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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 a national level. We aimed to get insight into current antibiotic regulatory processes in Europe in order to better understand 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) (**Table 1**).
- ✓ Prescriptions are commonly delivered through a **physical consultation** with the patient. In 7 countries (21%) it is also legally allowed to deliver an antibiotic by telephone consultation. This is a rather common practice in Denmark and Sweden for certain conditions (urinary tract infections). 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) (**Table 2**).

Table 1. Legal provisions with respect to prescribers of antibiotics in the ambulatory care sector

Country	Required by law that antibiotics are prescribed by a medical prescription?	Other healthcare professional who can prescribe an antibiotic?			
		Pharmacist	Nurse, midwife	Non practising clinician (research, retired)	than a practising medical doctor or dentist
Spain			1*		1
Austria					1
Croatia					1
Denmark					1
Greece					1
Iceland					1
Italy					1
Lithuania					1
Luxembourg	Yes, all antibiotics (systemic and topical use)				1
Malta					1
Norway					1
Portugal					1
France			1	1	
Czech Rep.				1	
Hungary				1	
Slovenia				1	
Estonia			1		
Ireland			1		
Netherlands		1			
Sweden		1			
Slovakia				1	
Belgium	Yes, all antibiotics except for topical use (e.g. creams)			1	
Bulgaria				1	
Cyprus				1	
Poland			1		
UK			1	1	
Latvia					
Total			1	8	7

* under development

Table 2. Legal provisions with respect to reimbursement of antibiotics in the ambulatory care sector

Country	How are antibiotic prescriptions delivered and what is the validity period	
	Physical consultation with patient	Telephone consultation with patient or relative
Czech Republic	3 days	Not allowed
Slovenia	3 days	
Greece	5 days	
Poland	7 days	
Austria	1 month	
Italy	1 month	
Portugal	1 month	
Estonia	2 months	
Belgium	3 months	
Ireland	6 months	
Spain	10 days	1 month
France	3 months	x
Iceland	1 year	x
Norway	1 year	x
Sweden	1 year, prescriber can limit validity period	
Denmark	2 years	7 days
Netherlands	x	x
Cyprus	x	x
Malta	x	x
Bulgaria	x	

Table 3. Existence of surveillance or audit procedure targeting antibiotic prescribing practices among general practitioners

Country	A surveillance or audit procedure targeting antibiotic prescribing practices exist among general practitioners						
	Obligatory	Voluntary	None	Intentions to start	don't know	Electronic	On Paper
Lithuania	1	1					
Sweden	1					1	1
Spain	1					1	
Italy	1					1	
Greece	1					1	
Denmark	1					1	
Hungary	1						
France	1						
Belgium	1						
Netherlands		1				1	1
Norway		1					
Ireland		1					
Austria		1					1
Slovakia			1				
Poland			1				
Malta			1				
Estonia			1	1			
Czech Rep.			1				
Cyprus			1	1			
Bulgaria			1				
Latvia						1	
Iceland						1	
Croatia						1	
UK							1
Slovenia							1
Portugal					1		
Luxembourg							1
Finland							
Total	9	5	7	2	1	9	6

- ✓ 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.
- ✓ Several countries reported that **OTC** may happen in some pharmacies, for example in Greece, Lithuania, Portugal, Belgium.
- ✓ Several countries reported that **internet shopping** is becoming an attractive source of obtaining antibiotics in an illegal way.
- ✓ **Surveillance** among GPs exist among 13 out of 21 countries (**Table 3**).

Conclusions

There is a lot of **heterogeneity in Europe** and 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.

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