the price of ITALY per capsule	0.9136
Average income Ecuador (according to the World Bank 2019 indicator) Source: https://datos.bancomundial.org/indicador/NY.GDP.PCAP.CD?locations=EC	6.183,8
Average income proportion ITALY (following the World Bank indicator 2019) Source: https://datos.bancomundial.org/indicador/NY.GDP.PCAP.CD?locations=EC	33.228,2
Average income ratio Ecuador to Italy	$6.183,8 / 33.228,2 = 0,18610096$
Tier royalty:	$0.9136 \times 0,18610096 = 0,17$ per tablet

4. For the purposes of the payment of financial compensation, the patent holder is provided to consign within a period of ten days starting from the notification of this resolution, the national bank account in which the deposit of said compensation should be made.

5. In accordance with the provisions of article 5 of the Guidelines for the Granting of Compulsory Licenses of Drug Patents, and in accordance with the request filed by SOULPHARMA CIA. LTD., Dated November 5, 2020, the compulsory license is granted exclusively for non-commercial public use for import of the active ingredient RALTEGRAVIR from India. In this regard, SOULPHARMA CIA. LTD., may only make use of the compulsory license to supply the domestic market and exclusively in drug procurement processes carried out by any of the entities of the public health sector, to cover their respective programs.

6. In accordance with the provisions of article 11 of the Guidelines for the Granting of Compulsory Drug Patent Licenses, in accordance with article 68 literal a) of Andean Decision 486, this compulsory license will not be exclusive. The licensee may not assign the rights granted by the compulsory license except with that part of the company or its intangible asset that enjoys them. The granting of the compulsory license shall not impair the right of the holder to continue exploiting their patent.

7. In accordance with the provisions of article 14 of the Guidelines for the Granting of Compulsory Licenses of Drug Patents, the National Directorate of Industrial Property, ex officio or at the request of a party, may revoke the compulsory license when the circumstances that gave rise to the license have disappeared and it is not probable that they will reappear, or when the licensee fails to comply with the provisions set forth in the resolution granting the compulsory license.

8. Order to the General Secretariat to register this compulsory license in favor of SOULPHARMA CIA. LTD. in the respective patent.

9. Notify the content of this resolution to the Ministry of Public Health - MSP, the National Agency for Regulation, Control and Sanitary Surveillance - ARCSA, the National Customs Service of Ecuador - SENA and the National Public Procurement Service - SERCOP, in order to communicate this matter to the Public Health Network.