LIST OF COUNTRIES AND REGULATORY AGENCIES WHOSE AND HEALTH REGISTRATIONS FOR DRUGS ARE SUSCEPTIBLE TO APPROVAL

Regulation states	Agency	Country	Comments
Regulation Authorities of Regional Reference qualified by the PHO/WHO	INVIMA ANVISA ANMAT COFEPRIS CECMED	Colombia Brazil Argentina Mexico Cuba	Health registration certificates or similar
United States of America	Food and Drug Administration	United States of America	Health registration or similar
Canada	Health Canada	Canada	Health registration or similar
Australia	Therapeutic Goods Administration	Australia	Health registration or similar
Japan	Pharmaceutical and Medical Devices Agency	Japan	Health registration or similar
European Medicine Agency (EMA)	European Medicine Agency (EMA)	All countries members of the European Union through EMA	Accepted only drugs certifications issued by the European Medicine Agency (EMA). Certifications of the regulation authorities of the member countries of the European Union separately are not accepted.
Ministry of Food and Drug Safety	Ministry of Food and Drug Safety	(South) Korea Republic	Health registration or similar

By Ministerial Agreement No. 4711 it is reformed the listing of health registrations issued by foreign health authorities susceptible to be approved in Ecuador. This ministerial agreement amends the 2883 Ministerial Agreement and the 2233 Ministerial Agreement whereby medicines in general and biological medicines approval process is affected. The text of the agreement states:

> **"Art …** For the purposes of health registration of medicines in general, approval means the official recognition of the Health Registrations issued by health authorities of the countries whose drug regulatory agencies, have been ranked by the Pan American Health Organization (PAHO) / World Health Organization (WHO)as Authorities of Regional Reference, as well as Health Registrations issued by the health authorities in the United States, Canada, Australia, Japan, the European Medicines Agency (EMA) and the Ministry of Food and Drug Safety of the Republic of Korea. "
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> With this it is added "Ministry of Food and Drug Safety of the Republic of Korea" to the list of comparable health certificates in Ecuador.

This reform does not affect the unnumbered article of the 2883 Ministerial Agreement of January 28, 2013 published in the official registration number 889 which states:

> **"Art…-** Health Registration approval shall be granted to all medicines which have been registered by the countries mentioned in the previous article; and biological drugs (among these: vaccines, blood products, biotechnological and biosimilar) when they have been registered by these countries, provided they have specific regulations for this purpose.
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> The countries mentioned in the preceding articles shall be included in the list of validated countries by the National Health Authority and by the National Agency for Regulation, Control and Health Surveillance –ARCSA- or the agency that performs its competences, which will keep regularly updated and published the list through its website. "