Commission and ECDC services' response to the competent authority's comments on draft report DG (SANTE)/2018-6517–Report of a One Health country visit to Bulgaria to discuss policies relating to antimicrobial resistance

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				Not accepted	Accepted	
Page	Section				Text amended	Footnote (no.)
9	22, 23	The competent authority provided the following comments: The pharmacist undertakes to record each prescription delivered in a logbook which may be in either paper or electronic form. It is not mandatory to record the treatment prescribed. Under the Regulation on the rules and procedures for the regulation and registration of the prices of medicinal products in Bulgaria, the National Health Insurance Fund (NHIF) provides detailed information on the reimbursed medicinal products on the Positive Medicine List. Such information is submitted to the Council also by the healthcare institutions under Article 5 of the Medical Establishments Act and by medical establishments with State and/or municipal ownership under Articles 9 and 10 of the Medical Establishments Act. Available software in community pharmacies can be consulted on the consumption of a specific product	A footnote has been added.		√	21

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		by brand name.				
10	25	The competent authority provided the following comments: Medicinal products falling within this group are prescription medicines, and the prescription regime of the medicinal product concerned is laid down by the Bulgarian Drug Agency in the marketing authorisation of the product. In Annex 1 to the Positive Medicine List (medicinal products intended for treatment of diseases reimbursed under the Health Insurance Act) 26 medicinal products, 7 of which are antibacterial medicinal products, were included for the following diseases by diagnoses under the ICD: Acute tubulo-interstitial nephritis N10, Non-obstructive reflux-associated chronic pyelonephritis N11.0, Other chronic tubulo-interstitial nephritis N.11.8, Cystic fibrosis with pulmonary manifestations E84.0, Gastric ulcer:	A footnote has been added.		√	22

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		chronic without haemorrhage or perforation K25.7, Duodenal ulcer: chronic without haemorrhage or perforation K26.7. The remaining 19 medicinal products belong to the group of antivirals mainly for the treatment of Hepatitis B and C and liver cirrhosis. Under the legislation currently in force in our country, only practicing doctors/dental practitioners have the right to prescribe medicinal products, including antimicrobials. Only pharmacists have the right to deliver prescription medicines. The Ministry of Health, the Bulgarian Drug Agency, the regional health inspectorates and the NHIF (for fully or partially reimbursed medicinal products) control the implementation of legislative provisions on the prescription and dispensing of medicinal products for human use in the country. In addition, pharmacists are held liable for breaches committed in the exercise of their profession in the event of failure to comply with the rules laid down				

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		in the Code of conduct of pharmacists and the rules of good pharmaceutical practice controlled by the Medical Supervision Executive Agency and the Bulgarian Pharmaceutical Union (the respective ethics committee of the regional order of pharmacists following a report by its members).				
13	39	The competent authority provided the following comments: Under the Medicinal Products in Human Medicine Act, the Bulgarian Drug Agency is to keep and maintain a register of authorised medicinal products and registered medicinal products in Bulgaria, the data in the register being published on the Agency's official website: www.bda.bg . Medical professionals prescribing medicinal products may not claim or accept any material or other benefits from producers of medicinal products, marketing authorisation/registration certificate	A footnote has been added.		√	23

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		holders, medical sales agents and traders in medicinal products. In the event of promotional meetings, scientific congresses, symposia or other events for scientific purposes attended by medical specialists, sponsors or organisers may bear medical specialists' travel and accommodation expenses and the registration fees in the country in which the event takes place, with the exception of expenses to persons holding a public office within the meaning of Article 3 of the Conflict of Interest Prevention and Ascertainment Act, committee members referred to in Article 107(1), Article 259(1), Article 265(1) of the Medicinal Products in Human Medicine Act and members of the Supreme Council of Pharmacy. The Association of Research-Based Pharmaceutical Manufacturers in Bulgaria (ARPharM) has implemented the EFPIA Disclosure Code in the country. The EFPIA Disclosure Code requires all member companies to document and disclose certain				

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		transfers of value, directly or indirectly made to the benefit of health professionals or health organisations. Healthcare professionals, however, should agree to disclose their financial relationship with pharmaceutical companies.				
14	44	The competent authority provided the following comments: The National Council on Prices and Reimbursement of Medicinal Products in Bulgaria draws up pharmaceutical and therapy guidelines, which include criteria for assessing the effectiveness of the treatment and algorithms for treatment with medicinal products paid for with public funds that are agreed with the relevant council of experts by medical speciality or medical activity. Adherence to the approved pharmaceutical and therapy guidelines in Bulgaria and, where such are not available, to treatment standards and good medical practice in the	A footnote has been added.		√	24

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		European Union countries, is mandatory for all medicinal products on the Positive Medicine List. The Medical Supervision Executive Agency monitors compliance with the approved pharmaceutical and therapy guidelines and the assessment of the effectiveness of treatment.				