

List of references

Kindly find below (version 1 - dated 11-10-2015) for the guidance list of reference countries to be used in checking the reference of your product **submitted for new request inquiry form acc. To ministerial decree 425/2015**

Name of regulatory authority	Online drug database
EMA	http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/epar_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d125
FDA	http://www.accessdata.fda.gov/scripts/cder/drugsatfda/
Orange Book	http://www.accessdata.fda.gov/scripts/cder/ob/docs/queryai.cfm
TGA (Australia)	https://www.ebs.tga.gov.au/ebs/ANZTPAR/PublicWeb.nsf/cuMedicines?OpenView
MHRA (UK)	http://www.mhra.gov.uk/spc-pil/?prodName=ADULT MELTUS CHESTY COUGHS SUGAR /// COLOUR FREE&subsName=&pageID=ThirdLevel&searchTerm=adult meltus#retainDisplayA
Health Canada	http://webprod5.hc-sc.gc.ca/dpd-bdpp/start-debuter.do?lang=eng
PMDA (Japan)	http://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0002.html
IMB (Ireland)	http://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/results?query=&field=
Italy	https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/farmaco?farmaco=036201
Germany	http://www.pharmnet-bund.de/dynamic/en/am-info-system/index.html
France	http://agence-prd.ansm.sante.fr/php/ecodex/index.php

Swissmedic (Switzerland)	http://swissmedinfo.oddb.org/
Spain	http://www.aemps.gob.es/cima/fichasTecnicas.do?metodo=detalleForm
Sweden	http://www.lakemedelsverket.se/Sok-efter-lakemedel-och-mediciner-i-Lakemedelsfakta/
Belgium	http://www.fagg-afmps.be/fr/items/banque_donnees/
Austria	https://asprester.basg.gv.at/asprester/faces/asprester.jspx?_afLoop=1299017030590697&_afWindowMode=0&_adf.ctrl-state=1ws96ccp4_4
Denmark	http://xnet.dkma.dk/indlaegssedel/leaflets/leaflets.faces
Finland	http://www.fimea.fi/medicines/fimeaweb
Iceland	http://serlyfjaskra.is/
Netherlands	http://www.cbg-meb.nl/CBG/en/human-medicines/geneesmiddeleninformatiebank/default.htm
New Zealand	http://www.medsafe.govt.nz/regulatory/DbSearch.asp
Norway	http://www.legemiddelverket.no/custom/Preparatsok/prepSearch_80333.aspx
Portugal	http://www.infarmed.pt/infomed/inicio.php
Other Authorized References	
BNF (Last Edition)	-----
PDR online	http://www.pdr.net/

Kindly note the following:

- You have to follow this list of references for submission of request inquiries form acc. To ministerial Dec. 425/2015.
- The submitted request inquiry form should be matched to the Reference (the same Active ingredient, Strength, Dosage Form, Route of administration) **otherwise it will be considered as no reference.**
- The submitted reference product should be **valid** (i.e. registered & marketed)
- Any modification on this list will be announced.