Bayerischer Landtag

17. Wahlperiode 02.02.2018 **Drucksache 17/18441**

Schriftliche Anfrage

der Abgeordneten **Rosi Steinberger**
BÜNDNIS 90/DIE GRÜNEN
vom 07.09.2017

Colistin

In der Sendung „Panorama 3“ des NDR vom 29.08.2017 wurde über den Einsatz des Reserveantibiotikums Colistin in der Tierhaltung berichtet. Colistin ist ein Reserveantibiotikum, das von der Weltgesundheitsorganisation (WHO) in die höchste Kategorie der für den Menschen wichtigen Antibiotika eingestuft worden ist.

Ich frage die Staatsregierung:

1. a) Welche Antibiotika werden von der WHO als Reserveantibiotika eingestuft?
   b) Welche Kategorien gibt es bei dieser Einteilung?

2. a) Welche Mengen an Antibiotika wurden in Bayern in den letzten fünf Jahren in der Tierhaltung eingesetzt?
   b) Welche Mengen an Reserveantibiotika wurden in den letzten fünf Jahren in Bayern eingesetzt (nach der Einstufung der WHO)?
   c) Welche Mengen des Antibiotikums Colistin wurden in Bayern in den letzten fünf Jahren eingesetzt (alle Angaben soweit der Staatsregierung bekannt)?

3. a) Muss der Einsatz von Reserveatibiotika bei den Behörden angezeigt bzw. genehmigt werden?
   b) Bei welchen Tierarten wurden Reserveantibiotika in Bayern in welcher Menge angezeigt bzw. genehmigt?

4. a) Welche Einsatzmengen pro Tier bzw. pro kg sind bei Reserveantibiotika vorgeschrieben bzw. empfohlen?
   b) Welche Einsatzmengen pro Tier bzw. pro kg sind insbesondere bei Colistin vorgeschrieben bzw. empfohlen?

5. a) Werden diese Einsatzmengen in der Praxis eingehalten oder werden sie überschritten?
   b) In welche Größenordnung werden sie überschritten?
   c) Welche Tierarten bzw. -haltungsformen sind von dieser Überschreitung betroffen?

6. Sind der Staatsregierung Resistenzen gegen Reserveantibiotika bekannt?

7. a) Müssen Tierärzte von der Verwendung von Reserveantibiotika einen Resistenztest vorweisen?
   b) Können Behörden den Einsatz von Reserveantibiotika verbieten? Unter welchen Umständen?

8. Soll Colistin ins nationale Rückstandskontrollprogramm aufgenommen werden?

Antwort

des Staatsministeriums für Umwelt und Verbraucherschutz
vom 04.10.2017

1. a) Welche Antibiotika werden von der WHO als Reserveantibiotika eingestuft?
b) Welche Kategorien gibt es bei dieser Einteilung?
Die Weltgesundheitsorganisation (WHO) hat ihr bisheriges Klassifikationsschema für antibiotisch wirksame Wirkstoffe überarbeitet und bei Veröffentlichung der neuen Klassifikation im Juni 2017 verschiedene Wirkstoffe bzw. Wirkstoffgruppen für die Humanmedizin erstmals als „reserve group antibiotics” bezeichnet. Zur weiteren Einstufung bzw. Kategorien wird auf die öffentlich zugänglichen Dokumente der WHO verwiesen.

Ein Teilabdruck der englischsprachigen Internetveröffentlichung „WHO Model List of Essential Medicines“ (S. 1–18) ist als Anlage beigefügt. Er enthält die aktuelle Klassifikation von antibiotischen Wirkstoffen bzw. Wirkstoffgruppen mit Erläuterungen zu deren Einstufung. Als antibiotisch wirksame Wirkstoffe im Sinn von „reserve group antibiotics“ werden Aztreonam, Cephalosporine der 4. und 5. Generation, Polymyxine wie z. B. Colistin, Fosfomycin, Oxazolidinone, Tigecycline sowie Daptomycin gelistet.

2. a) Welche Mengen an Antibiotika wurden in Bayern in den letzten fünf Jahren in der Tierhaltung eingesetzt?
b) Welche Mengen an Reserveantibiotika wurden in den letzten fünf Jahren in Bayern eingesetzt (nach der Einstufung der WHO)?
c) Welche Mengen des Antibiotikums Colistin wurden in Bayern in den letzten fünf Jahren eingesetzt (alle Angaben soweit der Staatsregierung bekannt)?
Die Informationen liegen der Staatsregierung nicht vor, da keine gesetzliche Pflicht zur Erfassung dieser Daten besteht.

3. a) Muss der Einsatz von Reserveatibiotika bei den Behörden angezeigt bzw. genehmigt werden?
Nein, der Einsatz der oben genannten antibiotischen Wirkstoffe muss nicht bei den Behörden angezeigt oder genehmigt werden.

b) Bei welchen Tierarten wurden Reserveantibiotika in Bayern in welcher Menge angezeigt bzw. genehmigt?
Die Informationen liegen der Staatsregierung nicht vor, da keine gesetzliche Pflicht zur Erfassung dieser Daten besteht.

4. a) Welche Einsatzmengen pro Tier bzw. pro kg sind bei Reserveantibiotika vorgeschrieben bzw. empfohlen?

b) Welche Einsatzmengen pro Tier bzw. pro kg sind insbesondere bei Colistin vorgeschrieben bzw. empfohlen?

Die Dosierungsempfehlung eines zugelassenen Fertigarzneimittels für Tiere ist der Packungsbeilage zu entnehmen. Die Dosierung eines Antibiotikums bei Tieren ist unter anderem von der zu behandelnden Tierart und dem verwendeten Arzneimittel abhängig, denn gleiche Wirkstoffe können in unterschiedlichen Formulierungen und/oder Stärken in Verkehr gebracht werden. Die Verabreichungsart spielt ebenfalls eine Rolle. Daher können Arzneimittel mit gleichem Wirkstoff trotzdem für eine unterschiedliche Dosierung bestimmt sein. Weitere Faktoren wie z. B. die Art der Infektion sowie das Gewicht bzw. die Verfassung der zu behandelnden Tiere sind zu berücksichtigen. Die jeweilige Anwendungsdosis bestimmt der behandelnde Tierarzt nach dem Stand der tierärztlichen Wissenschaft für den betreffenden Fall. Dies kann zur begründeten Abweichung von der Dosierungsempfehlung nach Packungsbeilage des gewählten Fertigarzneimittels führen.

Informationen zu Dosierungsvorschlägen für nach Übersichtsrecherche gut über 50 antibiotische Wirkstoffe bei verschiedenen Tierarten und Krankheitszuständen sind z. B. im Internet öffentlich zugänglich. Beispielhaft ist ein Rechercheergebnis zum Antibiotikawirkstoff Colistin als Anlage beigefügt.

5. a) Werden diese Einsatzmengen in der Praxis eingehalten oder werden sie überschritten?

b) In welche Größenordnung werden sie überschritten?

c) Welche Tierarten bzw. -haltungsformen sind von dieser Überschreitung betroffen?

Die Informationen liegen der Staatsregierung nicht vor, da keine gesetzliche Pflicht zur Erfassung dieser Daten besteht.

6. Sind der Staatsregierung Resistenzen gegen Reserveantibiotika bekannt?

Es ist allgemein bekannt, dass auch gegen Antibiotika, die von der WHO zu den „reserve group antibiotics“ gezählt werden, Resistenzen bei einzelnen Erregern oder Erregergruppen auftreten können.

7. a) Müssen Tierärzte von der Verwendung von Reserveantibiotika einen Resistenztest vorweisen?

Nein.

b) Können Behörden den Einsatz von Reserveantibiotika verbieten? Unter welchen Umständen?

Der rechtskonforme Einsatz von zugelassenen Arzneimitteln kann durch die Überwachungsbehörden nicht verboten werden.

8. Soll Colistin ins nationale Rückstandskontrollprogramm aufgenommen werden?

Colistin ist bereits Bestandteil des Untersuchungsspektrums des Nationalen Rückstandskontrollplans. Der zu den Polymyxinen gehörende Wirkstoff wird bei der Untersuchung auf Stoffe mit antibakterieller Wirkung in der Sparte „Tierarzneimittel und Kontaminanten“ erfasst.

WHO Model List of Essential Medicines

20th List
(March 2017)

Status of this document

This is a reprint of the text on the WHO Medicines website

http://www.who.int/medicines/publications/essentialmedicines/en/

20th edition

WHO Model List of Essential Medicines (March 2017)

Explanatory notes

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.

The **square box symbol (□)** is primarily intended to indicate similar clinical performance within a pharmacological class. The listed medicine should be the example of the class for which there is the best evidence for effectiveness and safety. In some cases, this may be the first medicine that is licensed for marketing; in other instances, subsequently licensed compounds may be safer or more effective. Where there is no difference in terms of efficacy and safety data, the listed medicine should be the one that is generally available at the lowest price, based on international drug price information sources. Not all square boxes are applicable to medicine selection for children — see the second EMLc for details.

Therapeutic equivalence is indicated only on the basis of reviews of efficacy and safety and when consistent with WHO clinical guidelines. National lists should not use a similar symbol and should be specific in their final selection, which would depend on local availability and price.

The **a** symbol indicates that there is an age or weight restriction on use of the medicine; details for each medicine can be found in Table 1.1.

Where the ***[c]*** symbol is placed next to the complementary list it signifies that the medicine(s) require(s) specialist diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training for their use in children.

Where the **[c]** symbol is placed next to an individual medicine or strength of medicine it signifies that there is a specific indication for restricting its use to children.

The presence of an entry on the Essential Medicines List carries no assurance as to pharmaceutical quality. It is the responsibility of the relevant national or regional drug regulatory authority to ensure that each product is of appropriate pharmaceutical quality (including stability) and that, when relevant, different products are interchangeable.

For recommendations and advice concerning all aspects of the quality assurance of medicines see the WHO Medicines website http://www.who.int/medicines/areas/quality_safety/quality_assurance/en/.

Medicines and dosage forms are listed in alphabetical order within each section and there is no implication of preference for one form over another. Standard treatment guidelines should be consulted for information on appropriate dosage forms.

The main terms used for dosage forms in the Essential Medicines List can be found in Table 1.2.

Definitions of many of these terms and pharmaceutical quality requirements applicable to the different categories are published in the current edition of *The International Pharmacopoeia* http://www.who.int/medicines/publications/pharmacopoeia.

WHO Model List of Essential Medicines

20th edition

1. ANAESTHETICS, PREOPERATIVE MEDICINES AND MEDICAL GASES	
1.1 General anaesthetics and oxygen	
1.1.1 Inhalational medicines	
halothane	Inhalation.
isoflurane	Inhalation.
nitrous oxide	Inhalation.
oxygen	Inhalation (medical gas).
1.1.2 Injectable medicines	
ketamine	**Injection:** 50 mg (as hydrochloride)/ mL in 10- mL vial.
propofol*	**Injection:** 10 mg/ mL; 20 mg/ mL. * Thiopental may be used as an alternative depending on local availability and cost.
1.2 Local anaesthetics	
☐ bupivacaine	**Injection:** 0.25%; 0.5% (hydrochloride) in vial. **Injection for spinal anaesthesia:** 0.5% (hydrochloride) in 4- mL ampoule to be mixed with 7.5% glucose solution.
☐ lidocaine	**Injection:** 1%; 2% (hydrochloride) in vial. **Injection for spinal anaesthesia:** 5% (hydrochloride) in 2- mL ampoule to be mixed with 7.5% glucose solution. **Topical forms:** 2% to 4% (hydrochloride).
lidocaine + epinephrine (adrenaline)	**Dental cartridge:** 2% (hydrochloride) + epinephrine 1:80 000. **Injection:** 1%; 2% (hydrochloride **or** sulfate) + epinephrine 1:200 000 in vial.
Complementary List	
ephedrine	*Injection: 30 mg (hydrochloride)/ mL in 1- mL ampoule.* *(For use in spinal anaesthesia during delivery, to prevent hypotension).*
1.3 Preoperative medication and sedation for short-term procedures	
atropine	**Injection:** 1 mg (sulfate) in 1- mL ampoule.
☐ midazolam	**Injection:** 1 mg/ mL. **Oral liquid:** 2 mg/ mL **[c]**. **Tablet:** 7.5 mg; 15 mg.
morphine	**Injection:** 10 mg (sulfate **or** hydrochloride) in 1- mL ampoule.

1.4 Medical gases	
oxygen*	**Inhalation** For use in the management of hypoxaemia. *No more than 30% oxygen should be used to initiate resuscitation of neonates less than or equal to 32 weeks of gestation.
2. MEDICINES FOR PAIN AND PALLIATIVE CARE	
2.1 Non-opioids and non-steroidal anti-inflammatory medicines (NSAIMs)	
acetylsalicylic acid	**Suppository:** 50 mg to 150 mg. **Tablet:** 100 mg to 500 mg.
ibuprofen [a]	**Oral liquid:** 200 mg/5 mL. **Tablet:** 200 mg; 400 mg; 600 mg. [a] Not in children less than 3 months.
paracetamol*	**Oral liquid:** 120 mg/5 mL; 125 mg/5 mL. **Suppository:** 100 mg. **Tablet:** 100 mg to 500 mg. * Not recommended for anti-inflammatory use due to lack of proven benefit to that effect.
2.2 Opioid analgesics	
codeine	**Tablet:** 30 mg (phosphate).
fentanyl*	**Transdermal patch:** 12 micrograms/hr; 25 micrograms/hr; 50 micrograms/hr; 75 micrograms/hr; 100 micrograms/hr *for the management of cancer pain
□ morphine*	**Granules (slow-release; to mix with water):** 20 mg –200 mg (morphine sulfate). **Injection:** 10 mg (morphine hydrochloride **or** morphine sulfate) in 1- mL ampoule. **Oral liquid:** 10 mg (morphine hydrochloride **or** morphine sulfate)/5 mL. **Tablet (slow release):** 10 mg–200mg (morphine hydrochloride or morphine sulfate). **Tablet (immediate release):** 10 mg (morphine sulfate). *Alternatives limited to hydromorphone and oxycodone

Complementary list	
*methadone**	*Tablet: 5 mg; 10 mg (as hydrochloride)* *Oral liquid: 5mg/ 5mL; 10mg/ 5mL (as hydrochloride)* *Concentrate for oral liquid: 5 mg/ mL; 10mg/ mL (as hydrochloride)* **For the management of cancer pain.*
2.3 Medicines for other common symptoms in palliative care	
amitriptyline	**Tablet:** 10 mg; 25 mg; 75 mg.
cyclizine **[c]**	**Injection:** 50 mg/ mL. **Tablet:** 50 mg.
dexamethasone	**Injection:** 4 mg/ mL in 1- mL ampoule (as disodium phosphate salt). **Oral liquid:** 2 mg/5 mL. **Tablet:** 2 mg **[c]**; 4 mg.
diazepam	**Injection:** 5 mg/ mL. **Oral liquid:** 2 mg/5 mL. **Rectal solution:** 2.5 mg; 5 mg; 10 mg. **Tablet:** 5 mg; 10 mg.
docusate sodium	**Capsule:** 100 mg. **Oral liquid:** 50 mg/5 mL.
fluoxetine **a**	**Solid oral dosage form:** 20 mg (as hydrochloride). **a** >8 years.
haloperidol	**Injection:** 5 mg in 1- mL ampoule. **Oral liquid:** 2 mg/ mL. **Solid oral dosage form:** 0.5 mg; 2mg; 5 mg.
hyoscine butylbromide	**Injection:** 20 mg/ mL.
hyoscine hydrobromide **[c]**	**Injection:** 400 micrograms/ mL; 600 micrograms/ mL. **Transdermal patches:** 1 mg/72 hours.
lactulose **[c]**	**Oral liquid:** 3.1–3.7 g/5 mL.
loperamide	**Solid oral dosage form:** 2 mg.
metoclopramide	**Injection:** 5 mg (hydrochloride)/mL in 2-mL ampoule. **Oral liquid:** 5 mg/5 mL. **Solid oral form:** 10 mg (hydrochloride).
midazolam	**Injection:** 1 mg/ mL; 5 mg/ mL. **Solid oral dosage form:** 7.5 mg; 15 mg. **Oral liquid:** 2mg/ mL **[c]**.

ondansetron **[c]** a	**Injection:** 2 mg base/ mL in 2- mL ampoule (as hydrochloride). **Oral liquid:** 4 mg base/5 mL. **Solid oral dosage form:** Eq 4 mg base; Eq 8 mg base. a >1 month.
senna	**Oral liquid:** 7.5 mg/5 mL.
3. ANTIALLERGICS AND MEDICINES USED IN ANAPHYLAXIS	
dexamethasone	**Injection:** 4 mg/ mL in 1- mL ampoule (as disodium phosphate salt).
epinephrine (adrenaline)	**Injection:** 1 mg (as hydrochloride **or** hydrogen tartrate) in 1- mL ampoule.
hydrocortisone	**Powder for injection:** 100 mg (as sodium succinate) in vial.
☐ loratadine *	**Oral liquid:** 1 mg/ mL. **Tablet:** 10 mg. **There may be a role for sedating antihistamines for limited indications (EMLc).*
☐ prednisolone	**Oral liquid:** 5 mg/ mL **[c]**. **Tablet:** 5 mg; 25 mg.
4. ANTIDOTES AND OTHER SUBSTANCES USED IN POISONINGS	
4.1 Non-specific	
charcoal, activated	**Powder.**
4.2 Specific	
acetylcysteine	**Injection:** 200 mg/ mL in 10- mL ampoule. **Oral liquid:** 10% **[c]**; 20% **[c]**.
atropine	**Injection:** 1 mg (sulfate) in 1- mL ampoule.
calcium gluconate	**Injection:** 100 mg/ mL in 10- mL ampoule.
methylthioninium chloride (methylene blue)	**Injection:** 10 mg/ mL in 10- mL ampoule.
naloxone	**Injection:** 400 micrograms (hydrochloride) in 1- mL ampoule.
penicillamine	**Solid oral dosage form:** 250 mg.
potassium ferric hexacyano-ferrate(II) - $2H_2O$(Prussian blue)	**Powder for oral administration.**
sodium nitrite	**Injection:** 30 mg/ mL in 10- mL ampoule.
sodium thiosulfate	**Injection:** 250 mg/ mL in 50- mL ampoule.
Complementary List	
deferoxamine	*Powder for injection: 500 mg (mesilate) in vial.*
dimercaprol	*Injection in oil: 50 mg/ mL in 2- mL ampoule.*

fomepizole	***Injection:*** *5 mg/ mL (sulfate) in 20- mL ampoule or 1 g/ mL (base) in 1.5- mL ampoule.*
sodium calcium edetate	***Injection:*** *200 mg/ mL in 5- mL ampoule.*
succimer	***Solid oral dosage form:*** *100 mg.*
5. ANTICONVULSANTS/ANTIEPILEPTICS	
carbamazepine	**Oral liquid:** 100 mg/5 mL. **Tablet (chewable):** 100 mg; 200 mg. **Tablet (scored):** 100 mg; 200 mg.
diazepam	**Gel or rectal solution:** 5 mg/ mL in 0.5 mL; 2- mL; 4- mL tubes.
lamotrigine*	**Tablet:** 25 mg; 50 mg; 100 mg; 200 mg. **Tablet (chewable, dispersible):** 2 mg; 5 mg; 25 mg; 50 mg; 100 mg; 200 mg. *as adjunctive therapy for treatment-resistant partial or generalized seizures.
□ lorazepam	**Parenteral formulation:** 2 mg/ mL in 1- mL ampoule; 4 mg/ mL in 1- mL ampoule.
magnesium sulfate*	**Injection:** 0.5g/ mL in 2- mL ampoule (equivalent to 1 g in 2 mL; 50% weight/volume); 0.5g/ mL in 10- mL ampoule (equivalent to 5 g in 10 mL; 50% weight/volume). * For use in eclampsia and severe pre-eclampsia and not for other convulsant disorders.
midazolam	**Solution for oromucosal administration:** 5 mg/mL; 10 mg/mL **Ampoule*:** 1 mg/ mL; 10 mg/mL *for buccal administration when solution for oromucosal administration is not available
phenobarbital	**Injection:** 200 mg/ mL (sodium). **Oral liquid:** 15 mg/5 mL. **Tablet:** 15 mg to 100 mg.
phenytoin	**Injection:** 50 mg/ mL in 5- mL vial (sodium salt). **Oral liquid:** 25 mg to 30 mg/5 mL.* **Solid oral dosage form:** 25 mg; 50 mg; 100 mg (sodium salt). **Tablet (chewable):** 50 mg. * The presence of both 25 mg/5 mL and 30 mg/5 mL strengths on the same market would cause confusion in prescribing and dispensing and should be avoided.

valproic acid (sodium valproate)	**Oral liquid:** 200 mg/5 mL. **Tablet (crushable):** 100 mg. **Tablet (enteric-coated):** 200 mg; 500 mg (sodium valproate).
Complementary List	
ethosuximide	*Capsule: 250 mg.* *Oral liquid: 250 mg/5 mL.*
valproic acid (sodium valproate)	*Injection: 100 mg/ mL in 4- mL ampoule; 100 mg/ mL in 10- mL ampoule.*
6. ANTI-INFECTIVE MEDICINES	
6.1 Anthelminthics	
6.1.1 Intestinal anthelminthics	
albendazole	**Tablet (chewable):** 400 mg.
ivermectin	**Tablet (scored):** 3 mg.
levamisole	**Tablet:** 50 mg; 150 mg (as hydrochloride).
mebendazole	**Tablet (chewable):** 100 mg; 500 mg.
niclosamide	**Tablet (chewable):** 500 mg.
praziquantel	**Tablet:** 150 mg; 600 mg.
pyrantel	**Oral liquid:** 50 mg (as embonate **or** pamoate)/ mL. **Tablet (chewable):** 250 mg (as embonate **or** pamoate).
6.1.2 Antifilarials	
albendazole	**Tablet (chewable):** 400 mg.
diethylcarbamazine	**Tablet:** 50 mg; 100 mg (dihydrogen citrate).
ivermectin	**Tablet (scored):** 3 mg.
6.1.3 Antischistosomals and other antitrematode medicines	
praziquantel	**Tablet:** 600 mg.
triclabendazole	**Tablet:** 250 mg.

Complementary List	
*oxamniquine**	***Capsule:*** *250 mg.* ***Oral liquid:*** *250 mg/5 mL.* * *Oxamniquine is listed for use when praziquantel treatment fails.*

6.2 Antibacterials

To assist in the development of tools for antibiotic stewardship at local, national and global levels and to reduce antimicrobial resistance, three different categories were developed – ACCESS, WATCH and RESERVE groups.

Group 1 - KEY ACCESS ANTIBIOTICS

To improve both access and clinical outcomes antibiotics that were first or second choice antibiotics in at least one of the reviewed syndromes are designated as key ACCESS antibiotics, emphasizing their role as the antibiotics that should be widely available, affordable and quality-assured. ACCESS antibiotics are listed below. Selected ACCESS antibiotics may also be included in the WATCH group.

6.2.1 Beta-lactam medicines		6.2.2 Other antibacterials	
amoxicillin	cefotaxime*	amikacin	gentamicin
amoxicillin + clavulanic acid	ceftriaxone*	azithromycin*	metronidazole
ampicillin	cloxacillin	chloramphenicol	nitrofurantoin
benzathine benzylpenicillin	phenoxymethylpenicillin	ciprofloxacin*	spectinomycin (EML only)
benzylpenicillin	piperacillin + tazobactam*	clarithromycin*	sulfamethoxazole + trimethoprim
cefalexin	procaine benzyl penicillin	clindamycin	vancomycin (oral)*
cefazolin	*meropenem*	doxycycline	*vancomycin (parenteral)**
cefixime*			

Italics = complementary list

*Watch group antibiotics included in the EML/EMLc only for specific, limited indications

The 2017 Expert Committee identified the following antibiotics or antibiotic classes that should be the subject of a specific stewardship focus. Antibiotics or antibiotic classes in these groups are designated accordingly in the EML/EMLc. The "WATCH" and "RESERVE" stewardship groups could assist in activities such as local, national and global monitoring of use; development of guidelines and educational activities.

Group 2 - WATCH GROUP ANTIBIOTICS

This group includes antibiotic classes that have higher resistance potential and so are recommended as first or second choice treatments only for a specific, limited number of indications. These medicines should be prioritized as key targets of stewardship programs and monitoring.

This group includes most of the highest priority agents among the Critically Important Antimicrobials for Human Medicine[1] and/or antibiotics that are at relatively high risk of selection of bacterial resistance.

Watch group antibiotics
Quinolones and fluoroquinolones e.g. ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin
3rd-generation cephalosporins (with or without beta-lactamase inhibitor) e.g. cefixime, ceftriaxone, cefotaxime, ceftazidime
Macrolides e.g. azithromycin, clarithromycin, erythromycin
Glycopeptides e.g. teicoplanin, vancomycin
Antipseudomonal penicillins + beta-lactamase inhibitor e.g. piperacillin-tazobactam
Carbapenems e.g. meropenem, imipenem + cilastatin
Penems e.g. faropenem

[1] http://apps.who.int/iris/bitstream/10665/251715/1/9789241511469-eng.pdf?ua=1

WHO Model List of Essential Medicines

Group 3 - RESERVE GROUP ANTIBIOTICS

This group includes antibiotics that should be treated as "last resort" options that should be accessible, but whose use should be tailored to highly specific patients and settings, when all alternatives have failed (e.g., serious, life-threatening infections due to multi-drug resistant bacteria). These medicines could be protected and prioritized as key targets of national and international stewardship programs involving monitoring and utilization reporting, to preserve their effectiveness.

Reserve group antibiotics	
Aztreonam	Fosfomycin (IV)
4th generation cephalosporins e.g. cefepime	Oxazolidinones e.g. linezolid
5th generation cephalosporins e.g. ceftaroline	Tigecycline
Polymyxins e.g. polymyxin B, colistin	Daptomycin

6.2.1 Beta-lactam medicines

amoxicillin	**Powder for oral liquid:** 125 mg (as trihydrate)/5 mL; 250 mg (as trihydrate)/5 mL **[c]**. **Solid oral dosage form:** 250 mg; 500 mg (as trihydrate). **Powder for injection**: 250 mg; 500 mg; 1 g (as sodium) in vial.	
	FIRST CHOICE - *community acquired pneumonia (mild to moderate)* - *community acquired pneumonia (severe)* **[c]** - *complicated severe acute malnutrition* **[c]** - *exacerbations of COPD* - *lower urinary tract infections* - *otitis media* - *pharyngitis* - *sepsis in neonates and children* **[c]** - *sinusitis* - *uncomplicated severe acute malnutrition* **[c]**	SECOND CHOICE - *acute bacterial meningitis*
amoxicillin + clavulanic acid	**Oral liquid:** 125 mg amoxicillin + 31.25 mg clavulanic acid/5 mL AND 250 mg amoxicillin + 62.5 mg clavulanic acid/5 mL **[c]**. **Tablet:** 500 mg (as trihydrate) + 125 mg (as potassium salt). **Powder for injection:** 500 mg (as sodium) + 100 mg (as potassium salt); 1000 mg (as sodium) + 200 mg (as potassium salt) in vial.	

WHO Model List of Essential Medicines

	FIRST CHOICE - *community acquired pneumonia (severe)* **[c]** - *complicated intraabdominal infections (mild to moderate)* - *exacerbations of COPD* - *hospital acquired pneumonia* - *low-risk febrile neutropenia* - *lower urinary tract infections* - *sinusitis* - *skin and soft tissue infections*	SECOND CHOICE - *bone and joint infections* - *community-acquired pneumonia (mild to moderate)* - *community acquired pneumonia (severe)* - *otitis media*
ampicillin	**Powder for injection:** 500 mg; 1 g (as sodium salt) in vial.	
	FIRST CHOICE - *community acquired pneumonia (severe)* **[c]** - *complicated severe acute malnutrition* **[c]** - *sepsis in neonates and children* **[c]**	SECOND CHOICE - *acute bacterial meningitis*
benzathine benzylpenicillin	**Powder for injection:** 900 mg benzylpenicillin (= 1.2 million IU) in 5- mL vial **[c]**; 1.44 g benzylpenicillin (= 2.4 million IU) in 5- mL vial.	
	FIRST CHOICE - *syphilis*	SECOND CHOICE
benzylpenicillin	**Powder for injection:** 600 mg (= 1 million IU); 3 g (= 5 million IU) (sodium **or** potassium salt) in vial.	
	FIRST CHOICE -*community acquired pneumonia (severe)* **[c]** - *complicated severe acute malnutrition* **[c]** - *sepsis in neonates and children* **[c]** - *syphilis*	SECOND CHOICE - *acute bacterial meningitis* **[c]**
cefalexin	**Powder for reconstitution with water:** 125 mg/5 mL; 250 mg/5 mL (anhydrous). **Solid oral dosage form:** 250 mg (as monohydrate).	
	FIRST CHOICE	SECOND CHOICE - *exacerbations of COPD* - *pharyngitis* - *skin and soft tissue infections*
cefazolin* [a]	**Powder for injection:** 1 g (as sodium salt) in vial. * also indicated for surgical prophylaxis. [a] >1 month.	
	FIRST CHOICE	SECOND CHOICE - *bone and joint infections*

cefixime WATCH GROUP	**Capsule or tablet:** 200 mg; 400 mg (as trihydrate). **Powder for oral liquid:** 100 mg /5 mL **[c]**	
	FIRST CHOICE	SECOND CHOICE - *acute invasive bacterial diarrhoea / dysentery* - *Neisseria gonorrhoeae*
cefotaxime* WATCH GROUP	**Powder for injection:** 250 mg per vial (as sodium salt) * 3rd generation cephalosporin of choice for use in hospitalized neonates.	
	FIRST CHOICE - *acute bacterial meningitis* *-community acquired pneumonia (severe)* - *complicated intraabdominal infections (mild to moderate)* - *complicated intrabdominal infections (severe)* - *hospital acquired pneumonia* *-pyelonephritis or prostatitis (severe)*	SECOND CHOICE - *bone and joint infections* *-pyelonephritis or prostatitis (mild to moderate)* - *sepsis in neonates and children* **[c]**
ceftriaxone* [a] WATCH GROUP	**Powder for injection:** 250 mg; 1 g (as sodium salt) in vial. * Do not administer with calcium and avoid in infants with hyperbilirubinaemia. [a] >41 weeks corrected gestational age.	
	FIRST CHOICE - *acute bacterial meningitis* *-community acquired pneumonia (severe)* - *complicated intraabdominal infections (mild to moderate)* - *complicated intrabdominal infections (severe)* - *hospital acquired pneumonia* - *Neisseria gonorrhoeae* *-pyelonephritis or prostatitis (severe)*	SECOND CHOICE - *acute invasive bacterial diarrhoea / dysentery* - *bone and joint infections* - *pyelonephritis or prostatitis (mild to moderate)* - *sepsis in neonates and children* **[c]**
☐ cloxacillin*	**Capsule:** 500 mg; 1 g (as sodium salt). **Powder for injection:** 500 mg (as sodium salt) in vial. **Powder for oral liquid:** 125 mg (as sodium salt)/5 mL. *cloxacillin, dicloxacillin and flucloxacillin are preferred for oral administration due to better bioavailability.	
	FIRST CHOICE - *bone and joint infections* - *skin and soft tissue infections*	SECOND CHOICE - *sepsis in neonates and children* **[c]**

phenoxymethylpenicillin	**Powder for oral liquid:** 250 mg (as potassium salt)/5 mL. **Tablet:** 250 mg (as potassium salt).	
	FIRST CHOICE - *community acquired pneumonia (mild to moderate)* - *pharyngitis*	SECOND CHOICE
piperacillin + tazobactam WATCH GROUP	**Powder for injection:** 2 g (as sodium salt) + 250 mg (as sodium salt); 4 g (as sodium salt) + 500 mg (as sodium salt) in vial	
	FIRST CHOICE - *complicated intraabdominal infections (severe)* - *high-risk febrile neutropenia* - *hospital acquired pneumonia*	SECOND CHOICE
procaine benzylpenicillin*	**Powder for injection:** 1 g (=1 million IU); 3 g (=3 million IU) in vial. * Procaine benzylpenicillin is not recommended as first-line treatment for neonatal sepsis except in settings with high neonatal mortality, when given by trained health workers in cases where hospital care is not achievable.	
	FIRST CHOICE - *syphilis* **[c]**	SECOND CHOICE - *syphilis*
Complementary List		
ceftazidime *WATCH GROUP*	*Powder for injection: 250 mg or 1 g (as pentahydrate) in vial.*	
*meropenem** [a] *WATCH GROUP*	***Powder for injection:** 500 mg (as trihydrate); 1 g (as trihydrate) in vial* [a] >3 months. **imipenem + cilastatin is an alternative except for acute bacterial meningitis where meropenem is preferred.*	
	FIRST CHOICE	SECOND CHOICE - *acute bacterial meningitis in neonates* **[c]** - *complicated intraabdominal infections (severe)* - *high-risk febrile neutropenia*
Complementary List – RESERVE GROUP		
aztreonam	*Powder for injection: 1 g; 2 g in vial*	
fifth generation cephalosporins *(with or without beta-lactamase inhibitor)* *e.g. ceftaroline*	***Powder for injection:** 400 mg; 600 mg (as fosamil) in vial*	

fourth generation cephalosporins (with or without beta-lactamase inhibitor) e.g., cefepime	***Powder for injection:*** *500 mg; 1g; 2g (as hydrochloride) in vial*	
6.2.2 Other antibacterials		
amikacin	**Injection:** 250 mg (as sulfate)/mL in 2- mL vial	
	FIRST CHOICE *-pyelonephritis or prostatitis (severe)*	SECOND CHOICE *- high-risk febrile neutropenia* *- sepsis in neonates and children* **[c]**
azithromycin* WATCH GROUP	**Capsule:** 250 mg; 500 mg (anhydrous). **Oral liquid:** 200 mg/5 mL. * also listed for single-dose treatment of trachoma and yaws.	
	FIRST CHOICE *- Chlamydia trachomatis* *- cholera* **[c]** *- Neisseria gonorrhoeae*	SECOND CHOICE *- acute invasive bacterial diarrhoea / dysentery* *- Neisseria gonorrhoeae*
chloramphenicol	**Capsule:** 250 mg. **Oily suspension for injection*:** 0.5 g (as sodium succinate)/ mL in 2- mL ampoule. * Only for the presumptive treatment of epidemic meningitis in children older than 2 years and in adults. **Oral liquid:** 150 mg (as palmitate)/5 mL. **Powder for injection:** 1 g (sodium succinate) in vial.	
	FIRST CHOICE	SECOND CHOICE *- acute bacterial meningitis*
ciprofloxacin WATCH GROUP	**Oral liquid:** 250 mg/5 mL (anhydrous) **[c]**. **Solution for IV infusion:** 2 mg/ mL (as hyclate) **[c]**. **Tablet:** 250 mg (as hydrochloride).	
	FIRST CHOICE *- acute invasive bacterial diarrhoea / dysentery* *- low-risk febrile neutropenia* *- pyelonephritis or prostatitis (mild to moderate)*	SECOND CHOICE *-cholera* *- complicated intraabdominal infections (mild to moderate)*

WHO Model List of Essential Medicines

<table>
<tr><td rowspan="3">clarithromycin*†
WATCH GROUP</td><td colspan="2">Solid oral dosage form: 500 mg.
Powder for oral liquid: 125 mg/5 mL; 250 mg/5 mL
Powder for injection: 500 mg in vial
*erythromycin may be an alternative.
†clarithromycin is also listed for use in combination regimens for eradication of H. pylori in adults.</td></tr>
<tr><td>FIRST CHOICE
-community acquired pneumonia (severe)</td><td>SECOND CHOICE
- pharyngitis</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td rowspan="3">clindamycin</td><td colspan="2">Capsule: 150 mg (as hydrochloride).
Injection: 150 mg (as phosphate)/ mL.
Oral liquid: 75 mg/5 mL (as palmitate) [c].</td></tr>
<tr><td>FIRST CHOICE</td><td>SECOND CHOICE
- bone and joint infections</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td rowspan="3">doxycycline [a]</td><td colspan="2">Oral liquid: 25 mg/5 mL [c]; 50 mg/5 mL (anhydrous) [c].
Solid oral dosage form: 50 mg [c]; 100 mg (as hyclate).
Powder for injection: 100 mg in vial
[a] Use in children <8 years only for life-threatening infections when no alternative exists.</td></tr>
<tr><td>FIRST CHOICE
- Chlamydia trachomatis
- cholera</td><td>SECOND CHOICE
- cholera [c]
-community acquired pneumonia (mild to moderate)
- exacerbations of COPD</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td rowspan="3">gentamicin</td><td colspan="2">Injection: 10 mg; 40 mg (as sulfate)/ mL in 2- mL vial.</td></tr>
<tr><td>FIRST CHOICE
- community acquired pneumonia (severe) [c]
- complicated severe acute malnutrition [c]
- sepsis in neonates and children [c]</td><td>SECOND CHOICE
- Neisseria gonorrhoeae</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td rowspan="3">metronidazole</td><td colspan="2">Injection: 500 mg in 100- mL vial.
Oral liquid: 200 mg (as benzoate)/5 mL.
Suppository: 500 mg; 1 g.
Tablet: 200 mg to 500 mg.</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td colspan="2"></td></tr>
</table>

Anlage zur Schriftlichen Anfrage MdL Rosi Steinberger (Bündnis 90/DIE GRÜNEN) betreffend Colistin

Redaktionell bearbeiteter Auszug von Informationen zur Dosierung von Colistin aus der schweizerischen veterinärmedizinischen Datenbank „Clinipharm/Clinitox“ (www.vetpharm.uzh.ch)

Katze - Colistin	
oral	- 2,5 mg/kg 3 × täglich
Katze - Colistinsulfat	
oral	- 2,5 mg/kg alle 8 h für 5 - 7 Tage

Hund - Colistinmethansulfonat-Natrium	
intramuskulär	- 1,1 mg/kg alle 6 h
Hund - Colistinsulfat	
oral	- 2,5 mg/kg 3 × täglich - 2,5 mg/kg alle 8 h für 5 - 7 Tage

Schwein (Jungtier) - Colistinsulfat	
intramuskulär	- 2,5 mg/kg alle 12 h - 3 mg/kg alle 24 h für 5 - 7 Tage - 2,5 mg/kg einer 2,5%iger Colistinsulfat-Lösung 2 × täglich für 3 Tage

Schwein - Colistin	
oral	- 5 mg/kg - 120 mg/kg Futter - 100 - 200 mg/kg Trockenfutter
Schwein - Colistinsulfat	
intramuskulär	- 3 mg/kg alle 24 h für 5 - 7 Tage
oral	- 6 mg/kg/Tag für 6 - 10 Tage - 2,5 mg/kg alle 12 h für 5 - 7 Tage

Rind (Jungtier) - Colistinsulfat	
intramuskulär	- 3 mg/kg alle 24 h ***Atemwegsinfektionen mit gramnegativen Erregern*** - 25'000 IU/kg alle 12 h für 3 Tage ***Harnwegsinfektionen mit Colibakterien*** - 25'000 IU/kg alle 12 h für 3 Tage ***Uterine Infektionen mit Colibakterien*** - 25'000 IU/kg alle 12 h für 3 Tage - 3 mg/kg alle 24 h für 5 - 7 Tage
oral	- 2,5 mg/kg alle 12 h für 5 - 7 Tage

Rind - Colistinsulfat	
intramuskulär	- 3 mg/kg alle 24 h
oral	- 2 mg/kg alle 12 h für 5 - 7 Tage - 3 mg/kg alle 24 h für 5 - 7 Tage

Chinchilla - Colistinsulfat	
intramuskulär	- Bis 50'000 I.E./Tier
oral	- Bis 50'000 I.E./Tier

Echsen & Krokodile - Colistinsulfat	
intramuskulär	***Bakterielle Infektionen, insbesondere Infektionen mit E. coli und Salmonellen*** - 50'000 I.E./kg 1 × täglich
intraperitoneal	***Bakterielle Infektionen, insbesondere Infektionen mit E. coli durch Salmonellen*** - 50'000 I.E./kg 1 × täglich

Schlangen - Colistinsulfat	
intramuskulär	- 50'000 I.E./kg 1 × täglich
intraperitoneal	- 50'000 I.E./kg 1 × täglich

Huhn, Trute, Fasan & Wachtel - Colistinsulfat	
oral	- 13 - 17 mg Reinsubstanz/kg KGW/Tag für 4 - 5 Tage - 90 - 120 mg/l Wasser für 4 - 5 Tage - **Huhn**: 3 mg/kg alle 12 h für 5 - 7 Tage