

Country Specific Nomenclature for Expanded Access Programs

Updated March 2019



Expanded Access
Resource Group

Extension of the Global Clinical Supplies Group

Country	Supports Individual Patient Requests	Name of program/Type of national procedure	Support Expanded Access as a Group/Cohort	Name of program/Type of national procedure
Algeria	Yes	Not Available	No	Not Applicable
Argentina	Yes	10874/2017: Request of drug importation under exception access program	No	Not Applicable
Australia	Yes	Special Access Scheme	Yes	Clinical Trial
Austria	Yes	Heilversuch ("Named Patient Use")	Yes	Compassionate Use Program (CUP)
Belarus	No	Not applicable	No	Not Applicable
Belgium	Yes	Early Temporary Access — Medical Need Program (MNP)	Yes	Early Temporary Access — Compassionate Use Program (CUP)
Brazil	Yes	Compassionate Use	Yes	Programa de Acesso Expandido
Bulgaria	Yes	Named Patient	Yes	Not Available
Canada	Yes	Special Access Program (SAP)	Yes	Special Access Program (SAP)
Chile	Yes	Provisional Use Authorization for Medicines	No	Not Applicable
China	Yes	Unapproved Drug Use: (The Drug Administration Law of the People's Republic of China, 2015-04-24)	No	Not Applicable
Colombia	Yes	Vital Unavailable Medicine (Medicamento Vital No Disponible)	Yes	Vital Unavailable Medicine (Medicamento Vital No Disponible)
Costa Rica	Yes	Acquisition and Import of Non Registered Medicines	No	Not Applicable
Croatia	Yes	Individual Treatment	Yes	Compassionate Use of Drugs (milosrdno davanje lijekā)
Czech Republic	Yes	Use of an unregistered medicinal product	Yes	Specific Therapeutic Programme (SpTP)



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Denmark	Yes	Compassionate Use	Yes	Compassionate Use
Ecuador	Yes	Exceptional Importation Authorization	Yes	Acquisition of Medicines Not Listed in the National Schedule of Basic Medicines (CNMB)
Egypt	Yes	Named Patient Supply	No	Not Applicable
Estonia	Yes	In Estonia, the Compassionate Use Programs (CUP) follow the EU legislation: Regulation (EC) No 726/2004, Art. 83 result in the national procedure as physician initiates import for named patient use. The State Agency of Medicines reviews the programs from patient safety point and makes sure the supply is ensured until the need of the patient persists.	Yes	Unapproved Drug Use or Compassionate Use
Finland	Yes	Special permission for compassionate use. Individual Patient	Yes	Special permission for compassionate use. Institutional permission
France	Yes	Nominative Temporary Use Authorization (Nominative ATU = nATU)	Yes	Cohort Temporary Use Authorization (Cohort ATU = cATU)
Georgia	Yes	Compassionate Use	Yes	Not Available
Germany	Yes	Named patient import	Yes	Hardship Case Program (AMHV)
Ghana	Yes	Named Patient Use (No specific name is determined)	Yes	As this would be an extension to a clinical trial protocol — the name would be reflected in the title of the extended use protocol
Greece	Yes	Individual early access program	Yes	Cohort Expanded Access Program
Guatemala	Yes	Final User Importation	No	Not Applicable
Hong Kong	Yes	Named Patient Program	Yes	Expanded Access Program
Hungary	Yes	Compassionate Use of Medicinal Products	Yes	Provisional and special marketing
India	Yes	Import of drugs for personal use	No	Not Applicable
Indonesia	Yes	Special Access Scheme (Pemasukan Obat Jalur Khusus) - for special therapeutic purpose	Yes	Special Access Scheme (Pemasukan Obat Jalur Khusus) - for clinical test purpose
Ireland	Yes	"Specials" to supply of unlicensed medicinal products	Yes	Not Available



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Israel	Yes	Urgent Care/Single Patient Access	Yes	Compassionate Care
Italy	Yes	Uso terapeutico nominale di medicinale sottoposto a sperimentazione clinica	Yes	Uso Terapeutico/Usso Compassionevole/Expanded Access/Named Patient program
Japan	No	Not Applicable	Yes	Extension trial (Clinical Trials Conducted on Ethical Grounds)
Kazakhstan	Yes	Clinical Trial (Phase IV or Special Assignment).	Yes	Clinical Trial (Phase IV or Special Assignment).
Kenya	Yes	Named Patient Use	Yes	Extended Access Program
Kuwait	Yes	Not Available	No	Not Applicable
Latvia	Yes	Not Available	Yes	Not Available
Lebanon	Yes	Compassionate Use	No	Not Applicable
Lithuania	Yes	Unregistered medicinal products (Vardinių vaistinių preparatų įsigijimo taisyklės)	Yes	Not Available
Macedonia	No	Not Applicable	No	Not Applicable
Malaysia	Yes	Named-Patient	No	Not Applicable
Malta	Yes	Compassionate Use/Unlicensed Medicinal Product	Yes	“Group of patients” can be interpreted as any set (i.e. more than one) of individual patients that would benefit from a treatment for a specific condition. The terms “cohort”, “collective use”, “patient group prescription” or “special treatment programme” used in some MSs (Member State), in accordance with national legislations, may correspond with this concept.
Mexico	Yes	Import Authorization of Drug Products for treatment, prevention or rehabilitation of diseases (for personal use)	Yes	Official Recognition of Orphan Drug
Moldova	No	Not Applicable	No	Not Applicable
Morocco	Yes	Special Access of Non-Registered Products	No	Not Applicable
Netherlands	Yes	Named Patient Product / Named Patient Programme	Yes	Compassionate use program
New Zealand	Yes	Special Access Scheme	Yes	Special Access Scheme



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Nigeria	Yes	No name allocated to these programs	Yes	If the access is via a protocol, the protocol title will be the identifier
Norway	Yes	Named Patient Program	Yes	Compassionate Use Program
Oman	No	Not Applicable	No	Not Applicable
Pakistan	Yes	Not Available	No	Not Applicable
Panama	Yes	No specific program	No	Not Applicable
Peru	Yes	Exceptional Importation Authorization	Yes	Not Available
Philippines	Yes	Compassionate Special Permit (CSP)	Yes	Compassionate Special Permit (CSP)
Poland	Yes	Named Patient Program	No	Not Applicable
Portugal	Yes	Exceptional use authorization (AUE = Autorização de Utilização Excecional)	Yes	Early Access Program (EAP) to medicinal products without MA; Previous Access Program to medicinal products without HTA assessment concluded
Romania	Yes	Unapproved Medicinal Products / Compassionate Use	Yes	Unapproved Medicinal Products / Compassionate Use
Russia	Yes	"Named patient supply under vital indications"	Yes	Not defined in regulation
Saudi Arabia	Yes	Unregistered/Non-prohibited/Compassionate Use	No	Not Applicable
Serbia	Yes	Patient name use for single patient	Yes	Not Available
Singapore	Yes	Special access scheme / Named patient basis / Exemption drug access	Yes	This will be treated and regulated under a clinical trial application process either under a clinical trial protocol or cEAP protocol
Slovakia	Yes	Therapeutical use of unauthorized medicinal product for individual patient (Terapeutické použitie neregistrovaného lieku pre jedného pacienta)	Yes	Therapeutical use of unauthorized medicinal product for group of patients (Terapeutické použitie neregistrovaného lieku pre skupinu pacientov)
Slovenia	Yes	Unapproved Drug Use	Yes	Unapproved Drug Use / Submission for approval of a clinical trial
South Africa	Yes	Named Patient Use	Yes	Extended Access clinical trial

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South Korea	Yes	Named Patient Use (Self Treatment)	Yes	Treatment use of an investigational new drug or Emergency use of an investigational new drug
Spain	Yes	Compassionate Use of Medicinal Products under Investigation	Yes	Temporary authorisation of use
Sri Lanka	Yes	Emergency and other special circumstances	No	Not Applicable
Sweden	Yes	Special Permission/Special License	Yes	Compassionate Use Programme (CUP)
Switzerland	Yes	Swissmedic Special Authorisation for Importation (Sonderbewilligung)	Yes	Swissmedic Special Authorisation for Importation (Sonderbewilligung)
Taiwan	Yes	Compassionate Use	Yes	Expanded Access Program
Thailand	Yes	Patient Use Program	No	Not Applicable
Tunisia	Yes	Compassionate Use/Named Patient Supply	No	Not Applicable
Turkey	Yes	Compassionate Use program (CUP)	Yes	Continued Access (Erken Erişim)
Ukraine	Yes	Not Available	No	Not Applicable
United Arab Emirates	Yes	Not Available	No	Not Applicable
United Kingdom	Yes	Supply of unlicensed medicinal products (“specials”)	Yes	Compassionate Use and Expanded Access Programmes.
United States	Yes	Expanded Access (Compassionate Use)	Yes	Expanded Access (Compassionate Use)
Uruguay	Yes	Medicines and medical devices not registered in uruguay	No	Not Applicable
Venezuela	Yes	"MEDICAMENTOS DE SERVICIO"	Yes	"MEDICAMENTOS DE SERVICIO"