

National list of essential medicinal products

The French Health Minister and its Inter-ministerial Delegate for Avian Influenza (DILGA) requested the French Agency for the Safety of Health Products (Afssaps) to draft a list of medicinal products to be recommended as "essential" in the event of an avian influenza pandemic declared at a national level.

This request falls within the scope of the French Governmental Preparedness Plan. The goal of establishing such a list is to identify the medicines for which the supply and distribution on the national territory should be maintained at high priority level in the event of a major health crisis.

Within this overall Plan of Preparedness Measures, the drafting of such a list represents the first step, the subsequent steps consisting of the set-up and maintenance of stocks of the medicinal products identified as essential, and their supply thereof on a national level. Economic considerations like drug price or cost-effectiveness of medicinal product were not taken into consideration in view of specific context of supposed health emergency.

Criteria were defined in order to facilitate the selection task and reduce the number of essential medicine:

- Categorisation of the medicinal products as either "essential" or "necessary" based on the impact on health of their lack at short or longer term
- Inclusion of two different pills stock outage timeframes in national hospitals
 - o from 0 to 14 days¹
 - o from 15 days to 3 months

The absence of one medicinal product from the list should not lead to the over interpretation that this medicine is not of therapeutic interest either for the *population* or at *individual patient level*.

This model list is to provide standardized *information* on the *medicinal products for which supply* should be guaranteed as a matter of priority in a health crisis context. This list should not be regarded or used for any other purposes or outside this specific circumstance.

The model list was finalized at the beginning of 2008 and will be updated as need.

Afssaps- 07/09/09

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¹ Average timeframe of drugs stocks in French Hospitals



INFORMATION NOTE

NATIONAL RECOMMENDATIONS ON THE ESSENTIAL MEDICINAL PRODUCTS IN THE CONTEXT OF AN PANDEMIC INFLUENZA

- Principles for the selection of medicinal products -

First Model List - January 2008 -

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General context

The French Health Minister and its Inter-ministerial Delegate for Avian Influenza (DILGA) requested the French Agency for the Safety of Health Products (Afssaps) to draft a list of medicinal products to be recommended as "essential" in the event of an avian influenza pandemic declared at a national level.

This request falls within the scope of the French Governmental Preparedness Plan. The goal of establishing such a list is to identify the medicines for which the supply and distribution on the national territory should be maintained at high priority level in the event of a major health crisis. Within this overall Plan of Preparedness Measures, the drafting of such a list represents the first step, the subsequent steps consisting of the set-up and maintenance of stocks of the medicinal products identified as essential, and their supply thereof on a national level.

Procedure for drafting a national list of essential medicinal products in the context of an Influenza Pandemic

The purpose of establishing a list of essential medicines is to identify the medicinal products for which supply must be guaranteed as a matter of priority in the event of national and/or international disorganisation of the industrial and manufacturing framework following the outbreak of an influenza pandemic.

In the worst scenario, there is a possibility that the first, second or even third wave of a pandemic may affect the functioning of industries following the illness of some members of personnel and/or following decisions by the national authorities to restrict trade, travel, etc... This situation could impact on the importation, manufacturing, and/ or procurement of health products.

Therefore, the goal has been to draft a list of medicinal products for which it would be critical to support a specific supply program for the whole population on the national territory.

Based on these considerations, two categories of medicinal products have been identified:

- ♦ The medicinal products *necessary for the health care of patients suffering from influenza*, with or without complications. This first list has already been drafted and is available on specific request.
- ♦ The essential medicinal products *necessary to ensure a health coverage of the whole population* in case of restriction of goods spread at the national level.

The purpose of the present initiative was to elaborate a national "model list" for the second category of medicinal products. This work has been validated by the French National Committee of Medicinal Products Marketing Authorisation in January 2008.

Warning

This list is to be regarded as **guidance** for pharmaceutical industry, participants of the supply chain as well as health professionals. This list is not intended for regulatory, legal or reimbursement purposes.

This model list is to provide standardized *information* on the *medicinal products for which supply should be guaranteed as a matter of priority in a health crisis context.* This list should not be regarded or used for any other purposes or outside this specific circumstance.

The absence of one medicinal product from the list should not lead to the over interpretation that this medicine is not of therapeutic interest either for the *population* or at *individual patient level*.

It is worth mentioning that the medicinal products not classified as "essential / necessary" in this list may still be "useful" for patients in a standard health context or for an individual subject.

The medicinal products selected are those which have been considered as a priority as they are used for *treating serious diseases*, or *specific fragile patient populations* (e.g. children), or deemed necessary for healthcare considerations (e.g. vaccines).

Principles and Methodology

1.1. General Principles

The approach was to draft a list of medicinal products necessary to ensure an appropriate level of health care management of the whole population in case of a national health emergency. The most critical clinical conditions to be covered in priority were identified as follows:

- Life-threatening conditions at immediate (within hours) or short-term (within few days)
- Severe conditions for which a lack of product or discontinuation of drug supply would lead to increased risk of mortality or disability at short or medium term
- Severe chronic conditions for which a drug supply discontinuation could lead to worsening of the disease prognosis in term of mortality or significant morbidity at medium or long term
- Chronic conditions for which disruption of the treatment could lead to severe flares or recurrence of the disease
- Conditions where disruptions of the product supply would lead to behaviours "at risk" for the patient it-self or the general population
- Conditions at high risk of leading to permanent disabilities without any appropriate treatment
- Conditions or symptoms for which lack of product would lead to an increased rate of clinic visits, hospitalisations

After a first round of work, these criteria have been fine-tuned in order to facilitate the selection task and reduce the number of essential medicine:

- Categorisation of the medicinal products as either "essential" or "necessary" based on the impact on health of their lack at short or longer term
- Inclusion of two different pills stock outage timeframes in national hospitals
 - from 0 to 14 days¹
 - from 15 days to 3 months
- The Model List of Essential Medicines by the WHO (15th edition, 2007) was not used as a reference source. This present work was deemed to be considered as a different initiative setting up in a specific context of public health management. Indeed, the WHO Model list of essential medicines is defined as follows:
- "The core list presents a list of minimum medicine needs for a basic health care system, listing the most efficacious, safe and cost effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost effective treatment."
- "The complementary list presents essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed. In case of doubt medicines may also be listed as complementary on the basis of consistent higher costs or less attractive cost effectiveness in a variety of settings."
- Figure 2. Economic considerations like drug price or cost-effectiveness of medicinal product were not taken into consideration in view of specific context of supposed health emergency.
- The legal MA position of the product as a princeps or a generic product was not a selection criterion to be taken into consideration.
- The blood products and cell or tissue therapies were not on the scope of this work initiative and were therefore excluding from this drafting list.
- The medicinal products used to treat avian influenza or their complications fall in the category of essential medicinal products and have been listed separately.

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¹ Average timeframe of drugs stocks in French Hospitals

1.2. Methodology

Selection of wording for the classification:

♦ Classification of medicines as "Essential":

The medicinal products for which an interruption of drug supply during a period of less than 15 days would result in an **increased risk of mortality/morbidity** in the general population have been classified as "essential".

♦ Classification of medicines as "Necessary":

The medicinal products for which an interruption in supply for 15 days to 3 months would result in an increased *risk of mortality/morbidity* in the general population have been classified as "necessary".

· Other criteria for selection:

The basic underlying criteria for the categorisation of medicinal products were their impact on public health caused by an interruption in supply taking into account the following criteria:

- ♦ impact on direct or indirect mortality
- ♦ impact on direct or indirect on notable morbidity

For determining the criteria for "notable morbidity", the main grounds more specifically taken into account were the following:

- ♦ the risk of permanent disability
- ♦ the risk of aggravation of the disease symptoms (e.g. increased rate of epilepsy crisis)
- ♦ the risk of worsening of the prognosis in terms of mortality or morbidity
- ♦ the need for *surgery* procedure if the medicinal product treatment was not available
- ♦ the need for *hospitalisation* if the medicinal product treatment was not available

Other considerations for the selection :

- ♦ It has been agreed upfront that the selection will not to limit the choice to only one single product per therapeutic area or therapeutic sub-class. This consideration was aiming to prevent the transfer of all prescriptions to only one single medicinal product jeopardising the amount of the total pill stock left available. Without the figures of the pills volumes and the duration of stocks to be required, the availability of only one essential product could be insufficient for the entire population to be treated. As a general recommendation, the number of selected products was limited to 2-3 medicines within the same therapeutic sub-class.
- ♦ It has been recommended to select one therapeutic drug sub-classes rather than an entire drug classes when possible and relevant in order to limit the final number of essential medicinal products to be selected.
- ♦ In the event of uncertainty relating to the "critical / necessary" criterion for a medicinal product, it has been recommended to classify the product according to the highest interest of the patients by default.
- ♦ For medicinal products used for treating several different conditions, it has been recommended to classify the medicinal product according to the most severe condition.
- ♦ Amongst the several medicinal products that could be selected, it has been recommended to chose the one(s) that could be used for several different therapeutic indications rather that the one(s) authorized for only for one single indication.
- It has been recommended to chose preferably the product(s) with a specific paediatric indication and/or a paediatric-adapted formulation when several products of the sale therapeutic sub-class where selected.
- ♦ It has been recommended to select medicines formulated as single active compounds rather than fixed dose combinations, unless justified.

1.3. Procedures

This work has been carried out with external expert sub-groups for each therapeutic area and has been validated by the French National Committee of Medicinal Products Marketing Authorisation in January 2008.

The list has been double crossed with the following lists of medicines:

- WHO Model list of Essential Medicines, 2007
- List of paediatric medicinal products (2005), Paediatric Experts Group- EMEA

It was acknowledged that the selection of the essential medicines should be based as much as possible on valid scientific evidence. However, in the absence of adequate or comparative scientific evidence on current treatment of critical diseases or in specific sub-groups of patients like the paediatric population, the working committees could chose to make recommendations based on expert opinion and experience.

The initial version of the report was reviewed by the French associations of the pharmaceutical industry representatives for commenting. The comments were reviewed by the working groups before finalising the final report of the list.

2. Report of the selection

2.1. Overall results

Oncology products:

In total, approximately 350 medicinal products were selected as "essential", and about 100 additional medicines reported as "necessary". The medicinal products are reported by therapeutic areas according to the ATC classification, and using the medicinal product INNs.

For some therapeutic sub-classes, it was not possible to select only 1 or 2-3 products/INN based on the predefined criteria. In that case, the entire sub-class has been selected and is highlighted in italics \Rightarrow In that case, one can recommend that at least 1 to 3 medicinal products from the sub-class should be made available.

The specific indication for which the medicinal product was selected as essential was generally noted in the "Comments" section of the list. The preferred pharmaceutical formulation, strength or preferred route of administration was also mentioned if of particular relevance to be taken into account.

For some product therapeutic sub-classes (e.g. cardiology, endocrinology or diabetology), the entire sub-class was selected. In that case, it was counted as a single medicinal product in the calculation of products retained in the final list (e.g. for insulin, this product was counted as a single product although there are 40 different INNs authorized in the same therapeutic sub-class).

2.2. Specific selection of authorized medicinal products

The herbal medicinal products and the homeopathic medicinal products were excluded from this list of essential/necessary medicines. The medicinal products with the regulatory status of without prescription were also not selected.

All the medicinal products for the following therapeutic area were considered to be critical: Intensive care products Anaesthesia medicinal products Medicinal products for bone marrow or organ transplants Anti-HIV medicinal products All blood-derived products were selected as essential products, except albumin classified as a necessary product. Anti-Infective products: Vaccines were included in the ATC medicinal product category under "Infectious disease". Only the vaccines that are to be administered in the case of "post-contact" prevention were selected as "essential" while the others were classified as "necessary".

Only the products required to treat malignancies impacted the *immediate survival prognosis* (e.g. ALL, compressive neurological tumour, etc.) or those requiring a daily administration, were selected as "essential". The other medicinal products were classified as "necessary", particularly in the view of the treatment scheme with administration intervals of a few weeks.

■ Endocrinology:

Oestro-progestative medicinal products used for contraception or as abortion medication were considered "essential" for national public health considerations.

2.3. Specific considerations for non marketing authorized products

• Products covered by a national Compassionate Use Authorisation :

Approximately two hundred medicinal products are currently covered by a national Compassionate Use Authorisation (at individual or cohort authorisation level) by the French Agency. These products were regarded as essential only for severe clinical conditions with no alternative therapeutics. These products are not listed in the current model list due the restricted national procurement process and the continuous changes in those listed products over time.

Conclusion

The implementation of such concept is intended to be flexible and adaptable to the specific circumstances by the national authorities, the health professionals and the manufacturers and pharmaceutical industry representatives.

The working committees have recommended revising and updating this model list at regular intervals of approximately two years, and also following occurrence of any health crisis.

This model list is intended as a guide for the national institutions and the pharmaceutical industry to drive the prioritisation of medicinal products supply and procurement, and is not designed as an international standard.

The concept of essential medicines in the context of a public health emergency has to be decided at a national level in each country. The criteria for product selection are to be defined with regard to national public health relevance and considerations which remain a national responsibility and decision. However, this kind of approach could also be relevant and helpful to some extent at an international level, and could be regarded as an illustration of a possible public health management measure of a preparedness plan for global health emergency.



LIST OF ESSENTIAL MEDICINAL PRODUCTS IN THE CONTEXT OF A PANDEMIC EMERGENCY (French National Recommendations)

ANNEX 1: First Model LIST – January 2008

Regarding the classification reporting system, the selected medicinal products are presented by therapeutic area and ATC codes, and specified by using their INN.

For some therapeutic classes, it was not possible to select one single DCI amongst the other medicinal products within the same therapeutic sub-class. In this case, the entire ATC sub-class was selected and is highlighted *in italics*.

In the "comments" sections, the specific therapeutic indication for which the medicinal product was selected in priority is generally specified.

Medicinal products to be selected for several indications may be indicated several times with the mention of its main indication and area.

The preferred pharmaceutical form, strength or the route of administration may also be mentioned when considered relevant for its selection.

When the medicinal product has a specific paediatric use even sometimes off label, the term "paediatric usage" has been added for explaining its selection and therapeutic use.

THERAPEUTIC AREA	COMMENTS	
ALLE	RGOLOGY	
Antiallergics and medicines used in Anaphyla	xis	
ESSE	ENTIAL	
Epinephrine (adrenaline)	IM and IV injectable forms (1 ml= 1mg in IV)	
	Formulation for <u>self-injection</u> for emergency treatment (<i>including dosage for children</i>)	
Hydroxyzine	Oral and injection route Form(s) for paediatric usage (see also ANAESTHETICS section)	
Corticosteroids	See ANTI-INFLAMMATORY section	
NECESSARY		
Cetirizine	Oral route Form(s) for paediatric usage	

RE PRODUCTS				
SENTIAL				
Skin surface/mucosal anaesthetics				
formulations for local application Form(s) for paediatric use				
Solution for injection for infiltration Paediatric use				
Solution for injection / for infiltration				
Peripheral, epidural and spinal block Form(s) for paediatric use				
Peripheral, epidural block Form(s) for paediatric use				
Injectable forms (See NEUROLOGY section for oral formulation)				
Injectable forms (See NEUROLOGY section for oral formulation)				
Injectable form Form(s) for paediatric use				
Injectable form				
Oral form (oral solution) Form(s) for paediatric use				
thetics				
Injectable form Form(s) for paediatric use				
Injectable form Form(s) for paediatric use				
Injectable form Form(s) for paediatric use				
Injectable form Paediatric use				
Paediatric use				

Vecuronium		
Postoperative treatment: anti-emetic		
Ondansetron	Injectable form Paediatric use	
Sympatheticomimetics	•	
• Ephedrine		
• Epinephrine		
 Dopamine 		
Isoprenaline		
Dobutamine		
Atropine		
Atropine	Injectable forms Paediatric use	
Solutions / nutrition		
Sodium bicarbonate	isotonic and hypertonic solutions	
Sodium chloride	isotonic and hypertonic solutions	
Calcium gluconate		
 Phosphorus 		
Potassium chloride		
Glucose		
Amino acids		
• Lipids		
Water for injection		
Sodium lactate compound solution		
Multi-vitamins	Injectable forms Paediatric use	
• Mannitol	See OPH section Paediatric use	

	7	CS / ANTIPYRETICS / ANTISPASMODICS
		ESSENTIAL
on-c	ppiate analgesics	
•	Paracetamol	Oral and IV forms
		Form(s) for paediatric use
•	Acetylsalicylic acid	Oral and IV forms
• .		Form(s) for paediatric use
iate	analgesics	large distance and famous
•	Tramadol	Immediate-action oral form(s)
		Form(s) for paediatric use Sustained-action oral form(s)
		Form(s) for paediatric use
		Injectable form(s)
		Form(s) for paediatric use
	Manahira	Immediate-action oral form(s)
•	Morphine	(Paediatric use)
		Prolonged- action oral form(s)
		(Paediatric use)
		Injectable form(s)
		(Paediatric use)
	N I a Harrison la tra-a	Injectable forms
•	Nalbuphine	(Paediatric use)
	Codeine	including Paediatric formulations
•	Codeine	
	ANII-INF	FLAMMATORY DRUGS
		ESSENTIAL
eroi	dal anti-inflammatory drugs	
•	Dexamethasone	Oral and injectable forms (immediate
		action) Forms for paediatric use
		Forms for paediatric use
•	Betamethasone	Forms for paediatric use
_	Mathydaradaiaalaaa	Injectable and oral form
•	Methylprednisolone	Forms for paediatric use
•	Prednisolone	Oral form
	teroidal anti-inflammatory drug	
		Oral and injectable forms
•	Ibuprofen	Form(s) for paediatric use
_	Naprovon	Oral forms
•	Naproxen	Form(s) for paediatric use
•	Diclofenac	Oral and injectable forms
-	Distriction	Form(s) for paediatric use

	CARD	IOLOGY/ANGIOLOGY	
	ESSENTIAL		
Beta-l	Blockers: oral and injectable forms		
•	Atenolol		
•	Acebutolol	Paediatric usage (including tachyarrythmia)	
•	Metoprolol	Tachyarrhythmia Paediatric usage	
•	Labetalol	Paediatric usage	
•	Propranolol	(other indications: MIGRAINE) Paediatric usage	
Calciu	ım Chanel Blockers: oral and injec	etable forms	
•	Amlodipine		
•	Nifedipine		
•	Nicardipine	Immediate and sustained-action forms Paediatric usage	
•	Verapamil		
•	Diltiazem		
Conv	ersion enzyme inhibitors		
•	Captopril		
•	Enalapril		
Antih	ypertensives: Others	·	
•	Clonidine	Oral and injectable forms	
•	Prazosine	Oral form	
•	Methyldopa	Oral form, pregnancy-induced hypertension	
•	Hydralazine	Oral and injectable forms pregnancy- induced hypertension (paediatric usage)	
•	Sodium nitroprusside	injectable form	
HEAR	TFAILURE	·	
	D Dlookars, arel rout	e: See ANTIHYPERTENSIVE section	
		route: See ANTIHYPERTENSIVE section	
	Trinitrin	Sublingual and spray route	
•	THIIIIII	Sustained-action oral form	
		Transdermal form	
		Injectable form	
•	Isosorbide dinitrate	Oral and injectable forms	
•	Heparin sodium		
•	Digoxin	Oral and injectable route Paediatric usage	
•	Carvedilol	Oral form Paediatric usage	
•	Milrinone	Injectable form Paediatric usage	
•	Dopexamine	Paediatric usage	

ANTIARRHYTHMICS	
Sotalol	Oral and injectable forms Paediatric usage
Nadolol	Oral forms Paediatric usage
Amiodarone	Oral and injectable forms Paediatric usage
Flecainide	Oral and injectable forms Paediatric usage
PROSTAGLANDIN DERIVATIVES	•
Epoprostenol	neonatalogy
Alprostadil	neonatology
OTHERS	
IV Ibuprofen	neonatology
	NECESSARY
Hydroquinidine	
 Disopyramide 	Oral and injectable forms
Adenosine ATP	Injectable form
 Losartan 	
Pravastatin	
Simvastatin	

		ONCOLOGY
ESSENTIAL.		
Antin	eoplastic agents: Oral and injectable	e form
•	Actinomycin D	Injectable form Paediatric use (sarcoma)
•	Bleomycin	Injectable form Paediatric use
•	Carmustine	Injectable form Paediatric use / brain tumours
•	Cisplatin	Injectable form Paediatric use
•	Cytarabine	Injectable form Paediatric use / ALL AML
•	Cyclophosphamide	Injectable (and oral) form Paediatric use (AL, neuroblastoma)
•	Dacarbazine	Injectable form Paediatric use /melanoma
•	Daunorubicin	Injectable form Paediatric use
•	Doxorubicin	Injectable form Paediatric use
•	Ifosfamid	Injectable form Paediatric use (AL)
•	Methotrexate	Oral and injectable forms Paediatric use /ALL
•	Melphalan	Injectable form Paediatric use (AL, neuroblastoma)
•	Mercaptopurine	Oral form Paediatric use / ALL
•	Temozolomide	Injectable form Paediatric use / gioblastoma, astrocyoma
•	Thiotepa	Injectable form Paediatric use / BMT
•	Thioguanine	Oral form Paediatric use / ALL AML
•	Vincristine	Injectable form Paediatric use / ALL AML
•	Vinblastine	Injectable form Paediatric use / brain tumours
•	Vindesine	Injectable forms Paediatric use ALL
•	Etoposide	Injectable form Paediatric use
•	L-asparaginase	Injectable form Paediatric use / ALL
Other	S	
•	Rituximab	
•	Trastuzumab	
•	Interferon alfa2ab	
Assoc	iated treatments	·
•	Androgens (norethandrolone)	
•	Leukocyte growth factors	Paediatric use

•	Ondansetron	See "Anaesthetics" sections
•	Mesna	Oral and injectable forms
•	Zoledronic acid	Oral and injectable form
•	Allopurinol	Potential paediatric use
•	Calcium folinate	
NECESSARY		
Antii	Antineoplastic agents: all the others	

DERMATOLOGY		
ESSENTIAL		
Chlorhexidine		
Povidone-iodine		
NECESSARY		
Sulfiram and benzyl benzoate		
Permethrin		
• Ivermectin	Indication for immunocompromised subjects See infectious disease section	
Topical steroids	Topical formulation (cream) for each CS Class	
Fluororacil	ointment formulation	

	ENDOCRINOLOGY		
	ESSENTIAL		
Thyroid	andantithyroid agents		
• L	evothyroxine	Oral and injectable forms Paediatric use	
• L	iothyronine		
• F	Propylthiouracil		
• (Carbimazole		
Pituitary	-adrenal axis agents		
• +	Hydrocortisone (succinate)	Oral and injectable forms	
• [Deoxycortone	Injectable form Acute adrenal failure	
• F	Fludrocortisone	Adrenal failure	
Others			
• [Desmopressin	Injectable and oral forms	
• 8	Somatropin	Specific paediatric indication Hyperinsulinism Hypoglycaemia following somatropin deficiency)	
• 8	Somatostatin	injectable see Gastroenterology section	
• (Cyproterone	Indication: paraphilia	
• E	Bromocriptine		
_	NE	CESSARY	
• F	ixed LT4 and LT3 association		
• (Cabergoline	Indication: prolactinoma	
• 1	Metyrapone Programme Technology	diagnostic testing	

	GASTROINTESTINAL MEDICINES		
	ESSENTIAL		
•	Omeprazole	Injectable and oral forms Paediatric use	
•	Metoclopramide	Oral and injectable forms	
•	Rectal corticoids		
•	Phloroglucinol	Injectable form	
•	octreotide	Injectable form	
•	Terlipressin	Injectable form	
•	Pancreatic extract		
•	Lactulose		
•	Ursodeoxycholic acid		
•	Biologic adhesive glue		
	NE	CESSARY	
•	Loperamide		
•	Mesalazine		
•	Sulfasalazine		
•	Infliximab	See also RHEUMATOLOGY	
•	Ampho B suspension	Oral form	
•	Phloroglucinol	Oral form	

	GYNAECOLOGY OBSTETRICS			
	ESSENTIAL			
•	0xytocine			
•	Progesterone acetate	Injectable forms		
•	Atosiban			
•	Terbutaline	Injectable form		
•	Salbutamol	Oral and injectable forms see also PNEUMOLOGY section		
•	Methylergometrine	Oral and injectable forms		
•	Prostine	Oral and local forms Indication: induction of labour		
•	Sulprostone			
•	Norethisterone	Genital bleeding prevention in haemorrhagic diseases		
•	Leuproreline	Injectable form Indication: endometriosis (other indication in cancerology)		
•	Mifepristone			
•	Gemeprost			
•	Misoprostol			
•	Oral contraceptives			
	NE	CESSARY		
•	Econasole	vaginal suppository		
•	Dihydrogesterone	test in cases of amenorrhoea		
•	Danatrol	Oral form Indication: endometriosis		
•	Other progestative antigonadotropic agents	Oral form Indication :endometriosis		

	HAEMOSTASIS MEDICINAL PRODUCTS		
	ESSENTIAL		
A	nti-thrombotic agents		
•	Warfarin		
•	Acenocoumarol		
•	Fluindione		
•	Heparin calcium		
•	Low molecular weight heparin		
•	Danaparoid		
•	Lepirudin		
•	Clopidogrel		
•	Abciximab		
•	Tirofiban	Paediatric use	
•	Urokinase		
•	Alteplase		
Anti-ha	nemorrhagic agents		
•	Vitamin K1	Oral and injectable use	
•	Aprotinin	Paediatric use not covered by marketing authorisation	
•	Protamine sulfate		
	N	ECESSARY	
•	Ticlopidine	Indications: Stent requiring two anti-clotting agents	
•	Tranexamic acid	Oral and injectable forms	

METABOLISM - DIABETOLOGY			
ESSENTIAL			
Oral antidiabetic agents			
metformin			
glibenclamide			
gliclazide			
glipizide			
Insulins and analogues: for syringe and in	ijection pens		
Very brief duration of action			
Brief duration of action			
Intermediate duration of action			
Long duration of action			
Insulin for pumps			
Hyperglycaemic agents			
glucagon			
diazoxide	Adults and children: essential in cases of		
	hypoglycaemia (e.g. hyperinsulinism caused by benign or malignant pancreatic or		
	extrapancreatic tumour)		
	For children: Essential in cases of		
	hypoglycaemia occurring during glycogenosis		
Minerals and vitamins	Ovel forms (see Interesive core for injectable forms)		
Potassium chloride	Oral form (see Intensive care for injectable forms)		
Sodium Chlorure	Oral form (see Intensive care for injectable forms)		
alfacalcidol	Injectable form		
ergocalciferol	Oral and injectable forms / paediatric forms		
vitamins A/D/E/C	Oral form / Forms for paediatric use / neonatology		
• vitamin B1 (thiamine)	Oral and injectable form		
ferrous iron	Injectable form		
folinic acid	Injectable form (see ONCOLOGY section)		
	NECESSARY		
Minerals and vitamins			
folic acid	Oral forms		
ferrous iron	Oral forms		
vitamin D3	Oral and injectable forms		
alfacalcidol	Oral forms		
• pyridoxine	Oral and injectable forms		

	ANTIINFECTIVES	MEDICINES	
ESSENTIAL (with paediatric formulations)			
	Antibacterial medicine	es (Injectable and oral forms)	
Betalact	ams		
•	Cloxacillin		
•	Oxacillin		
•	Amoxicillin		
•	Amoxicillin + clavulanic acid		
•	Piperacillin		
•	Tazobactam		
•	Cefatzidime		
•	Ceftriaxone		
•	Cefotaxime		
•	Cefpodoxime-proxetil		
•	Imipenem + cilastatin		
Others	·		
•	Doxycycline		
•	Amikacin		
•	Gentamycin	bead forms	
•	Tobramycin		
•	Clarithromycin		
•	Erythromycin-sulfisoxazole		
•	Clindamycin		
•	Pristinamycin		
•	Telithromycin		
•	Ciprofloxacin		
•	Levofloxacin		
•	Teicoplanin		
•	Vancomycin		
•	Metronidazole		
Φ Λ ::4:4: .la	Sulmethoxazole+ trimetroprim		
	erculosis agents		
•	Rifabutin	Injectable and oral	
•	Rifampicin	Injectable and oral	
•	Isoniazid		
•	Pyrazinamide		
Othors	Ethambutol		
Others	The season is a season in the	Injectable	
•	Ticarcillin +clavulanic acid	Injectable	
•	Cefepime	Injectable	
•	Cefpirome	Injectable	
•	Fosfomycin	Injectable	
•	Colimycin	Inhalation form and injectable form	
•	Aztreonam	Inhalation form	
•	Benzathine-benzyl-penicillin		
•	Spiramycin	Injectable and oral	

Antifungal agents				
•	Amphotericin B	Standard and lipid formulations		
•	Fluconazole			
•	Caspofungin			
•	Voriconazole			
	Vacc	ines (post-contact prevention)		
•	Combined MMR			
•	Anti-Hepatitis B			
•	Anti-rabies			
	Anti-tetanus			
	Anti-meningitis C			
•	Yellow fever			
		Antiviral agents		
Antiret	roviral			
•	Abacavir			
•	Didanosine			
•	Emtricitabine			
•	Lamivudine			
•	Stavudine			
•	Tenofovir			
•	Zidovudine			
•	Amprenavir			
•	Atazanavir			
•	Fosamprenavir			
•	Indinavir			
•	Nelfinavir			
•	Saquinavir			
•	Tipranavir			
•	Lopinavir + ritonavir			
•	Darunavir			
•	Enfuvirtide			
•	Nevirapine			
•	Efavirenz			
	rpes medicines			
•	Aciclovir			
•	Cidofovir			
•	Foscarnet Ganciclovir			
•	Valaciclovir			
•	Valgancyclovir			

•	Chloroquine	I.V. and oral forms
•	Mefloquine	
•	Proguanil + Atovaquone	
•	Quinine	I.V. and oral forms

	OTHERS
Albendazole	Indication: diffuse or peroperative hydatid disease or hydatid cysts
• Ivermectin	Indication: MALIGNANT ANGUILLOSIS
● Metronidazole	
antimony: Glucantime	Indication: Leishmanias visceral forms
Atovaquone	
Cotrimoxazole	
Pentamidine	
Pyrimethamine	
Eflornithine	Indication: injectable form - TRYPANOSOMIASIS neurological forms -
	NECESSARY
Vaccines	
Chickenpox	
Combined diphtheria/ tetanus / polio	
Typhoid fever	
Influenza	
Hepatitis A	
Haemophilus b DT pertussis polio	
Leptospirosis	
Meningitis A and C	
Pneumococcal infection	
Other medicines	
Pegylated alpha-interferons	HCV and HBS
Adefovir	
Ribavirin	
Pentacarinate	

IMMUNOLOGY		
ESSENTIAL		
•	Ciclosporin	Oral and IV forms
•	Tacrolimus	Oral and IV forms
•	Sirolimus	
•	Azathioprine	
•	Mycophenolate	
•	Anti-thymocyte polyclonal antibodies	
•	Anti-lymphocyte polyclonal antibodies	
•	Muromonab CD3	
•	Anti-R-IL2 monoclonal antibodies	
•	Busulfan	Oral and injectable forms
•	Chlorambucil	Oral forms
•	Cyclophosphamide	Oral and injectable forms

BLOOD-DERIVED MEDICINAL PRODUCTS		
ESSENTIAL		
IV Huma	an immunoglobulins	IV and SC forms
Anti-ven	om immunoglobulins	
Anti-D ir	nmunoglobulins	
Anti-Her	patitis B immunoglobulins	
Anti-rab	ies immunoglobulins	
Fibrinog	en	
Alpha 1	antitrypsin	
Antithror	mbin III	
Activated	d Prothrombin Complex	
Activated	d Factor VII	
• Plasma	Factor VIII	
Recomb	inant factor VIII	
• Plasma	factor IX	
Recomb	inant factor IX	
Von Will	ebrand Factor	
Factor >	(I	
Protein	С	
• Factor	XI	
NECESSARY		
Albumin		4% and 20%

NE	UROLOGY
ES	SENTIAL
Anti-epileptics	
Valproic acid	Oral and injectable forms
Phenobarbital	Oral and injectable forms
Carbamazepine	Oral and injectable forms
Ethosuximide	Paediatric use
Felbamate	Paediatric use
Gabapentin	Paediatric use
Phenytoin	Oral and injectable forms Paediatric use
Fosphenytoin	Injectable forms Paediatric use
Lamotrigine	Paediatric use
Levetiracetam	Paediatric use
Oxcarbazepine	Paediatric use
Tiagabine	Paediatric use
Topiramate	Paediatric use
Vigabatrin	Paediatric use
Tetracosactide (ACTH)	Injectable form IM Paediatric use
Magnesium sulphate	Injectable form (Eclampsia)
Benzodiazepines	
Midazolam	Injectable forms See ANAESTHETICS
Clonazepam	Oral and injectable forms See ANAESTHETICS
Diazepam	Oral and injectable forms See ANAESTHETICS
Others	
Bromocriptine	
Levodopa with dopadecarboxylase inhibitor	
Ropinirole	
Pramipexole	
Amantadine	
Tropatepine	
Pyridostigmine	
Neostigmine	
Ambodenium chloride	
Baclofen	Oral and intrathecal forms
Dantrolene	
	I .

•	Sumatriptan	Oral, spray and injectable forms Paediatric use
•	Modafinil	Indications: narcolepsy
	NEC	ESSARY
•	Glatiramer	
•	Interferon betas	
•	Donepezil	
•	Galantamine	
•	Rivastigmine	
•	Riluzole	Indications: ALS

	OPHTHALMO	OLOGICAL MEDICINES
ESSENTIAL		
Anti-inf	ective medicines	
•	0.3% tobramycin	Eye drops and ointment
•	0.3% ciprofloxacin	Eye drops and ointment
•	Sulfadiazine (adiazine)	
•	3% aciclovir	Eye ointment
•	5% Povidone-iodine	Solution for ocular irrigation
Anti-gla	aucoma medicines	
•	Acetazolamide	Tablet and freeze-dried product for injectable solution
•	Mannitol	20% IV strength
Anti-inf	lammatory medicines	
•	0.1% dexamethasone	Eye ointment
Others		
•	0.9% NaCl	Unitary doses
•	Acetylcholine chloride	
Mydriat	tics	
•	0.5% tropicamide ointment	
•	Atropine ointment	1% 0.3% and 0.5% strengths Paediatric usage
Diagno	stics	- · · ·
•	0.5% fluorescein	Eye ointment
•	10% fluorescein	For injection
Anesth	netics	
•	0.4% oxybuprocaine hydrochloride	Eye ointment
		NECESSARY
Anti-gl	aucoma medicines	
•	0.5% timolol	Eye ointment
•	Prostaglandin analogue	Eye ointment
•	0.2% brimonidine	Eye ointment
•	2% pilocarpine miotic	Eye ointment
Mydria	tics	
•	10% neosynephrine ointment	
Diagno		•
•	2.5% indocyanine green cyanine	For injection

RADIOCONTRATS MEDIA			
ESSENTIAL			
Injectable contrast media			
Water-soluble iodine contrast media For opacification of vessels (and other structures)			
Gadolinium contrast medium	For MRI		
NEC	NECESSARY		
Others			
Colonic investigation preparation substances			

RESPIRATORY TRACT MEDICINES				
ESSENTIAL				
Antiasthmatic medicines				
Brief-action beta 2+ bronchodilators	Inhalation therapy: inhalation form in nebulisation solution for treatment of attacks <u>AND</u> powder form: may meet the needs of some asthmatics with poor hand/lung coordination Injectable forms			
Inhaled corticoids	FLUTICASONE or BUDESONIDE OR BECLOMETASONE- pressurised vial form and powder form meeting needs of patients with poor hand/lung synchronisation			
Nebulised inhaled corticoids	For infants			
Pulmonary arterial hypertension				
Endothelin antogonist				
Prostacyclines (epoprostenol)	With suitable infusion equipment (portable pump)			
Sildenafil				
Surfactant and treatment for respiratory distre	· ·			
Pulmonary surfactants	Hyaline membrane disease of the premature new born: respiratory distress syndrome			
Nitrogen monoxide	Refractory hypoxaemia of the newborn: respiratory distress			
Injectable caffeine	Treatment of apnoea in the newborn: respiratory distress			
Doxapram	Treatment for apnoea of the newborn, not covered by marketing authorisation			
Others				
Oxygen	in bundle, cylinders, and vaporiser			
NECESSARY				
Sustained-action beta 2+ bronchodilators	inhalation forms			
Nebulised inhaled corticoids	nebulisation			
Codeine-based opiate antitussive agents: codeine				
Mesna	Solution form for endotracheobronchial instillation			
Endotracheal fluidifiers	Endotracheal route			
Endotracheal fluidifiers				

	PSYCHOTHERAPEUTIC medicines				
		ESSENTIAL			
•	Haloperidol	Injectable and oral forms			
•	Chlopromazine	Injectable and oral forms Paediatric use			
•	Cyamemazine				
•	Butyrophenones	Injectable oral forms Paediatric use			
•	Amisulpride	Paediatric use			
•	Tiapride				
•	Clozapine				
•	Olanzapine				
•	Lozapine	Injectable form			
•	Risperidone	Immediate-action form			
Agent	s for depressive disorders				
•	Amitriptyline				
•	Clomipramine	Injectable oral forms Paediatric use			
•	Fluoxetine	Paediatric use			
Thymoregulators					
•	Lithium	Paediatric use			
•	Valpromide	Paediatric use possible			
•	Valproic acid	see EPILEPSY			
Others	Others				
•	Methadone				
•	Buprenorphine				
NECESSARY					
•	short half-life benzodiazepines	Oral form (only one necessary)			
•	Methylphenidate	Oral form Paediatric use			

RHEUMATOLOGY				
ESSENTIAL				
Thiocolchicoside	Oral and injectable forms			
Zoledronic acid	Other indications: see ONCOLOGY			
NECESSARY				
Hydroxychloroquine and chloroquine				
D penicillamine / derivatives				
Sulfasalazine	Other indications: See Gastroenterology			
Methotrexate	Oral and injectable forms			
Adalimumab				
Infliximab	Other indications: See Gastroenterology			
Anakinra				
Etanercept				
Calcitonin	Paget's disease			
Leflunomide				
Colchicine	In cases of contraindications to NSAIDs			

	UROLOGY - NEPHROLOGY				
	ESSENTIAL				
Diure	tics				
•	Furosemide	Oral and injectable forms Paediatric use			
•	Hydrochlorothiazide	Paediatric use			
•	Spironolactone	Paediatric use			
Treati	ment of kidney disease				
•	peritoneal dialysis solutions				
•	haemodialysis solutions				
•	haemofiltration solutions				
•	Erythropoietin				
•	Calcium carbonate	Oral forms			
•	Sodium polystyrene sulfonate				
Other	s				
•	Oxybutynin	Immediate and sustained-action forms Paediatric use			
•	Pyridoxine	Hyperoxaluria type I Paediatric use			
•	Tiopronin	Cystinuria Paediatric use			
	NECESSARY				
•	Sevelamer				
•	Cinacalcet				
•	Mitomycin				
•	Thiotepa				
•	Alfuzosine				

MEDICINAL PRODUCTS FOR ORPHAN DISEASES			
ESSENTIAL			
Laronidase (human rec α-L-iduronidase)	Injectable forms <i>Paediatric</i> use		
Sodium phenylbutyrate			
Carglumic acid			
Imiglucerase			
Anhydrous betaine			
Vitamin B12 (cobalamin)	Oral form		
Cysteamine bitartrate			
Idursulfase			
Nitisinone			
Agalsidase alpha			
NECESSARY			
• Zinc	Gaucher disease		
Miglustat	Gaucher disease type 1		
Alpha alglucosidase	Fabry disease		

ANTIDOTES and other substances used in poisonings **ESSENTIAL** Fabry disease Agalsidase beta (human rec α galactosidase A) Injectable form Calcium gluconate Charcoal, activated e N-acetylcysteine Nalorphine • EDTA / BAL/ DMPS/ DTP Dimercaprol Naloxone • lodure potassium Nydroxcobolamine Glucagon Injectable form Sodium Thiosulfate tablet DL methionine Injectable form Methylene blue • Protamine sulfate Flumazenil Antidigitalic antibodies • NECESSARY • Deferoxamine • Nitrite d'Amyle