GOVERNMENT OF MALTA

Government response to the Consultation on draft Legal Notice on Veterinary Medicinal Products (Amendment No 4) Regulations 2020

02/09/2020

Ministry for the for Agriculture, Fisheries and Animal Rights

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Executive Summary

Introduction and overview

1. The Legal Notice intends to address unregulated areas in the retail, distribution, manufacture and use of veterinary medicinal products (VMPs). The thorough regulation of these areas is deemed as important to honour the commitments that Malta has with EU/International institutions that have the collective aim of safeguarding animal and human health. The changes allow Malta to regulate and control better veterinary medicinal products, including antimicrobials. Malta can therefore meet the objectives of the National '*Strategy and Action Plan for the Prevention and Containment of Antimicrobial Resistance (AMR) in Malta 2020 - 2028*

The changes are aimed also at creating a level playing field for businesses in this area while increasing predictability and certainty. This will provide the right and fair environment for industry and related professions to flourish.

2. The public consultation date was 31-07-2020

On 31 July 2020 the Government published a consultation paper setting our proposals for a Legal Notice that intends to address unregulated areas in the retail, distribution, manufacture and use of veterinary medicinal products. The objective was to receive comments from the widest possible range of persons who might be affected and have diverse or even competing direct/indirect interest in it. In this way the Department would have a clearer picture of the needs and expectations of each party.

3. This consultation sought views on all the Legal Notice, particularly on any issues that may contribute to the fight against the rising threats of antimicrobial resistance.

Responses to the consultation and process used to seek stakeholder views

This document is the Government Response to this consultation and sets out the Government's decisions on these matters.

4. The consultation closed on 14th August 2020. Respodents were invited to provide feedback through a 'Feedback Form' available from the Public Consultation website https://meae.gov.mt/en/Public_Consultations/MAFA/Pages/Consultations/PublicconsultationondraftLegalNoticeonVeterinaryMedicinalProductsAmendmentNo4Regulations2020.aspx

A URL to the Public Consultation website was also made available from the Animal Health and Welfare Department (AHWD) 's website. https://agrifish.gov.mt/en/nvl/Pages/home.aspx

Once sent the 'Feedback Form' was received to an AHWD generic e-mail. Feedback received through e-mail of the responsible person of the AHWD entasked with the legislation was also accepted. In total, there were 23 responses. These were received from across the industry including veterinary surgeons, pharmacists, public authorities, organisations and animal keepers(individuals).

5. Include (if any) meetings with stakeholders and list who the stakeholders were.

Three meetings were held before the consultation period. One was with the Veterinary Surgeon Council on the 11th June 2020, another with the Pharmacy Council on 19th June 2020 and the third meeting with Malta Enterprise on the 19-08-2020 A meeting is planned to be held with one organisation on their request Koperattiva Produtturi tal-Halib (KPH) on their first available date.

Summary of responses and decisions

The following is a summary of the consultation responses received. We would like to thank all those who took the time to respond to the consultation and participate in stakeholder meetings around the consultation exercise.

6. Statistics.

- Total feedback received: 23
- Total feedback received by individuals: 13
- Total feedback received by organisations: 10
- Total feedback received through email: 2
- Total feedback received through online form: 21
- Total feedback received by post: 0

7. Summary of feedback received.

The respodents were not opposed to the Government's proposal. However, the majority raised some points regarding certain parts of the Legal Notice. The opposing comments by the individuals were particularly prominent in the requirement for an Animal Health Plan under the responsibility of a veterinary surgeon for every registered farm or licenced place where animals are kept for display to the public or for breeding purposes. Most of the respondents acknowledged that controls are necessary but disagreed particularly on applying the requirement for those places where very few animals are kept. Another comment was to express disagreement with the possibility for veterinary surgeons to dispense veterinary medicinal products (VMPs) and medicinal products for human use. This point was raised in 3 feedbacks provided by organisations related with medicinal products for human use (Pharmacy Council, Medicines Authority, Malta Chamber of Pharmacists) and 3 individuals. The Pharmacy Council and Malta Chamber of Pharmacists disagreed with VMP on General Sales List while the Medicines Authority queried its introduction. Other points raised were

about the proposed amendments in the authorisation of VMPs. The comments focus on Regulation 7, 10 and 11.

8. Your assessment and the Government's decision.

In view of the comments received and taking in consideration the main aims of the Legal Notice in the context of the local situation, the importance of the amendments of this Legal Notice was reinforced. There was however a need to improve the text further, and in some cases make further amendments in the regulations. In view of the opinions received during the the consultation exercise, the Government has decided to take the decisions as summarised below:

- Changes were made in Regulation 79 to address the concerns regarding places where few animals are kept. We have amended the Regulation so that those establishments of food producing animals that are excluded from official controls by the veterinary services shall also be excluded from this regulation. The requirements related to animal health control programmes may be further detailed in the Government Gazzette by the Veterinary Services as stipulated in the same regulation.

- Some of the comments received by the organisations were related to the dispensing of medicinal products for human use. It is to be noted that this proposed Legal Notice will not regulate medicinal products for human use as these are regulated under Chapter 458, The Medicines Act. The proposed LN regulates only Veterinary Medicinal Product for use in animals. These comments were not relevant.

- After consultation with concerned organisations (as per point 5), and considering that 24 out of 31 European countries permit the dispensing of the VMPs by veterinary surgeons, we are convinced that the proposed Legal Notice achieves the right balance between the prescribing and dispensing of VMPs by veterinary surgeons, by imposing certain restrictions mentioned in the regulations. Both the current Directive 2001/82 and the new EU regulation (that will come into force in January 2022), do not forbid the dispensing of VMPs by veterinary surgeons.
  Moreover, in the veterinary sector there is no form of roster whereby named pharmacies are obliged to open on Sundays and public holidays. This creates VMPs availability issues which may give rise to animal welfare issues. Under Chapter 437, veterinary establishments are obliged to provide 24/7 emergency cover, including public holidays.

- Some of the comments received by the organisations were related to the dispensing of the General Sales List. This needs to be left in place as otherwise the Veterinary Services could not exempt sale of certain items which definitely do not need a veterinary prescription, such as collars and certain antihelminthics. It is to be noted that to date there is no control on the sale and distibution of these products and thus this Legal Notice is enhancing controls, by setting out the General Sales List.

- A number of modifications were made in the regulations related with the authorisation of VMPs, mainly in Regulation 7, 10 and 11. The intention of many of these modifications was to clarify the text and reduce any percieved confusion.

- To further address a number of concerns, transitional periods were added in 3 instances. These shall apply to the following regulations:

- Regulation 79(3) (Requirement for a Health Plan in all establishments were animals are kept) These will come into force 2 years from publication of the LN . This will allow the industry to adjust to the new requirements.

- Regulation 4(2)(11) (Exemption from Marketing Authorisation rules in line with Regulation 4(2)). These will come in force as from 1st November 2021, to be in line with the new Regulation 2019/6 which will come into force on the 28th January 2022.

- Regulation 28(15) (Exemption for retailers from keeping records of company name and permanent address or registered place of business of the supplier in the event of purchase, or of the recipient in the event of sale until 31-10-21). This will approximately coincide with the coming into force the EU Regulation 2019/6 on 28-01-2022.

Implementation

9. When you intend to implement the decisions

Subject to the necessary approvals, we intend to implement our decision on the 15th October 2020 with the aim of the amendments coming into force by end of 2020.

Contact Details

If you have any questions regarding this response, please contact veterinarymedicine@gov.mt