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On 5 September 2016, the CPME Executive Committee adopted the 'CPME response to public consultation on "Proposals for draft EU guidelines on the prudent use of antimicrobials in human medicine"' (CPME 2016/075 FINAL)

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**CPME response to public consultation on  
"Proposals for draft EU guidelines on the prudent use of antimicrobials in human medicine"**

## **ECDC Public consultation**

### **"Proposals for draft EU guidelines on the prudent use of antimicrobials in human medicine"**

Please refer to the [guidelines for submission of comments](#) and the [privacy statement](#).

**Deadline for comments:** Monday 5 September 2016 sent to [ARHAI@ecdc.europa.eu](mailto:ARHAI@ecdc.europa.eu).



Section of document (Introduction, Definitions, etc)	Page and line number	Comment and rationale	Proposed change
2. National and regional	Page 2- lines 79 to 83	<p>A precondition for doctors to ensure appropriate prescribing of antibiotics is to have access to precise and updated guidelines.</p> <p>The guidelines should provide with a basis for giving the correct antibiotic in the necessary quantity. It should also specify in which infections/cases of illness the patient may/must await natural recovery – and, where necessary, state how many days the patient must wait before consulting the doctor again.</p> <p>Consequently, CPME fully support the recommendations under intends f) and g).</p>	
	Page 3 - after line 83	<p>In general, the draft guidelines do not address in detail the issue of point-of-care diagnostics and laboratory tests.</p> <p>However, CPME believes that ensuring access to better and faster diagnostics is a decisive factor to prevent antimicrobial resistance. If the doctor has early confirmation of the patient’s diagnosis, it can be</p>	<p>(new indent) <b><u>“Ensure the availability of national guidelines for point-of-care diagnostics and laboratory tests to support the prescriber’s decision.”</u></b></p>



		<p>avoided that antibiotics are prescribed “to be on the safe side”.</p> <p>Consequently, national guidelines should also indicate which point-of-care diagnostics and laboratory tests can be carried out in practice in aid of a diagnosis and when a test should be submitted for further bacteriological diagnoses.</p>	
	Page 3 – before line 97	<p>In all European countries, only doctors and dentists are allowed to prescribe antibiotics to humans. CPME encourages all countries to enforce these regulations very strictly as the only possible way to control antibiotic consumption. In addition, doctors, dentists and veterinarians should not be allowed to sell antibiotics apart from in pre-existing exceptional circumstances.</p> <p>Consequently, CPME suggest adding a new indent (before indent n) to ensure a strict implementation of national regulation on antibiotic prescribing.</p>	(new indent) <b><u>“Ensure a strict implementation of national regulations on antibiotics prescribing to humans.”</u></b>
	Page 3 - lines 97/98	This indent states that national and regional policy shall <i>“Ensure compliance with the regulations with</i>	



		<p><i>regards to the dispensing of antimicrobials without prescription and over the internet.” (indent n))</i></p> <p>The meaning of this statement is unclear and should be further specified to ensure that a strict framework is in place at national and/or regional level.</p>	
<b>5. Prescribers</b>	Page 4 - before line 173	<p>Under the prescriber’s section, CPME believes that EU guidelines should contain key messages relating to antibiotic prescribing, starting with basic principles before moving on to more specific recommendations.</p> <p>As such, the first indent should emphasise the fact that the prescriber should diagnose the patient in person before prescribing antibiotics, except in exceptional circumstances.</p>	(new indent) <b><u>”diagnose the patient in person before prescribing antibiotics, except in specific circumstances.”</u></b>
	Page 4 - lines 173/174	<p>The first statement refers to the case of a patient with sepsis. In such circumstances, the draft guidelines provide that an antimicrobial treatment should be started within one hour via the intravenous route.</p> <p>Considering that this statement refers to exceptional cases, CPME would suggest moving it at the end of the sub-section.</p>	<b><u>xiv. †</u></b> for a patient with sepsis, start antimicrobial treatment via the intravenous route within 1 hour of 173 recognition of sepsis [28]



	Page 4 – line 177	For the sake of clarity, we would suggest to specify the sentence as follows :	iii. avoid treatment for colonisation without evidence of <b><u>bacterial</u></b> infection <b><u>after a relevant clinical and diagnosis examination.</u></b>
	Page 4 – line 198	The prescriber should ensure that patients are well informed that antibiotics must be taken long enough, as their physician has prescribed in order to improve compliance and prevent antimicrobial resistance.	xi. inform the patient about their antimicrobial treatment <b><u>and the importance to respect the treatment duration.</u></b>
<b>10. Public / patients</b>	Page 6 – after line 290	In line with the previous comment, CPME suggest to also emphasise the importance of compliance under the public section.	(new indent) <b><u>“respect the treatment duration following physician/dentist’s prescription”</u></b>