Sundhedsstyrelsen
Danish Health and Medicines Authority

GUIDELINES ON PRESCRIBING ANTIBIOTICS

2013

For physicians and others in Denmark

Guidelines on prescribing antibiotics
For physicians and others in Denmark

© 2013 by the Danish Health and Medicines Authority. All rights reserved.

Danish Health and Medicines Authority
Axel Heides Gade 1
DK-2300 Copenhagen S
Denmark

URL: http://www.sst.dk

Keywords: antibiotics, prescription, antibiotic resistance, resistance

Language: English

Version: 1.2

Version date: October 8, 2013.

Format: pdf

ISBN online: 978-87-7104-496-6

English version published by the Danish Health and Medicines Authority, November 2013.

Contents

1 Introduction 2

2 Background 2

3 Aims and target group 2

4 General rules for physicians prescribing antibiotics 3

5 Special rules for general practitioners and other primary care physicians prescribing specific types of antibiotics 4

5.1 Carbapenems 4
5.2 Fluoroquinolones 4
5.3 Cephalosporins 4

6 General rules on prescribing antibiotics at hospitals 5

7 Special rules governing the prescription of specific antibiotics by hospital physicians 6

7.1 Carbapenems 6
7.2 Fluoroquinolones 6
7.3 Cephalosporins 6

8 Entering into force 7

Summary

1 Introduction

In accordance with § 17 of Consolidated Act No. 877 of 4 August 2011 on the authorization of health personnel and on professional health activities (the Authorization Act), physicians carrying out their activities are obligated to be meticulous and conscientious.

These guidelines outline the standards required for the meticulousness and conscientiousness physicians must demonstrate in prescribing antibiotics, including the special procedures applying to certain specific groups of antibiotics.

2 Background

All antibiotics influence the overall bacterial flora and result in the selection of resistant types of bacteria. This increases the proportion of bacteria that are resistant and the risk of developing and disseminating resistant pathogenic bacteria.

Some pathogenic bacteria have become so resistant to antibiotics that the available antibiotics are barely adequate to treat the people who acquire the resulting infections. In addition, few new antibiotics are expected to become available in the near future.

This trend highlights the urgency of demonstrating great caution in using antibiotics. The Danish Health and Medicines Authority therefore wants to narrow the indications for prescribing antibiotics and to use medicines that less often cause resistance to develop. This will probably require many physicians and the public to change their attitudes, but this is necessary to continue to be able to successfully treat the people who acquire severe infections.

These guidelines define “critically important antibiotics” as antibiotics that are especially important in treating people who have severe infections caused by resistant bacteria.

3 Aims and target group

These guidelines aim:

to change the pattern of prescription of antibiotics to become more rational – including ensuring that unnecessary use is reduced – with the aim of preventing the development of antibiotic resistance; and

to ensure that the critically important antibiotics are reserved for severely ill people or are only used when there are no alternatives, including especially targeting the use of carbapenems, fluoroquinolones and cephalosporins.

These guidelines are not general clinical guidelines on treatment with antibiotics but have the specific aims outlined above.

Further, these guidelines apply solely to the antibiotics prescribed for systemic use.

The Authority intends to develop these guidelines in accordance with the trends in antibiotic resistance and to provide more detail on the individual points as needed.

The Authority requests that relevant clinical societies, universities, pharmaceutical committees, administrators and others incorporate the new rules into the applicable guidelines, textbooks, local instructions etc.

Since the patterns of illness and the diagnostic potential differ greatly between the primary and secondary health care sectors, the rules differ also. Nevertheless, the guidelines start with a general set of rules that apply to the prescription of antibiotics by all physicians.

4 General rules for physicians prescribing antibiotics

Antibiotic treatment considered to be life-saving should be initiated immediately. The goal is to limit ineffective and unnecessary treatment. Further, the Authority wants antibiotic treatment to increasingly be based on microbiological testing. The basic rules that apply to physicians' prescription of antibiotics for systemic use are as follows.

- Antibiotic treatment must be expected to prevent severe or life-threatening events or to reduce the period of illness considerably.
- Clinical and diagnostic testing must be carried out such that it at least determines that bacteria are the likely cause of illness.
- The antibiotic selected must be as narrow spectrum as possible and influence the normal bacterial flora as little as possible in accordance with the general and local guidelines for the use of antibiotics.
- If the initial treatment is not successful, the choice of antibiotic must be reassessed and perhaps changed based on microbiological testing.
- The treatment must be as brief as possible and be in accordance with the evidence available in the field.
- The diagnosis that results in the prescription must be specifically outlined in the prescription system, including on the prescription and in the medical records.

5 Special rules for general practitioners and other primary care physicians prescribing specific types of antibiotics

5.1 Carbapenems

General practices and other practitioners in primary health care may not prescribe carbapenems.

5.2 Fluoroquinolones

Practitioners in primary health care may prescribe fluoroquinolones but should only use them in connection with microbiological testing demonstrating that other types of antibiotics cannot be used.

Treatment with fluoroquinolones before the microbiological test results are available may only be initiated among:

- people allergic to penicillin who have acute exacerbation of chronic obstructive pulmonary disease, are clinically affected and fulfil the following criteria: increased dyspnoea, increased expectoration and increasing purulent expectorate;
- people allergic to penicillin who have pyelonephritis;
- people with severe gastroenteritis who have a higher risk of complications (such as those older than 60 years, with arteriosclerosis or with immune suppression) and among whom Salmonella infection is suspected; and
- men older than 35 years with epididymitis.

5.3 Cephalosporins

Primary care practitioners may prescribe cephalosporins but should only use them in connection with microbiological testing demonstrating that other types of antibiotics cannot be used.

Treatment with cephalosporins before the microbiological test results are available may only be initiated among:

- pregnant women allergic to penicillin who have infections requiring treatment (fluoroquinolones and macrolides are not recommended for use among pregnant women); and
- people allergic to penicillin among whom meningococcal disease is suspected, in accordance with the Authority's Guidelines No. 9235 of 23 May 2012 on the treatment of meningococcal disease by general practitioners and physicians from the emergency service.

6 General rules on prescribing antibiotics at hospitals

- Each department or hospital must have instructions for prescribing and using antibiotics.
- If there is a reason to deviate from these instructions, the reason for this must be entered into the medical records in connection with prescription.
- The department or hospital should always take samples for microbiological testing before initiating antibiotic treatment. Occasional exceptions might include cholecystitis and erysipelas.
- For all treatment with antibiotics, the indication, dose and expected duration of treatment must be entered in the person's medical record.
- A physician must reassess the indication, choice of medicine, dose and duration of treatment within 48 hours and should assess this at least every 3 days thereafter.
- Critically important antibiotics should be primarily used when the person has or may be expected to have life-threatening illness or relevant microbiological test results are available.

7 Special rules governing the prescription of specific antibiotics by hospital physicians

7.1 Carbapenems

Carbapenems as first-line treatment should only be used empirically when septic shock or severe sepsis, synergistic gangrene or a similar life-threatening acute infection is suspected.

Carbapenems may be used as second-line treatment if the symptoms progress during treatment with another less broad-spectrum antibiotic treatment for infections of unknown cause.

For microbiologically verified infections, carbapenems should only be used if the paraclinical results indicate that less broad-spectrum treatment is inadequate.

7.2 Fluoroquinolones

Fluoroquinolones should only be used in connection with microbiological testing demonstrating that other antibiotics cannot be used or if the pharmaceutical properties of fluoroquinolones are especially suitable and/or if the person is allergic to penicillin.

7.3 Cephalosporins

Cephalosporins may be used empirically after samples have been obtained for microbiological testing from normally affected people suspected of having an infectious disease with unknown bacterial origin.

Cephalosporins may be used for surgical prophylaxis in accordance with the local instructions on the use of antibiotics if they are validated as being the best choice: that is, more narrow-spectrum antibiotics or combinations thereof would not have the same effect.

Cephalosporins should otherwise only be used in connection with microbiological testing demonstrating that penicillin products or other less broad-spectrum medicines cannot be used.

8 Entering into force

These guidelines shall enter into force on 15 November 2012.

Danish Health and Medicines Authority, 15 November 2012

On 10 December 2012, the following was added: the guidelines solely cover antibiotics for systemic use (sections 3 and 4), on meningococcal disease (subsection 5.3) and on epididymitis (subsection 5.2).

Søren Brostrøm

Head of unit, senior medical officer

Tove Rønne

Senior medical officer