Case studies: the dispensing of veterinary drugs in Switzerland, Austria, Germany, France and the United Kingdom

General dispensing policies

Distribution categories are defined for veterinary drugs according to the risk they represent both for animals and consumers if used incorrectly. In all four EU countries, all veterinary drugs for livestock require a prescription, whereas Switzerland has not adopted this EU requirement yet. In Austria, Germany and France, a clinical assessment of the animal(s) by a veterinarian is required. In Switzerland and the UK, this is only the case for certain drugs. It is generally only permitted to dispense the minimal amount of medicine needed for one treatment, Austria and especially Germany have stricter rules.

The medicines are usually prescribed by a veterinarian and may be distributed to the end user only by veterinarians, or, seldom, pharmacies. However, in an innovative interpretation of the EU's general prescription requirement, the UK has defined an additional category of actors that are allowed to both prescribe and dispense veterinary drugs. In France, agricultural producers' associations may, under certain circumstances, also dispense a clearly defined category of drugs to their members. Internet retail of prescription drug is only legal in the UK. Switzerland, Austria and France allow a loosening of dispensing rules if there is a written agreement between the veterinarian and the livestock holder, bound to clearly defined conditions. Furthermore, there are specific rules defining the procedure in cases when no suitable medicine is available in a country. All countries also know the possibility of in-house production of veterinary drugs according to a prescription (formula magistralis) or to a pharmacopoeia (formula oficinalis). Nonetheless, only in France and in the UK do veterinarians have the right do to so equally as pharmacies.

Medicated feedstuffs

Medicated feedstuffs are a mixture of a veterinary drug with feed, through which it is applied. The blending of the premixture into the feed is regarded as “fabrication” of a veterinary medicine and regulated in a separate set of Medicated Feed and Feedstuffs Directives. Medicated feedstuffs are fabricated either by industrial manufacturers of feedstuffs (feed mills), or under certain conditions by the livestock owners themselves on the farm (on farm manufacturing, OFM). They can only be dispensed by authorized feed mills.

In all countries under examination, medicated feedstuffs require a prescription by a veterinarian on a standardized form. The amount of medicated feedstuffs that may be dispensed is restricted in EU law to what is needed for one month of treatment. Germany is even more restrictive when it comes to antibiotics, whereas Switzerland has not established equivalence to the EU yet. OFM is legally prohibited in Germany and de facto impossible in France.

Ensuring traceability: documentation requirements

The documentation of the dispensing processes enables the authorities to control compliance with the regulations and to trace back the sources of animal diseases or contaminated end products across national borders.

In all countries, the basic indications about the dispensing process must be recorded by at least the dispensing actor. Some of Switzerland’s rules are still not equivalent with the EU, where prescriptions always have to be stored by the veterinarian and the dispensing actor. In

Switzerland this is not always the case and only for the dispensing actor.1 All prescriptions and the documentations of dispensing have to be kept for only three years, compared to five years in the EU. The prescriptions for medicated feedstuffs are kept at least by the feed mill or livestock owner. Switzerland and Germany have additional requirements.

Ensuring compliance: controls of dispensing

EU law prescribes frequent controls of the compliance with the dispensing rules. The further regulation and implementation of enforcement is left to the member states. We consider only comparable aspects of the national control arrangements, which can vary independently of the countries' politico-institutional organisation.

The dispensing actors are subject to official controls whose frequency differs remarkably between nations. All countries except Germany envisage more or less comprehensive additional inspections by different kinds of private institutions. The quality assurance systems of British retailers of food products provide an interesting example of self-regulation by the private sector.

In federal Germany, superintendence of the controls is the responsibility of the sixteen Länder, with varying organisational levels at which the controls are implemented. By contrast, the federal systems of Switzerland and of Austria centralize the responsibility for superintendence at the national level. The inspections are carried out by cantonal authorities in Switzerland, and by both regional and municipal authorities in Austria. Centralized Great Britain also assigns superintendence to one body at the national level, but the implementation to the local or regional level. In France as a unitarian state, there are myriads of inspectors by three national ministries and departmental authorities.

[1] If the same veterinarian prescribes and dispenses a drug, no prescription has to be issued.

Table A: Selection criteria for non-EU member countries

European non-EU member country	*Democratically stable and peaceful since Maastricht treaty in 1993*[1]	*Value added to GDP by agriculture in per cent s within the range of 1 (UK) and 4.7 (France)* [2]	*Trade surplus for fishery products*[3]
Switzerland	Yes	Yes (1.6)	No
Norway	Yes	Yes (2.1)	Yes
Moldova	Relatively	No (29)	
Albania	No		
Belarus	No		
Bosnia	No		
Croatia	No		
Kosovo	No		
Macedonia	No		
Montenegro	No		
Serbia	No		
Ukraine	No		

Notes: GDP = Gross domestic product. EU = European Union. UK = United Kingdom.

European countries according to United Nations with non-EU membership by 2010. Does not include the very weakly populated countries of Iceland and Liechtenstein.

[1]Not given if periods of non-democratically elected leadership or significant internal or external conflicts involving armed violence have occurred.

[2]Sources: Switzerland: http://de.statista.com. Other countries: World Development Indicators. Reference year: 2000.

[3]Source: Switzerland: Federal Statistical Office. Norway: Eurostat. Fishery statistics. Data 1990-2006. Reference year: 2000.

Table B: Operationalisation and description of the regulation of the dispensing of veterinary drugs for livestock

Indicator	*Switzerland*	*European Union*	*Austria*	*Germany*	*France*	*United Kingdom*
Regulation of dispensing of VMPs						
Distribution categories of VMPs	Prescription drug Prescription drug, no repeated dispensing OTC drug Drug requiring documentation	Prescription drug OTC drug Directive 2001/82/EC	Prescription drug Prescription drug, no repeated dispensing OTC drug NE, TGD, TGD/NE, TGD-AB	Prescription drug OTC drug Pharmacy only drug General sale drug	Prescription drug Prescription drug, repeated dispensing possible OTC drug Drug released for dispensing in GDS or GPA	Prescription drug: POM-V and POM-VPS OTC drug: AVM-GSL CD Schedules 1-5
Actors authorized to prescribe VMPs	Veterinarians	X	Veterinarians	Veterinarians	Veterinarians	Veterinarians Pharmacies SQPs
*Actors authorized to dispense VMPs**	Veterinarians Pharmacies Minor exceptions	Duty for authorisation and registration by responsible authorities Directive 2001/82/EC	Veterinarians Pharmacies	Veterinarians Pharmacies	Veterinarians Pharmacies GDSs and GPAs	Veterinarians Pharmacies SQPs
Written agreements between veterinarian and livestock holder	Yes	X	Yes	No	Yes	No
General prescription requirement	No	Yes Commission Directive 2006/130/EC	Yes	Yes	Yes	Yes
Clinical assessment requirement	For drugs requiring documentation	X*	Yes	Yes	Yes	For POM-V drugs
*Amount of prescription drug to be dispensed**	Amount needed for 1 treatment	Minimal amount needed for treatment Directive 2001/82/EC	Maximum is amount needed for 1 month of treatment	Maximum is amount needed for 1 month of treatment Antibiotics: amount needed for 7 days of treatment	Amount needed for 1 treatment	Amount needed for 1 treatment
Exemptions from the requirement of authorisation for the respective species and indication in case of supply shortfalls	Identical to European Cascade rule	European Cascade ruleDirective 2001/82/EC	European Cascade rule	European Cascade rule	European Cascade rule	European Cascade rule
Possibilities of in-house production (formulae oficinalis and magistralis)	Yes	X	Yes	Yes	Yes	Yes
Veterinarians	No	X	Only	Only	Yes	Yes

*authorized for in-house production**			homeopathic drugs	homeopathic drugs and mixing of substances under exceptional circumstances		
Mail order dispensing (mail, internet) allowed?	No Exemptions require authorisation	X	No Very minor exemptions	No	No Very minor exemptions	Yes
Regulation of dispensing of MFS						
Prescription requirement for MFS	Yes	Yes Council Directive 90/167/EEC	Yes	Yes	Yes	Yes
Prescription form containing indications prescribed by EU	Yes	Yes Council Directive 90/167/EEC	Yes	Yes	Yes	Yes
Actors allowed to fabricate and dispense MFS	Authorized feed mills Livestock owners (requires supervision by a veterinarian)	Authorized feed mills Livestock owners Council Directive 90/167/EEC	Authorized feed mills Livestock owners (strict qualification requirements)	Authorized feed mills	Authorized feed mills Livestock owners (requirements too strict to be fulfilled in practice)	Authorized feed mills Livestock owners (requires supervision by "qualified person")
Amount of MFS to be dispensed	Amount needed for 1 treatment	Amount needed for 1 month of treatment Council Directive 90/167/EEC	Amount needed for 1 month of treatment	Amount needed for 1 month of treatment Antibiotics: amount needed for 7 days of treatment	Amount needed for 1 month of treatment	Amount needed for 1 month of treatment
Documentation requirements for dispensing						
*Storage of prescription required?**	Rarely	Always Directive 2001/82/EC	Always	Always	Always	Always
*Storage of prescription: minimum duration**	3 years	5 years Directive 2001/82/EC	5 years	5 years	5 years	5 years
*Storage of prescription by**	Dispensing actor, if not simultaneously prescribing actor	Veterinarian Dispensing actor Directive 2001/82/EC	Veterinarian Dispensing actor Livestock owner	Veterinarian Dispensing actor Livestock owner	Veterinarian Dispensing actor Livestock owner	Prescribing actor Livestock owner
Storage of MFS prescription required?	Always	Always Council Directive 90/167/EEC	Always	Always	Always	Always
Storage of MFS prescription: minimum duration	3 years	3 years Council Directive 90/167/EEC	5 years	5 years	5 years	5 years
Storage of MFS prescription by	Producer Livestock owner Veterinarian Official veterinarian	Producer Council Directive 90/167/EEC	Producer	Producer Responsible authority	Producer	Producer
Documentation of dispensing required by	Dispensing actor End user	Dispensing actor Directive 2001/82/EC	Dispensing actor	Veterinarian	Dispensing actor	Dispensing actor Livestock owner

Documentation of dispensing: minimum duration of storage	3 years	5 years Directive 2001/82/EC	5 years	5 years	5 years	5 years
Controls of dispensing*						
Who is controlled	Veterinarians' dispensaries Pharmacies Other dispensing actors	X	Veterinarians' dispensaries Pharmacies	Veterinarians' dispensaries Pharmacies Other dispensing actors	Veterinarians' dispensaries Pharmacies	Veterinarians' dispensaries Pharmacies Other dispensing actors
Minimum frequency of inspections	5 years	X	5 years	2 years	Random Very frequently	4 years
Superintendence for controls: organisational level and number of responsible authorities	National 1	X	National 1	Regional 16	National 3	National 1
Organisational level of implementation of controls	Regional	X	Regional and local	Differing according to region	Regional	Regional and local
Additional controls by Non-official instances legally designated	Some	X	Comprehensive	None	Some	None But: private quality assurance system
Compliance with regulations regarding documentation and other aspects of dispensing must be frequently controlled by officials	Yes	Yes Directive 2001/82/EC	Yes	Yes	Yes	Yes

Source: Sager et al. 2011. VMP = Veterinary medicinal product EU = European Union
SQP = Suitably qualified person MFS = Medicated feedstuffs
OTC = over-the-counter (no prescription required)
*Except for MFS X = not regulated by EU law

Distribution categories

Austria:
NE = Abgabemöglichkeit nicht eingeschränkt
TGD = Abgabe im Rahmen eines Tiergesundheitsdienstes
TGD/NE = Zur Herstellung von FüAM nur im Rahmen des TGD erlaubt; Zur sonstigen peroralen Anwendung nicht eingeschränkt
TGD-AB = Abgabe ist im Rahmen des TGD nur auf Basis besonderer veterinärmedizinischer Erfordernisse gestattet und der Einsatz ist durch geeignete objektivierbare diagnostische Massnahmen zu rechtfertigen

France:
GDS = Groupements de Défense Sanitaire
GPA = Groupements de producteurs agréés

United Kingdom:
AVM-GSL = authorized veterinary medicine – general sales list
CD = controlled drug
POM-V = prescription only medicine – veterinarian
POM-VPS = prescription only medicine – veterinarian, pharmacist or suitably qualified person

Table C: Analysis of similarity of veterinary drugs regulations between countries

Indicato	*CH-AU*	*CH-GE*	*CH-FR*	*CH-UK*	*AU-GE*	*AU-FR*	*AU-UK*	*GE-FR*	*GE-UK*	*FR-UK*
Regulation of dispensing of VMPs										
Actors authorized to prescribe VMPs	Yes	Yes	Yes	Partly	Yes	Yes	Partly	Yes	Partly	Partly
Written agreements between veterinarian and livestock holder	Yes	No	Yes	No	No	Yes	No	No	Yes	No
Clinical assessment requirement	Partly	Partly	Partly	Partly	Yes	Yes	Partly	Yes	Partly	Partly
Possibilities of in-house production (formulae oficinalis and magistralis)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
*Veterinarians authorized for in-house production**	No	No	No	No	Yes	Partly	Partly	Partly	Partly	Yes
Mail order dispensing (mail, internet) allowed?	Partly	Partly	Partly	No	Partly	Yes	No	Partly	No	No
Distribution categories of VMPs	Partly	Partly	Partly	Partly	Partly	Partly	Partly	Partly	Partly	Partly
*Actors authorized to dispense VMPs**	Partly	Partly	Partly	Partly	Yes	Partly	Partly	Partly	Partly	Partly
General prescription requirement	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
*Amount of prescription drug to be dispensed**	No	No	Yes	Yes	Partly	No	No	No	No	Yes
Exemptions from the requirement of authorisation for the respective species and indication in case of supply shortfalls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Regulation of dispensing of MFS										
Prescription requirement for MFS	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Prescription form containing indications prescribed by EU	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Actors allowed to fabricate and dispense MFS	Partly	No	Partly	Partly	No	No	Partly	Partly	No	Partly
Amount of MFS to be dispensed	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Documentation requirements for dispensing										
*Storage of prescription required?**	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
*Storage of prescription: minimum duration**	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
*Storage of prescription by**	Partly	Partly	Partly	Partly	Yes	Yes	Partly	Yes	Partly	Partly
Storage of MFS prescription required?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Storage of MFS prescription: minimum duration	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Storage of MFS prescription by	Partly	Partly	Partly	Partly	Partly	Yes	Yes	Partly	Partly	Yes
Documentation of dispensing required by	Partly	Partly	Partly	Partly	Partly	Yes	Partly	Partly	Partly	Partly
Documentation of dispensing: minimum duration of storage	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Controls of dispensing*										
Who is controlled	Partly	Yes	Partly	Yes	Partly	Yes	Partly	Partly	Yes	Partly
Minimum frequency of inspections	Yes	No	No	No	No	No	No	No	No	No
Superintendence for controls: organisational level and number of responsible authorities	Yes	No	Partly	Yes	No	Partly	Yes	No	No	Partly
Organisational level of implementation of controls	Partly	Partly	Yes	Partly	Partly	Partly	Yes	Partly	Partly	Partly
Additional controls by Non-official instances legally designated	Partly	No	Yes	No	No	Partly	No	No	Yes	No
Compliance with regulations regarding documentation and other aspects of dispensing must be frequently controlled by officials	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

CH = Switzerland AU = Austria GE = Germany FR = France
UK = United Kingdom VMP = Veterinary medicinal product EU = European Union
MFS = Medicated feedstuffs
*Except for MFS