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*Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne*

**PGEU Position Paper on
Proposal for a Regulation on
Veterinary Medicinal
Products**



Introduction

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 34 European countries. In Europe over 400.000 community pharmacists provide services through a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.

PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.

Community pharmacies distribute veterinary medicines in all EU Member States. While national legislation often allows pharmacies to distribute a wide range of veterinary medicines, in practice most community pharmacies focus on medicines for companion animals, including prescription medicines such as antibiotics or vaccines and non-prescription medicines such as anti-parasitic drugs or repellents. In some Member States, such as Belgium and Ireland, rural pharmacies also dispense a broad range of veterinary medicines for food producing animals. In countries where the prescribing and the dispensing of veterinary medicines is separate, such as Denmark and Sweden, a high proportion of veterinary medicines are dispensed in pharmacies.

General Remarks

PGEU welcomes the Commission proposal on veterinary medicinal products. In particular we welcome the measures aimed at tackling antibiotic resistance, given the need to ensure rational use of antimicrobials in the veterinary sector.

We note that the Commission has included a number of proposals with the aim of regulating the retail dispensing of veterinary medicines. We note also that the proposal develops principles set out originally in the Patients' Rights Directive¹ and the Falsified Medicines Directive², with respect to the recognition of prescriptions and the Common Logo, but in some respects goes beyond the measures put in place by these Directives, and extends the reach of European regulation. Moreover, key additional controls included in those Directives have not been included in the current proposal.

As a general principle, we question whether an appropriate balance has been achieved between the discretion of Member States to regulate retail activity as they see fit within the parameters of the Internal Market, and the legitimate scope of European legislation.

We have specific concerns in respect of the following provisions:

- 1. Internet sale of medicines:** The proposed legislation aims at removing existing restrictions on the internet sale of prescription medication. We believe that this is inappropriate and represents a possible threat to public health.
- 2. Record keeping obligations** when supplying non-prescription veterinary medicinal products. We believe that this obligation may impose an unnecessary burden on community pharmacies and the proportionality of the measure will need to be assessed at national level.

¹ DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare

² DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products



3. **Recognition of prescriptions issued for human medicines prescribed for veterinarian purposes:** We believe this possibility needs to be limited to avoid cross border veterinary prescription abuse.
 4. **Special licence for certain medicines:** The supply or purchase of certain medicines by pharmacists must not be subject to an additional licence.
 5. **Manufacturing Authorisation Exception:** All retailers of veterinary medicinal products are excluded from a manufacturing authorisation when preparing a veterinary medicinal product. We believe that this exception should be revised and limited to suppliers who have the necessary qualification and equipment
1. **Internet Sale of Veterinary Medicinal Products (Article 108)**

1.1. National rules

Under the proposal, retailers authorised under national law to supply veterinary medicinal products will also be allowed to offer veterinary medicinal products at a distance as long as those medicinal products comply with the legislation of the destination Member State.

This measure would apply to both prescription and non-prescription veterinary medicinal products. The proposal recognises that Member States may impose conditions on the internet sale on their territory which are justified in the public interest. However, since sale through the internet of prescription medicines is widely prohibited, the measure necessarily entails that many Member States would have to remove restrictions, particularly on prescription sale.

In addition, Article 108(1) states that the medical products must comply with the legislation of the country of destination. It is not clear that this provision includes rules as to distribution of products from non-pharmacy outlets. However, some Member states, exercising their discretion established under EU case law, require all non-prescription products to be distributed by pharmacies. Even if the Commission is successful in liberalising internet sale, it has no scope under EU law to override restrictions put in place by Member States on legitimate public health grounds.

No proper assessment of impact of liberalisation

The Impact Assessment for this measure incorrectly states that 'Rulings of the European Court of Justice oblige Member States to allow online sales'. This is only partially accurate, since the same rulings referred to explicitly recognise that Member States may prohibit online sale of *prescription* medicines. The proposal would require the removal of this discretion.

The Impact Assessment bases its case on alleged increases in access (although it presents no evidence of access problems) and price reductions, which it claims will lead to 'better treatment compliance', although it gives no evidence for this and cites no studies making this claim. The Impact Assessment itself admits that is unable to quantify any financial benefits from the measure. But, most notably, it completely fails to assess any negative impacts in terms of costs arising from either increased availability of falsified medicines or possible public health problems arising from uncontrolled distributions. This is a significant omission.

It is true that the proposal also requires the use of a Common Logo for internet sales, a measure borrowed from the Falsified Medicines Directive. As the Common Logo for human internet sales has yet to be fully implemented in Member States, its effectiveness in preventing illegal sales is as yet unproven. Nonetheless, even on narrow financial grounds, the cost of monitoring and administering the Common

Logo may be significant, but again the Impact Assessment admits that it cannot calculate such costs. There is little doubt, however, that more legal internet sale is also correlated with more illegal internet sale, and that can only mean more falsified medicines and more abuse. To repeat, the Impact Assessment makes no attempt to calculate these costs.

1.2. Public Health Consequences

Internet sales *can* have negative consequences for human health.

If medicinal products are consumed unnecessarily or incorrectly, they may cause serious harm. The European Court of Justice (the Court) has recognised the very particular nature of medicinal products whose therapeutic effects and potential dangers distinguish them from other goods. In addition the Court has recognised in the Doc Morris ruling³ – dealing with the distribution of human medicines – that controls on the supply of prescription medicines are justified in view of the risks which prescription medicines in particular may present (although, of course, non-prescription medicines are also potentially harmful).

The Court has also stated that in the light of public health risks Member States may put conditions on the way medicinal products are distributed⁴. Additionally, the Falsified Medicines Directive makes clear that Member States can prohibit the internet selling of prescription medicines. We believe that animal health deserves the same consideration and level of protection as human health.

But this is not simply a question of animal health, important as that is. To take one example, antibiotics are widely used in the veterinary sector (as the proposal itself recognises). Some argue that there are already insufficient controls on the dispensing of antibiotics for veterinary purposes. But internet sale necessarily reduces the degree of control on the dispensing of antibiotics, not just because, as we point out above, reducing restrictions on *legal* sale tends to give rise to more *illegal* sale, but also because evidence from the sale of human medicines shows that some – legitimate – internet sellers will use all means possible to avoid prescription control, for example by the use of so called 'online consultations'. Given that there is already no separation between prescribing and dispensing in many countries for veterinary medicines, the scope for abuse is real and substantial. None of these issues feature in the Impact Assessment. Indeed, the proposed liberalisation of internet sale undermines the sensible approach to the control of antimicrobials evident elsewhere in the proposal.

Additionally there is a risk of human misuse of some veterinary medicines. As an example, in France the distribution of Clenbuterol (Prescription Only Medicine) is highly controlled - Clenbuterol is available only for highly controlled veterinary use for horses or cattle. Clenbuterol is frequently misused for purposes of performance-enhancement and weight loss in humans. In countries where it is not available for human use, misusers are known to buy it over the Internet. Widening the legal or seemingly legal online offer, with very poor possibilities of control, will widen the scope for abuse.

The Court has acknowledged that it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved⁵. We believe that this principle should be respected.

³ Case C-322/01 Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval

⁴ Cases C-171/07 and C- 172/07 Apothekerkammer des Saarlandes and Others v Saarland

⁵ Cases C-171/07 and C- 172/07 Apothekerkammer des Saarlandes and Others v Saarland



We would argue that forcing Member States to remove restrictions on internet sale can only be appropriate if we accept that no Member State can legitimately take the view that internet sale of prescription veterinary medicines can ever in any circumstances pose a threat to health, animal or human. That is simply not a realistic position.

Therefore we call to include in the proposal a right for Member States to prohibit the sale at a distance of prescription veterinary medicinal products.

1.3. Legislation on veterinary medicines should include similar protection as that for human medicines

When comparing the two sets of provisions on Internet sales, there are some regrettable differences. For example, the Falsified Medicines Directive proposes strong conditions for control and access to internet sellers of medicines, such as obligations to notify authorities, national registries. The FMD has more clarity with regard to the applicable rules in the country of destination.

We believe that the provisions of the human medicines legislation should be reflected in the veterinary proposal.

1.4. Need for additional license

Finally, the proposal states that any authorised retailers of veterinary medical products may sell online (Article 108). However, in some Member States where online sale is permitted (such as Germany), an additional license is required for online sale. This facilitates supervision of sale, and should be permissible for Member States.

We call for the removal of the requirement that Member States must permit online sale of prescription veterinary medicines

2. Record Keeping of Retail Veterinary Medicines (Article 107)

Retailers, and hence pharmacists distributing veterinary products, will need to keep record of each purchase. There are two important new provisions as regards the need to keep records by retailers in the provision on retail of veterinary medicinal products: (1) records will need to be kept for all veterinary medicinal products [In the previous Directive those records were only requested for veterinary medicinal products subject to prescription]; (2) there is a new obligation to store data on the prescribing vet and also a copy of the prescription for particular veterinary medicinal products such as antibiotics [in the previous Directive this requirement was requested only when relevant].

We welcome the idea of further record keeping for certain veterinary medicinal products and in particular for antibiotics. However we believe that keeping records of non-prescription veterinary medical products may be disproportionate in terms of time and administration and may not be justified on public health grounds. The potential impact of this measure is not considered in the Impact Assessment. We believe that in this case Member States are better positioned to decide whether non-prescription veterinary medicines distribution need to be recorded, and as a consequence this measure should be optional for Member States.

We call for the right of Member States to decide whether to require the keeping of records on the supply of non-prescription medicines



3. Recognition of Veterinarian Prescriptions (Article 110)

The proposal establishes a standard prescription for veterinary medicinal products that must be recognisable through the Union.

We welcome the principle of the recognition of prescriptions. This recognition could facilitate in some cases the mobility of animals and animal owners.

However we have strong concerns as regards the recognition of veterinarian prescription of human medicines issued for veterinary purposes. The proposal establishes that human medicines can be used for treating animals in exceptional circumstances and under the direct responsibility of the veterinarian responsible when there is no veterinary medicinal product available. Therefore community pharmacists may be faced with a veterinary prescription for a human medicinal product which was issued in another Member State. In the cross border context the situation gets complicated. For instance, it will be difficult for the pharmacists to verify the exceptional character of the prescription and the identity of the veterinarian. Furthermore sedation drugs (hypnotics, anxiolytics etc.) used in pets are mostly human medicinal products. These are a clear target for individuals to wish to 'game' the recognition system to obtain medicines for their own use.

Therefore we call for derogation for the recognition of veterinary prescriptions issued to cover human medicinal products in the cross border context.

In addition, we believe that following the example settle in the Patients` Rights Directive⁶, the right to refuse the recognition of a veterinarian prescription on professional or ethical grounds should be clearly stated in the core text of the Regulation, not only the recitals as is the case in the proposal.⁷

We call for a provision in the core text establishing the right to refuse to dispense a prescription when this is justified on professional or ethical grounds.

4. Special licence for certain medicines (Article 109)

This Article proposes that manufacturers, wholesaler's distributors and retailers must be *specifically* authorised to supply and purchase veterinary medicinal products which have anabolic, anti-infectious, anti- parasitic, anti-inflammatory, hormonal or psychotropic proprieties. Licensed pharmacies should be exempt from this requirement, since the right of pharmacists to dispense medication of this nature is recognised in all European countries. It would be absurd if pharmacists were able to dispense these kinds of medication for humans under the normal pharmacy license, but need a specific license for veterinary products.

⁶ DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare

⁷ Recital number 62



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We call for the removal of the need for special licences for pharmacies when supplying and purchasing certain medicines

5. Manufacturing authorisation' exception (Article 91)

According to the proposal retailers do not need a manufacturing authorisation for the preparation, dividing up, changes in the packages or presentation of the veterinarian medical products. The current Directive only excludes pharmacies from the need to get manufacturing authorisation for the purposes of preparation a medical products in a pharmacy in accordance with a prescription (magisterial formula or officinal formula). The current regime follows a practice established in most Member States where pharmacists prepare medicines on demand following veterinarian instructions or processes established in the pharmacopeia. These medicines are always prepared for individual animals or a small groups of animals or are supplied to the end user. Taking into account that typically retailers which are not pharmacies do not have the necessary qualification and equipment to prepare those medicine, we would like to see this exception again limited to pharmacies

We call for the reintroduction of the provision in the current Directive and for the exclusion of only pharmacies from the need to get a manufacturing authorisation for the purposes of preparation of a veterinary medicine

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