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ePoster Viewing

Pharmacoepidemiology, improved prescribing and antibiotic stewardship

Regulation and authorization of antibiotics in Europe

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Background: European member States have their own national standards and provisions on the regularization of antibiotics and these have an impact on dispensing and the consumption of antibiotics at national level. We aimed to get insight in current antibiotic regulatory processes in Europe in order to better understand European observed variations of antibiotic consumption in the outpatient setting.

Methods: In 2015, representatives of 28 EU-countries and 3 European Free trade Association countries were invited to complete a questionnaire on the regularization and authorization of antibiotics, in collaboration with the ARNA-project (www.nivel.nl/en/arna). The questionnaire collected information regarding legal provisions for the prescription and procedure of the reimbursement status of antibiotics, pharmacovigilance, good manufacturing and distribution practice in the ambulatory care (n=35 questions).

Results: 26 EU-countries, Iceland and Norway responded. In 13 countries (46%) only a practising medical doctor or dentist can prescribe an antibiotic; elsewhere also non-practising clinicians prescribe antibiotics (n=13, 46%); or nurses and midwives (n=7; 25%) under certain circumstances (e.g. after obtaining a licence in Ireland, specialized nurses in Sweden). Prescriptions are delivered through physical consultation with the patient. In 6 countries (21%) it is also legally allowed to deliver an antibiotic by telephone consultation. This is rather common practice in Denmark and Sweden for certain conditions (urinary tract infections). In most EU countries, pharmacists are allowed to sell antibiotics with a delayed prescription (N=17 countries, 61%). Four countries reported that this practice is forbidden by law. A third-party payment reimbursement system applies to antibiotics in 11 countries (39%). Some countries have specific regulations on refunding of antibiotics depending on specific disorders (e.g., Norway) or conditions (e.g. Ireland). In Iceland and Malta, antibiotics are not reimbursed. The validity period of a prescription varies a lot by country from 3 days in Slovenia, 6 months in Ireland to 2 years in Denmark for an antibiotic prescription through physical consultation. Over the counter (OTC) sales of antibiotics is forbidden by law in all countries, but it is allowed for some specific formulations (creams in Norway and Denmark or eye drops in the UK). Several countries however reported that OTC may happen in some pharmacies, for example in Greece, Lithuania, Portugal, Belgium. Beside, several countries reported that internet shopping is becoming an attractive source of obtaining antibiotics in an illegal way.

Conclusions: Certain regulations, or lack thereof, enhances inappropriate antibiotic consumption. The question raises if it is justified to allow non-practising doctors (retired, researchers) not seeing patients (any more) to deliver antibiotic prescriptions. Half of the countries allow such practices. Also the need

of a long-term availability prescription could be revised. Obtaining antibiotics through internet might become a future emerging source of OTC use requiring attention from policy makers.