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List of the "main therapeutic groups" (MTGs) in crisis preparedness

Regulation (EU) 2022/123 provides the European Medicines Agency with a framework to monitor and mitigate potential and actual shortages of centrally and nationally authorised medicinal products for human use considered as critical to address a given 'public health emergency¹ or 'major event'².

As further defined in the Regulation, the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) is responsible for establishing a list of the "main therapeutic groups" (MTGs) of medicinal products that are necessary for emergency care, surgeries and intensive care.

This list was adopted on 7 July 2022 by the MSSG and includes the relevant pharmacological or therapeutic subgroups according to the WHO ATC classification³ (level 3) and was established based on the agreed "methodology for the establishment of lists of "main therapeutic groups" in crisis preparedness and of the lists of "critical medicines" in the context of a major event and/or public health emergency"⁴.

The MSSG adopted the list after consultation with the Medicines Shortages SPOC Working Party (SPOC WP), and other relevant groups, including EMA's Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP), learned societies and EU Industry (Trade) Associations.

The list of MTGs will be used to help setting up any future lists of critical medicines to be used to respond to a public health emergency or major event. Only medicines included on a list of critical medicines will be subject to the reporting requirements foreseen in the Regulation, and supply and demand will be closely monitored to identify and manage potential or actual shortages. The list of MTGs itself does not directly lead to reporting requirements.

The list of MTGs may be updated to add or remove therapeutic subgroups reflecting approval or withdrawals of medicines. It does not pre-empt or reflect national procurement decisions, nor should it be read as recommendations on national stockpiles. It also should not be read as providing guidance on the use of any specific products in individual Member States and also does not reflect recommendations for use of any specific products.

⁴ https://www.ema.europa.eu/en/documents/other/methodology-establishment-lists-main-therapeutic-groups-crisis-preparedness-lists-critical-medicines/public-health-emergency_en.pdf



 $^{^1}$ '<u>public health emergency'</u> means a public health emergency recognised by the European Commission in accordance with Decision No 1082/2013/EU

² 'major event' means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply, demand or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection according to Article 2(b) of Regulation (EU) 2022/123.

³ https://www.whocc.no/atc_ddd_index/

Table 1. List of MTGs necessary for emergency care, surgery, and intensive care

Therapeutic subgroup	Pharmacological subgroup
Level 2	Level 3 A02B DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX
Drugs for acid related disorders	DISEASE (GORD)
Drugs for functional	A03A DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
gastrointestinal disorders	A03B BELLADONNA AND DERIVATIVES, PLAIN
	A03F PROPULSIVES
Antiemetics and antinauseants	A04A ANTIEMETICS AND ANTINAUSEANTS
Drugs for constipation	A06A DRUGS FOR CONSTIPATION
Antidiarrheals, intestinal	A07A INTESTINAL ANTIINFECTIVES
anti-inflammatory/anti-	A07B INTESTINAL ADSORBENTS
infective agents	A07D ANTIPROPULSIVES
Drugs used in diabetes	A10A INSULINS AND ANALOGUES
Mineral supplements	A12A CALCIUM
Antithrombotic agents	B01A ANTITHROMBOTIC AGENTS
Antihemorrhagics	B02A ANTIFIBRINOLYTICS
	B02B VITAMIN K AND OTHER HEMOSTATICS
Antianemic preparations	B03A IRON PREPARATIONS
Blood substitutes and	B05A BLOOD AND RELATED PRODUCTS
perfusion solutions	B05B I.V. SOLUTIONS
	B05X I.V. SOLUTION ADDITIVES
	B05Z HEMODIALYTICS AND HEMOFILTRATES
Other hematological agents	B06A OTHER HEMATOLOGICAL AGENTS
Cardiac therapy	C01A CARDIAC GLYCOSIDES
, and a second p	C01B ANTIARRHYTHMICS, CLASS I AND III
	C01C CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES
	C01D VASODILATORS USED IN CARDIAC DISEASES
	C01E OTHER CARDIAC PREPARATIONS
Antihypertensives	C02A ANTIADRENERGIC AGENTS, CENTRALLY ACTING
,, p o. co	C02C ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING
	C02D ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON
Diuretics	C03C HIGH-CEILING DIURETICS
Beta blocking agents	C07A BETA BLOCKING AGENTS
Calcium channel blockers	C08D SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS
Antiseptics and disinfectants	D08A ANTISEPTICS AND DISINFECTANTS
Sex hormones and	G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE
modulators of the genital system	
Pituitary and hypothalamic	H01B POSTERIOR PITUITARY LOBE HORMONES
hormones and analogues	H01C HYPOTHALAMIC HORMONES
Corticosteroids for systemic use	H02A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN
Pancreatic hormones	H04A GLYCOGENOLYTIC HORMONES
Antibacterials for systemic	J01A TETRACYCLINES
use	J01B AMPHENICOLS
	J01C BETA-LACTAM ANTIBACTERIALS, PENICILLINS
	J01D OTHER BETA-LACTAM ANTIBACTERIALS
	J01E SULFONAMIDES AND TRIMETHOPRIM
	J01F MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS
	J01G AMINOGLYCOSIDE ANTIBACTERIALS
	J01M QUINOLONE ANTIBACTERIALS
	J01X OTHER ANTIBACTERIALS
Antimycotics for systemic	JO2A ANTIMYCOTICS FOR SYSTEMIC USE
use	JULY ANTIFICOTICS FOR STSTERIC USE
	J04A DRUGS FOR TREATMENT OF TUBERCULOSIS
I Antimycopacteriais	
Antimycobacterials Antivirals for systemic use	J05A DIRECT ACTING ANTIVIRALS

Therapeutic subgroup	Pharmacological subgroup
Level 2	Level 3
Immune sera and	J06A IMMUNE SERA
immunoglobulins	J06B IMMUNOGLOBULINS
Vaccines	J07A BACTERIAL VACCINES
	J07B VIRAL VACCINES
Immunosuppressants	L04A IMMUNOSUPPRESSANTS
Antiinflammatory and	M01A ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-
antirheumatic products	STEROIDS
Muscle relaxants	M03A MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS
	M03B MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS
	M03C MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS
Anesthetics	N01A ANESTHETICS, GENERAL
	N01B ANESTHETICS, LOCAL
Analgesics	NO2A OPIOIDS
_	N02B OTHER ANALGESICS AND ANTIPYRETICS
Antiepileptics	N03A ANTIEPILEPTICS
Psycholeptics	N05A ANTIPSYCHOTICS
	N05B ANXIOLYTICS
	N05C HYPNOTICS AND SEDATIVES
Psychoanaleptics	N06A ANTIDEPRESSANTS
Other nervous system drugs	N07A PARASYMPATHOMIMETICS
Antiprotozoals	P01A AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES
	P01B ANTIMALARIALS
Drugs for obstructive airway	R03A ADRENERGICS, INHALANTS
diseases	R03B OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS
	R03C ADRENERGICS FOR SYSTEMIC USE
	R03D OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
Antihistamines for systemic	R06A ANTIHISTAMINES FOR SYSTEMIC USE
use	
Other respiratory system	R07A OTHER RESPIRATORY SYSTEM PRODUCTS
products	
All other therapeutic	V03A ALL OTHER THERAPEUTIC PRODUCTS
products	
Diagnostic agents	V04C OTHER DIAGNOSTIC AGENTS
All other non-therapeutic	V07A ALL OTHER NON-THERAPEUTIC PRODUCTS
products	
Contrast media	V08A X-RAY CONTRAST MEDIA, IODINATED