EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2023
EMA/CVMP/855384/2022
Committee for Veterinary Medicinal Products (CVMP)

Overview of comments received on CVMP guideline on NVR Art 34 for the classification of VMPs (EMA/CVMP/273040/2022)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	Access VetMed
2	AnimalhealthEurope
3	Dogs Trust
4	German Pharmaceutical Industry Association (BPI)
5	Federation of Veterinarians of Europe (FVE)
6	Société Nationale des Groupements Techniques Vétérinaires
7	The Norwegian Medicines Agency (NoMA)
8	Dr. Filippo Bosi - Brisighella RA
9	ASEMAZ-ASA (Asociación Para La Salud Animal)

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1. General comments – overview

Stakeholder no.	General comment (if any)	Outcome (if applicable)
2	AnimalhealthEurope thanks the CVMP for this important Guideline and is grateful for the opportunity to comment. Please find some comments below. Should you have further questions, AnimalhealthEurope is happy to provide any clarification needed.	Noted.
	The format adopted for this GL is appreciated – having the actual text from the legislation to which the GL applies helps the reader to quickly and more easily review and understand the guidance being presented. While the GL text may be longer, this format reduces the effort required to make full use of the GL.	Noted.
	In general, the approach of Article 34 and this GL assumes that "subject to prescription" makes a product safer or at least, is a means to improve compliance with the SPC. This seems to be mainly because of the assumption that veterinarians will have and/or take time to provide detailed explanations and information about the product to their customers. This may not always be the case. Even in the human domain, product leaflets are not checked very frequently by healthcare professionals, so communication of relevant recent updates may fail. Ideally, direct communication with the help of product information can be even more effective, regardless of the prescription status. We suggest that consideration be given to addressing this aspect in this GL – i.e., VMP subject to prescription status is not the only way to ensure safe and compliant use of VMPs. Further, if subject to prescription does not make a difference compared to the alternative (for example pharmacy only) in relation to a specific warning, authorities should be enabled to classify them as non-prescription.	It is acknowledged that the prescription only status is not the only way to communicate risks to the final user or to improve compliance with the SPC. Nevertheless, this is a reflection that does not fit into the scope of the GL, as it only intends to enable a consistent implementation of Article 34 of Regulation (EU) 2019/6 and not to deal with issues such as risk communication. No changes are made.

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	AnimalhealthEurope acknowledges that the scope of this guidance focuses on scientific criteria and does not elaborate on considerations regarding harmonisation of prescription status for VMPs that are not authorised in the centralised procedure. It is important for marketing authorisation holders to uphold the possibility for different classifications in different countries for the same product authorised in the MRP/DCP/SRP procedure provided that this is supported by adequate justifications in line with this proposed guideline. Clarification over this matter could be detailed in a CMDv guidance document if not relevant in this proposed guideline. AnimalhealthEurope notes that this guideline focuses on risks to the health of animals, users, the public or the environment. There is no reference to the expected benefits of non-prescription status which is an important aspect for authorising new non-prescription products and also avoiding restricting current practices. It is proposed to add a section to this effect in the proposed guideline, for instance in the introduction. In all cases, the benefits expected from the non-prescription status should be carefully considered with respect to any risks. Benefits range from product availability to distribution organisations, which can differ from one country to another.	Noted. Noted. However, the CVMP considers the availability of VMPs in the market (always desired) and the accessibility of these VMPs to the users to be two different aspects. A non-prescription classification will increase the accessibility of the VMP to the general public. As mentioned in the draft GL, the prescription status is an outcome of the product assessment and should, therefore, be based on the information provided in the dossier. No changes are made.
4	The BPI representing more than 270 members, comprises the whole spectrum of the pharmaceutical industry, ranging from multinational corporations to SMEs, Mid-Caps as well as startups. These companies ensure timely and safe supply of medicinal products for human and veterinary use in the EU and globally. BPI very much appreciates the possibility to comment on the present Draft of the Guideline on the application of Art. 34 of Regulation (EU) 2019/6 ('Draft Guideline'). BPI welcomes the fact	Noted.

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	that the Draft Guideline does not intend to elaborate on harmonisation of the prescription status of veterinary medicinal products ('VPMs') not authorised through the centralised procedure. The Draft Guideline wisely distinguishes in lines 59-65 between the envisaged harmonisation of the prescription status of VMPs authorised through the centralised procedure and the VMPs authorised through national/decentralised procedures in the Member States. Thus, the Draft Guideline regarding the prescription status of VMPs pursues a balanced approach between harmonisation and regional needs for flexibility. However, for the sake of clarity some minor adaptations of the Draft Guideline would be appreciated in order not to jeopardise the market launch of new and the availability of existing VMPs in the Member States. The discretion granted to the competent authorities by Regulation (EU) 2019/6 in some points should be well reflected by the Draft Guideline.	Noted.
5	FVE welcomes the effort of CVMP to ensure a harmonised EU approach to classify veterinary medicinal products. Our main comment on this guideline is about the scope of this paper. On the description of the scope (point 2) we read that it is "***not within the scope*** *of this guideline to elaborate on considerations regarding harmonization of prescription status for veterinary medicinal products that* ***are not authorised through the centralized*** *procedure, or on the impact, if any, from the application of Article 34 of Regulation (EU) 2019/6 to veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004*." However, later in the text, the guideline suggests some recommendations relevant for nationally or via de-centralised procedure authorised products. We suggest reviewing	Noted. A consistency check has been performed and reference to national or decentralised procedures is found where (i) the legislation does mention them or (ii) where it is unavoidable to refer to them (e.g. under Art. 34[3][e] in the guideline). No changes are made.

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	the document to ensure clarity and consistency about the scope and focus of this advice.	
6	VMPs for bees: On line 326, you write that "Products for bees whose active substances are natural extracts are considered as commonly used without prescription". Does that mean that the other VMPs for bees must remain under veterinary prescription? Anti-varroa VMPs for bees are known to be dangerous for the environment, humans, and bees. For example, SPC of VMPs for bees whose active substance is amitraz or fluméthrine report an increased risk of developing resistance due to the misuse of the VMP (in French : « Une utilisation inappropriée du produit peut entraîner une augmentation du risque de développement de résistance et peut finalement résulter en une inefficacité du traitement. »). Should this mention of the SPC be considered in the interpretation of the article 34(3)(g) and lead to remain these VMPs under veterinary prescription? SPC of VMPs for bees whose active substance is amitraz report potential neurological adverse effects in humans (in French : « Ce médicament vétérinaire contient de l'amitraz, ce qui peut entraîner des effets indésirables neurologiques chez l'homme. »). SPC of VMPs for bees whose active substance is fluméthrine report that the active substance is toxic to fish and aquatic organisms (in French : « Le principe actif, la fluméthrine, est toxique pour les poissons et les organismes aquatiques. »). Should these mentions of the SPC be considered in the interpretation of the article 34(3)(b) and lead to remain these VMPs under veterinary prescription?	The concerns expressed are noted. However, text in line 326 has to be interpreted within the meaning of section 4.3.5., where a non-exhaustive list of VMPs that are currently considered as commonly used without prescription is provided. The word 'currently' has been included in the text to clarify this fact. It is important to note that, as provided for in section I.2.1. of the Annex II to Regulation (EU) 2019/6, a critical review of the product characteristics will in all cases be performed for applications proposing a "not subject to veterinary prescription" classification, taking into consideration target and non-target animal safety, public health as well as environmental safety. No changes are made.

Stakeholder no.	General comment (if any)	Outcome (if applicable)
7	It is acknowledged that it is not within the scope of the current guideline to *elaborate on considerations regarding harmonisation* of prescription status for veterinary medicinal products (VMPs) authorised through other procedures than the centralised. However, it is our understanding that it will be relevant for Member States to refer to this guideline when the prescription status for VMPs authorised through "non-centralised" (national) procedures are to be determined. Our comments are generally made to take this into account. Article 34(3) reads that the competent authority or Commission ***may*** classify a veterinary medicinal product (VMP) which falls under Article 34(19 points (b), (d), (f), or (g) as *not* subject to veterinary prescription if all conditions of 34(3) are met. It is therefore felt that the currently proposed schematic representation depicting the application of Article 34 (Figure 1) goes beyond the wording of the regulation as it in our opinion indicates that VMPs ***shall be/will have to be*** classified as not subject to veterinary prescription if the conditions in Article 34(3) are met. This is not in line with the NoMA's interpretation of the article. We do not consider that a Member State is obliged to classify a product listed in art 34(1) as 'not subject to veterinary prescription' if the conditions in art 34(3) are met, but consider that meeting the art 34(3) criteria is a prerequisite to allow for *the possible derogation* from the otherwise mandatory "subject to veterinary prescription" classification. For nationally authorised products, the competent authority may also take into account national legislation and considerations.	Noted. The proposed schematic representation aims to serve as a clear, user-friendly tool for the interpretation of Article 34. It provides the reasonably expected outcome for each of the possible scenarios foreseen in this Article. It is acknowledged that some minor changes might help to provide a more accurate picture. See response below (specific comment on lines 97-190; stakeholder 7).

Stakeholder no.	General comment (if any)	Outcome (if applicable)
	In our opinion, the wording of Regulation (EU) 2019/6 provides for some subsidiarity for Member States to decide on the prescription status classification – as did the wording of the Directives 2001/82/EC Article 67 and 2006/130/EC before. This subsidiarity is not reflected in the current draft guideline. Please consider our specific comments/proposals below.	
8	(…) However, it is acknowledged that for some provisions the guidance provided is general and a case-by-case approach will be needed. • I fully agree on the need to take into account case by case, in fact one should consider the peculiarities of some specific sectors, e.g. that of beekeeping, which differs considerably both from other livestock sectors and from the keeping of animals not intended for food production e.g. PET. • The peculiarities of beekeeping are many and originate first of all from the characteristics of the animal raised (defined as "super organism"), which is not comparable to other animals kept. • The context and nature of the condition to be treated should also be considered; I refer primarily to the infestation by Varroa destructor ("listed disease" according to EU Reg. 2016/429) whose spread is ubiquitous in EU countries (with the exception of few islands) and which constitutes a major public health problem. • Varroa destructor infestation can be controlled through coordinated territorial plans that are based above all on	It is acknowledged that the fight against notifiable diseases will require consideration of local and regional situations. It is also understood that bee farming has peculiarities that need to be taken into account when defining programs to fight against certain disease such as varroa infestation. Nevertheless, the legislation (not the guideline) clearly states that VMPs for food-producing animals may be exempted from requiring a veterinary prescription if all conditions listed in Art. 34(3) (a) to (h) are fulfilled. This guideline cannot deviate from the wording in the legislation and only intends to provide clear guidance where there is scope for it. No changes are made.

Stakeholder no.	General comment (if any)	Outcome (if applicable)
	periodic large-scale treatments, with veterinary medicines with acaricidal action. • The control by the single beekeeper would have no effect, unless it was included in a collective and almost synergistic control of the apiaries of a territory. • Without an adequate fight against varroa, there would also be consequences for agricultural production and biodiversity, which make use of the pronuba action ensured by honey bees. • The control plans, if they are not mandatory according to the individual national laws, are in any case a necessity and are based (at least in Italy) on the synergy between various components in the field, with wide dissemination of the control methods through the veterinary medicines available. • Annually, the Italian health authorities issue indications in this regard, also through specific guidelines for the control of varroa destructor infestation (IZSVenezie), which illustrate the medicines that can be used and their characteristics of use. • Further plans at local level then address the treatment periods, which vary according to the climatic and production characteristics. • These joint actions are the expression of the work of various professionals and find the support of producer organizations to inform beekeepers in a comprehensive manner, in order	

Stakeholder no.	General comment (if any)	Outcome (if applicable)
	to control both the health risk and that resulting from the use of veterinary medicines. • In Italy, veterinary medicines authorized for the treatment of varroa are currently all exempt from veterinary prescription (in the majority of other Member States the situation is similar). • Part of the costs for the purchase of antivarroa veterinary medicines is covered by public funds (EC Reg. 1308/2013 or others). • Although there is no large-scale data available, at least in Italy, it does not appear that the dispensing of these medicines without a veterinary prescription is at the basis of particular problems, whether for treated animals, people or the environment. • Probably the various actions to address and support beekeepers produce their effects, even without veterinary prescriptions. • The strict application of art. 34 of reg. UE 2019/6, to veterinary medicines for the control of Varroa destructor, which does not take into account the very particular context, could instead lead to necessarily provide for the veterinary prescription. • It is reasonable to imagine that even with cascade mechanisms, the aspect could subsequently also concern veterinary medicines already authorized under previous regulations.	

Stakeholder no.	General comment (if any)	Outcome (if applicable)
	• The impact that this could derive on the territory could be significant and, instead of improving the situation, it could worsen it • It could in fact represent an obstacle to the implementation of generalized plans to combat varroa, rather than a valuable added value that the veterinary profession can bring to the beekeeping sector (as foreseen by the EU regulation 2016/429, in particular with "animal health visits ", With frequency foreseen according to the risk). • Consider that at least in Italy (but probably also in other EU countries), the majority of private veterinarians have little knowledge and familiarity with honey bees and beekeeping and would probably have difficulty in guaranteeing in a capillary way, the prescription to individuals beekeepers for the supplies of the necessary antivarroa medicines. • Similarly, sometimes the judgment of the individual professional, eg. on the risk that phenomena of resistance to certain substances arise or not, could be distorted by insufficient information, not in the possession of the individual professional if he does not operate precisely inserted in a territorial system coordinated by the same competent authority • Personally, I am therefore of the opinion that in applying art. 34 all these particular aspects must be taken into account. • Not separating the control of veterinary medicines from other health needs.	

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	• Last but not least, guaranteeing at the same time the necessary support to this particular and fundamental but fragile sector. • I would therefore consider it reasonable that even in the specific Guidelines these aspects were mentioned, thus admitting a certain degree of flexibility and accepting that in individual States it is possible to better regulate these very complex aspects, which on the other hand is a necessity based on to reg. 2016/429.	
9	The Asociación para la Salud Animal (ASEMAZ ASA) considers that certain veterinary drugs that are currently considered not subject to veterinary prescription should be classified as subject to veterinary prescription because they do not meet the conditions established in article 34.3 of the Regulation (EU) 2019/6. The reasoning is: a) The pharmaceutical forms in which they are presented, require particular knowledge or skills for their administration: for example medications with the active ingredient Lufenuron in injectable suspension; b) The veterinary drugs can cause serious harmful effects, including death, as occurs with drugs whose active ingredients are Fipronil, Permethrin, Pyriproxyfen, Niclosamide; c) The summary of characteristics of the veterinary drugs contains warnings of possible serious adverse events derived from its correct use, as occurs with drugs that have active ingredients such as Dinotefuran, Propoxur, Diazinon, Tetramethrin, Piperonil, Imidacloprid. In conclusion, ASEMAZ-ASA considers that all veterinary drugs containing the aforementioned active ingredients should be classified as subject to veterinary prescription because they pose risks to animals, people who administer them or the environment.	Noted. However, it is not within the scope of this guideline to provide recommendations on the re-classification of already authorised VMPs. No changes required.

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
39-40	7	**Comment**: Rewording proposed to address the following: - Double use of the word 'consideration' in the same sentence - Article 33(1)(b) includes the prescription status classification as a "condition or restriction to be *imposed*" **Proposed change**: ~~Consideration of w~~Whether a veterinary medicinal product is needs to be subject to veterinary prescription or not is an outcome of product assessment1 and therefore requires detailed consideration.	Partially accepted. The text will be amended as follows: ~~*Consideration of*~~ *Whether a product is classified as subject to veterinary prescription or not is an outcome (…).*
45	3	**Comment**: HMA acronym **Proposed change**: Head of Medicines Agencies (HMA)	Accepted. Additionally, reference to the specific task force involved has been removed.
45-47	7	**Comment**: The guideline will be used by national competent authorities (NCAs) in different procedures, and the guideline cannot *ensure* a harmonised approach and outcome between NCAs, procedures and products. 'Facilitate' would be a more appropriate wording, in our opinion. **Proposed change**: The HMA Task Force… agreed that guidance was needed to ~~ensure~~ facilitate a harmonised EU approach to classification of veterinary medicinal products.	Accepted.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
50-52	7	**Comment**: Same as above **Proposed change**: To ~~ensure~~ facilitate a consistent implementation and a harmonised EU approach, the assessment principles for the various provisions of Article 34 of Regulation (EU) 2019/6 are laid out.	Accepted. Additionally, the word 'implementation' is changed to 'understanding'.
60-62	2	**Text referred to: "**It is, however, not within the scope of this guideline to elaborate on considerations regarding harmonisation of prescription status for veterinary medicinal products that are not authorised through the centralised procedure,.." **Comment**: While this sentence addresses an earlier comment on the concept paper that Article 34 does not require one single prescription status be adopted across the Union for a product, we feel this could be stated more clearly. **Proposed change:** Please modify the sentence to read "It is, however, not within the scope of this guideline to ~~elaborate~~ require harmonisation of prescription status for veterinary medicinal products that are not authorised through the centralised procedure,…"	Not accepted. The scope as it is, is descriptive enough and it would not be appropriate in any case for the guideline to address a requirement or non-requirement for a regulatory exercise since this guideline would not be the platform for that message.
61-65	5	**Comment**: Please clarify the scope of this paper. Is it intended for centrally authorised products only or does it have to apply to nationally authorised products as well? **Proposed change**: please clarify	Not accepted. The scope as it is, is considered descriptive enough. Regulation (EU) 2019/6 does apply to all VMPs authorised in the Union.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
63	3	**Comment**: correction **Proposed change**: procedure, nor on the impact, if any	Accepted.
69-71	7	**Comment**: We consider that the current wording is not an accurate reflection of Article 33(1)(b) and propose to use the actual wording instead. **Proposed change**: Article 33(1)(b) of Regulation (EU) 2019/6 specifies that in case of a favourable assessment, the ~~outcome of a competent authority's~~ assessment report or opinion on an initial marketing authorisation application shall include "details of any conditions or restrictions to be imposed as regards the supply or safe and effective use of the veterinary medicinal product concerned, including the classification of a veterinary medicinal product in accordance with Article 34".	Not accepted. The need for this change is not shared. Besides, the intention of the paragraph as it is currently worded is to make clear that the decision on a prescription status derives from the assessment.
93	2	**Comment**: To be in line with article 34 (2), it is recommended to modify line 93. **Proposed change**: Please amend to read: "... but likely to contain… to "… and likely to contain…"	Not accepted. The current wording is preferred.
94	2	**Comment**: The text refers to products with "special precautions" which are those concerned by the need for a critical review to justify a non-prescription status. Presumably this refers to article 35 (1) I (v) of the Regulation (special precautions for use, including in particular special precautions for safe use in the target species, special precautions to be taken by the	Not accepted. The current text is preferred as it is a verbatim of Article 34(2) (i.e. special precautions). Section 4.2 of this guideline elaborates on what is to be understood by "special precautions", which has been legally confirmed.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		person administering the veterinary medicinal product to the animals and special precautions for the protection of the environment). It is necessary to clarify that only critical or serious special precautions with respect to the safety and efficacy are relevant in order to better define the scope. Standard warnings such as "In the event of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician" are not expected to justify on their own a prescription only status. **Proposed change**: Please change "special precautions" by "serious special precautions"	
97-109	7	**Comment**: The currently proposed schematic representation depicting the application of Article 34 (Figure 1) goes beyond the wording of the regulation as it in our opinion indicates that VMPs ***shall be/will have to be*** classified as 'not subject to veterinary prescriptio'n if the conditions in Article 34(3) are met. This is not in line with the NoMA's interpretation of the article. Not only may the conclusion that a classification as 'not subject to prescription' according to Art 34(3) has been *adequately* justified by the applicant differ between members and Member States (which is already reflected in the current flow chart). The competent authority may also take into account national legislation and considerations when deciding if they will derogate from art 34(1) and classify the	Partly accepted. The proposed schematic representation aims to serve as a clear, user-friendly tool to the interpretation of Article 34. It provides the reasonably expected outcome for each of the possible scenarios foreseen in this Article. It is acknowledged that some minor changes might help to provide a more accurate picture. The following is being implemented: - the blue box depicting Article 34 paragraph (2) is expanded to account for the provision of a VMP being "classified as a narcotic drug in accordance with **national** law". [emphasis added] - an explanatory note (*) is added to the blue boxes depicting Article 34 paragraphs (2) and (3) to indicate that, in both cases, the decision will be made on a case-by-case basis, thus accounting for the 'may' provision used in paragraphs (2) and (3) of Regulation (EU) 2019/6

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		product as 'not subject to veterinary prescription'. This flexibility – which we consider is provided by the wording of art 34(3) - is currently not reflected in the text. **Proposed change**: To add the following: "For veterinary medicinal products that are not authorised through the centralised procedure, it should be noted that the decision to grant an exception according to Article 34(3) and classify a product as "not subject to veterinary prescription" will ultimately be at the discretion of the national competent authority, which may also take into account national legislation and considerations." Additionally, we propose that a footnote referring to this statement is included in the "YES"-bubble in the flow chart (Figure 1), following the question on whether the applicant has adequately justified that the art34(3) conditions are met.	It is not considered necessary to elaborate further on specific scenarios or national issues and further elaboration risks loss of flexibility.
106	2	**Comment**: In order to better reflect the legal framework, it is recommended to modify line 106. **Proposed change**: Please modify from "... but will ultimately be based on the provisions of Article 34(2)." By "... and will ~~ultimately~~ be based on the provisions of Article 34(2)."	Not accepted. The word "but" divides what is contingent (the justification provided by the applicant in line with Annex II requirement) and what is necessary (the provisions within Art. 34[2]).
104-107	2	**Comment**: From a strict reading of article 34, products not listed in article 34(1) are eligible to the non-prescription status unless they are concerned by	Not accepted. This paragraph already mentions Article 34(2), which specifically mentions narcotic drugs under national law

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		article 34.2 (are narcotics under national law or present special precautions in their SPCs). Indeed, derogations to the compulsory prescription-only status offered by article 34 (3) only concern products listed in article 34(1). Nevertheless, it is acknowledged that for products not listed in article 34(1) the classification decision will be based on justifications provided by the applicant and by article 34(2) and therefore there is a need to better define what the criteria "special precautions" means. **Proposed change**: It is therefore proposed to add at the end of the line 107 the following: "with respect to narcotics defined under national law and to serious/critical special precautions".	and special precautions. It is therefore not considered necessary to explicitly refer to this matter.
108	2	The central box seems to overlook the possibility to apply for release from "subject to prescription" to products that are not included in any of the categories listed in Article 34(1) – it seems that only those listed under 34(1) b, d, f, or g could be released. However, it is possible that products (especially if authorised prior to EU 2019/6) are subject to prescription but are not among any of the Article 34(1) categories. **Proposed revision:** Revise the central box to say "Does the VMP fall under Article 34(1) categories b, d, f or g or under none of the categories listed in Article 34(1)?"	Not accepted. The top and central blue boxes depict paragraph (1) of Article 34, distinguishing between the VMP categories which could never be classified as non-POM (i.e. categories [a], [c], [e], or [h]) as per Article 34. Therefore, the central box does not overlook the possibility for a product not listed in any of the categories of paragraph (1) to be classified as non-POM. If such VMP is not listed under paragraph (1) (i.e. if the response to the two first questions is "no") then paragraph (2) applies to ultimately determine the prescription status of such VMPs. No changes in the schematic representation are therefore needed.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
108	3	**Comment**: SPC acronym **Proposed change**: summary of product characteristic (SPC)	Accepted. Please note that the acronym is now given in section 3, where *summary of product characteristics* is first mentioned.
108	4	**Comment:** In Figure 1 ("*Schematic representation depicting application of Article 34 of Regulation (EU) 2019/6*") the Draft Guideline provides for a useful and practical visualisation of the possible routes for the classification of VMPs. Though, in BPI's opinion the yellow box on the lower left side of the figure, which refers to "*VMP subject to veterinary prescription*" after answering with "*YES*" the question "*Does the SPC of the VMP contain special precautions?*" should be clarified. Art. 34(2) Regulation (EU) 2019/6 is a clear "may-provision", which gives discretion to the competent authorities to classify a VMP not falling under Art. 34(1) Regulation (EU) 2019/6 as subject to prescription, when special precautions are included in the summary of the products characteristics ('SPC'). This discretion regarding the classification should be distinguished from the compulsory classification as subject to prescription for VMPs falling under Art. 34(1) lit (a), (c), € and (h) Regulation (EU) 2019/6 (cf. the box on the upper right side in the same figure 1 of the guideline). Thus, the wording in the yellow box on the lower left side should be amended in order to highlight the discretion of the authority as foreseen by Article 34(2) Regulation (EU) 2019/6. **Proposed change:**	Partly accepted. See response above (lines 97-190; stakeholder 7).

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		To amend the wording in yellow box on the left: "VMP may be subject to veterinary prescription"	
107-108	2	**Comment and rationale**: Article 34 identifies some conditions that always by default preclude a VMP to be classified as 'not subject to veterinary prescription' (example Art 34.1 a, c, e, h) and conditions that are not automatically precluding the classification as 'not subject to veterinary prescription' (example Art 34.1 b, d, f, g). This second group contains the provision of Article 34.2, which provide discretion to the authorities to classify a VMP as subject to veterinary prescription if special precautions are contained in the SPC. The flow chart incorrectly implies that veterinary medicinal products which do 'not fall under Art 34.1 categories (b), (d), (f) or (g)' must be classified as subject to prescription if the SPC contains special precautions. Article 34(2) states that the competent authority or the Commission may classify a product subject to prescription in that circumstance. In other words, authorities are not obliged to identify "special precautions" in the SPC as potential reason to classify a product as subject to prescription. It is likely that some special precautions may not be considered to warrant prescription status and the legislation allows for competent authorities or the EU Commission to accept the product as NOT subject to prescription. As written, the flow chart implies that any "special	Partly accepted. See response above (lines 97-190; stakeholder 7). In addition, point 4.2. in the guideline elaborates on what should (and should not) be understood as a "special precaution". It is not considered necessary to further elaborate on this in the schematic representation.

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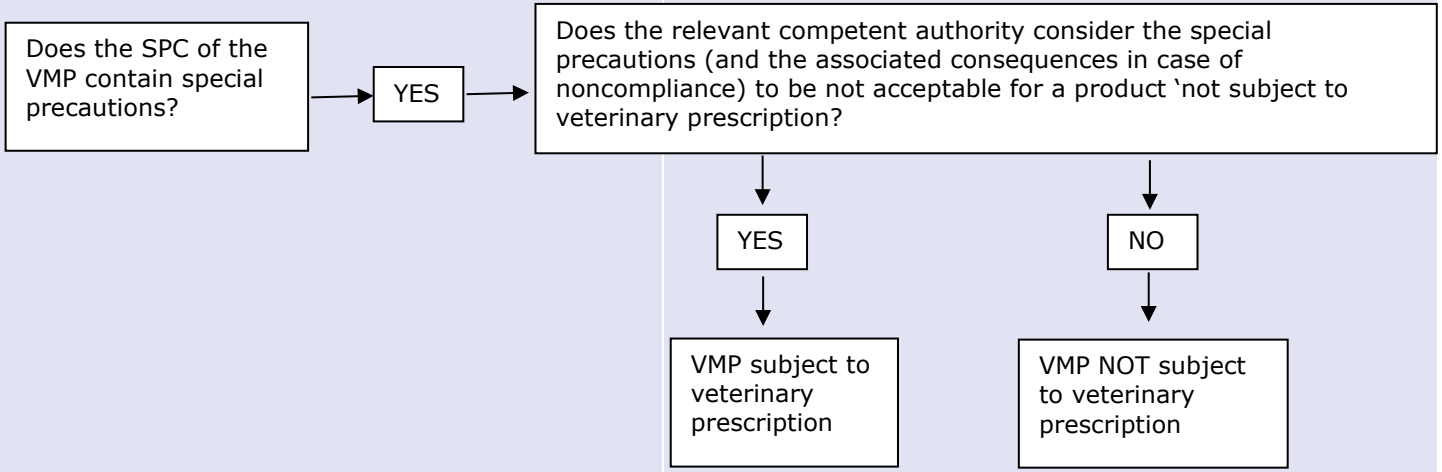
		warnings" in the SPC automatically mean the product is subject to prescription. The question "does the SPC of the VMP contain special precautions? "should better read "does the SPC of the VMP contain serious/critical special precautions? "and or the flowchart should contain an additional box to represent that special precaution and assessment of the relevant authority is required to lead to "VMP subject to veterinary prescription". Indeed, only relevant special precautions as per the guideline should justify a VMP to be restricted to veterinary prescriptions. **Proposed change**: Please modify the flowchart as follows:  	

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
108	2	**Comment**: The flow chart does not address the part of Article 34(2) which states a competent authority may classify a VMP as subject to prescription if it is classified as a narcotic drug in accordance with national law. **Proposed revision:** This option should be added to the flow chart (either combined with the box asking if special precautions are in the SPC or in a separate box in the flow chart)	Partly accepted. See response above (lines 97-190; stakeholder 7).
137-164	6	**Comment**: Remain under veterinary prescription VMPs intended to detect, diagnose, prevent or control categorized diseases (according to the LSA classification, resulting from regulation 2018/1882).	Not accepted. Notifiable diseases, by definition, require precise and prior diagnosis. It is found unnecessary to remark this.
141-142	5	**Comment**: A "precise prior diagnosis" requires an examination by a veterinarian. We suggest the following amendment. **Proposed change**: Concerning the requirement for a "precise prior diagnosis", the term "precise" is understood as clearly implying that a veterinarian has visited the animal for clinical and when needed laboratory examination and has made the ("precise") diagnosis.	Not accepted. It is not considered necessary to make the changes requested as the current wording is sufficiently clear.
144-147	1	**Comment**: The relevance of "precise" and "prior" is discussed in reference to pathological processes that could lead to negative consequences on the animal's health and welfare if not adequately diagnosed and	Not accepted. It is considered that current text is self-explanatory. Additional examples are not considered to add value to the text.

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		managed. It may be beneficial to provide some examples. **Proposed change**: Some examples may be provided of "pathological processes that could lead to negative consequences on the animal's health and welfare if not adequately diagnosed by a veterinarian and thereby managed appropriately", similar to those for symptomatic treatment of non-specific conditions that could mask potentially severe underlying disease (lines 158-164).	
148-153	1	**Comment**: "A precise prior diagnosis" is not relevant for VMPs used exclusively for prevention or for symptomatic treatment or for easily diagnosed conditions and conditions not endangering animal's health and welfare in case of delayed diagnosis. However, the indications as presented in the SPC for various VMPs may not claim "prevention", but "treatment" or "control" although they are commonly used for prevention (e. g. some anthelmintics). Therefore, the requirement may be modified appropriately to reflect the anticipated use. Alternatively, the claims may be modified as per expected use. In case that precise prior diagnosis is desirable (but may not be pivotal), appropriate precautions to consult a veterinarian may be inserted in the SPC and in the product literature. **Proposed change**: Determining "a precise prior diagnosis" is not relevant for VMPs with ~~exclusive~~	Partly accepted. To provide more clarity on what is meant by exclusive preventive claims the following change will be made: *"Determining "a precise prior diagnosis" is not relevant for VMPs <u>intended exclusively to prevent a certain condition</u> or indicated (…)"*. The second amendment proposed does not fall within the scope of this guideline and is thus not accepted.

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		predominantly preventive claims (use) or indicated for symptomatic treatment of nonspecific conditions or indicated for diseases that can be easily diagnosed by a non-veterinarian and where no threatening consequences for the animal's health and welfare could be identified in case of delayed precise diagnosis. If veterinary consultation is relevant for preventive use, an appropriate precaution should be inserted in the SPC. However, Article 34(1)(d) may still apply if the treatment has the potential to impede or interfere with subsequent diagnostic or therapeutic measures.	
148-153	2	**Comment**: When covering "a precise prior diagnosis," the GL should be made clearer that combinations of all three of the mentioned types of claims/indications, i.e. preventative claim, indicated for symptomatic treatment and indicated for treatments of easily diagnosed diseased and parasites (such as tick/fleas) might be on the label of the same VMP and still be covered by the word "exclusive". Anti-parasitics for prevention and/or treatment should for example fall into this category to facilitate a strategic, risk-oriented parasite health management regime carried out by animal owners without prescription. The specific case of recurring conditions is not covered by the current text. Some diseases need a diagnosis by a veterinarian but are easily recognised	Partially accepted. The addition of 'and' is only accepted for the second case since a VMP would not be 'exclusively preventive' and 'intended for a treatment' at the same time. The word 'disorders' has been changed to 'pathological processes', which is the terminology used in the article itself. The last addition proposed is not accepted since it is considered to be covered by the current text.

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		by non-professional users once the first diagnosis is established. Animal's health and welfare can only benefit from a quick action by the owner of the animal (e.g. Flea Allergy Dermatitis) who can always revert back to a veterinarian if no improvement is seen. Such case would need to be justified in the applicant's critical review and assessed on a case-by-case basis to ensure that adequate warnings are covered in the product information. **Proposed change:** Change "or" at the end of line 148 and in line 149 to "and/or". Change "diseases" in line 149 to "diseases/parasites" and introduce the recurrent conditions. Please amend the sentence to read: *"Determining "a precise prior diagnosis" is not relevant for VMPs with exclusive preventive claims and/or indicated for symptomatic treatment of nonspecific conditions and/or indicated for diseases/parasites that can be easily diagnosed by a non-veterinarian or where this has been previously diagnosed by a veterinarian, when and where no threatening consequences for the animal's health and welfare could be identified in case of delayed precise diagnosis."*	
149-150	5	**Comment**: Diseases are diagnosed by veterinarians. General symptoms or disorders may be observed by non-veterinarians. **Proposed change:** Determining "a precise prior diagnosis" is not relevant for VMPs with exclusive	Partially accepted. Please note that the word 'disorders' has been changed to 'pathological processes', which is the terminology used in the article itself (please refer to the previous comment). The 'diagnosed' has been changed, as proposed.

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		preventive claims or indicated for symptomatic treatment of nonspecific conditions or indicated for ~~diseases~~ disorders that can be easily ~~diagnosed~~ observed by a non-veterinarian and where no threatening consequences for the animal's health and welfare could be identified in case of delayed precise diagnosis.	
155	2	**Comment**: Would propose that the lameness example is removed here (see rationale below line 163-164). **Proposed change**: Please delete "… (e.g. lameless)"	Accepted.
163-164	2	**Comment**: Would propose that the example of pain treatment, lameness and osteosarcoma is removed. The pain associated with an osteosarcoma would not be resolved by an NSAID (as an example of a widely used analgesic) and therefore even if such a VMP were given OTC (if licensed as such) it would not mask this potentially serious condition. Moreover, the likely first line treatment by a veterinary surgeon for a suspected osteosarcoma would be an NSAID and a watch and wait approach. It is considered disproportionate to prevent the potential opportunity to provide valuable pain relief to an animal to treat a more common musculoskeletal conditions (e.g. transient lameness due to over exercise) by citing the comparatively rare example of osteosarcoma.	Accepted.
172-173	5	**Comment**: Please clarify if this guideline refers to centrally authorised products (CAPs). Is it possible	Not accepted. Regulation (EU) 2019/6 does apply to all VMPs authorised in the Union and thus Article 34(2) is not

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		that a CAP has different SPCs in different countries? If this is possible there is no problem with the clarifications under 4.2 session, if not this seems redundant. It seems that Article 34, paragraph 2, of Regulation (EU) 2019/6 is addressed to non-CAP VMPs. **Proposed change**: clarification	exclusively referring to non-CAP products (the Commission is mentioned as regards centralised products). As a consequence, the text is not considered redundant. No changes are therefore required.
176-177	2	**Comment**: It is our understanding that the annexe II section I.2.1 covers any type of application and variation to change the prescription status. Suggest modifying the sentence that this sentence reflect that the Annex II reference applies to any type of applications and variations. **Proposed revision**: Please add "…if they submit a variation to change the status to not subject to prescription" at the end of the sentence to read: "…applicants are strongly advised to justify a "not subject to veterinary prescription" status according to the dossier requirement whether they submit an application for marketing authorisation for which a classification "not subject to prescription" is requested or a variation to change the status to not subject to prescription."	Not accepted. The suggested clarification is not considered necessary since the text is sufficiently clear. Please note that section 5 of the guideline deals with variation applications to change the classification (prescription status) of a VMP.
178-181	2	**Comment**: This sentence describes how the term "special precaution" is to be understood within Article 34(2). However, in the past, there have been some	Not accepted. The GL does not affect already authorised VMPs. And it is clearly stated that the special precautions should be of such nature that not complying with them could lead to a negative outcome. Please note that the word serious has been added in order to give additional guidance

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		things included into the "special precautions" sections of SPCs that do not fully fit this description/definition. **Proposed change:** Suggest that the GL acknowledge that some things in "Special Precautions" sections of SPCs may not trigger classification as subject to prescription status and clearly state that the fact that even if something is included in these sections, it does not automatically require "subject to prescription" classification.	to what is understood by special precautions (see comment below).
183	2	**Comment**: The GL does not provide precise and strong enough description of what "special precautions" means in the context of Article 34(2). While it does say "… *should be of such a nature that not complying with them could lead to negative consequences for the treated animal, the user, or to the environment*", this is still quite weak and in too broad. We suggest that "special precautions" be defined in a less vague manner. By nature, there is often negative consequence of not complying with precautions of use but this should not be always a reason for prescription-only status decision. This is already observed with a lot of chemicals available without distribution restrictions in various areas (cosmetics, hygiene, gardening, crafting...) where the noncompliance of precaution of use has often negative consequence for the user or environment such as eye/skin irritation, cutaneous sensitization, pollution. That being said, these negative consequences are not reasons for restricting the	Partly accepted. The word serious has been added in order to give additional guidance to what is understood by special precautions. The proposal to involve the need of a veterinarian to qualify as a special precaution is not supported, neither the reference to national particulars. Thus, the proposal for the "special precautions" to qualify only by its nature, noting that the expert intervention of a veterinarian will not be able to minimise the risks of certain "special precautions" occurring in some cases, is retained.

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		access to the product. It is proposed to qualify the "negative consequences" and restrict to the "serious negative consequences" in order to clarify that minor negative consequences of not complying with some precautions of use (minor in nature, minor in severity, reversible, transitory) are not a reason for POM decision. Special precautions should, in addition to the described nature in this sentence, be of a nature that compliance with them can be improved by involving the veterinarian (for example when veterinary expertise/skill for diagnosis are essential). It should be considered whether the alternative makes a difference. National authorities have for example (in most countries) the alternative to restrict retail of non-prescription VMPs to certain retail categories such as 'pharmacy only' which can be expected to equally remind customers on adhere to certain precautions and be prepared for questions. **Proposed change**: Please consider changing from "The special precautions should be of such a nature that not complying with them could lead to negative consequences for the treated animal, the user, or to the environment." To: "The special precautions should be of such a nature that not complying with them could lead to serious negative consequences for the treated animal, the user, or to the environment and please add "Special	

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		precautions should in addition be of a nature that compliance with them can be improved by involving the veterinarian (for example when veterinary expertise/skill for diagnosis are essential). It should be considered whether the alternative makes a difference. National authorities have for example (in most countries) the alternative to restrict retail of non-prescription VMPs to certain retail categories such as 'pharmacy only' which can be expected to equally remind customers on adhere to certain precautions and be prepared for questions."	
182-183 & 228-240	2	**Comment**: The applicability of certain provisions depends by thresholds defined by vague statements: e.g. the applicability is linked to the possibility of causing 'negative consequences' (Art 34.2), or 'potential serious consequences' or showing/not showing 'good tolerance' (Art.34.3. b). **Proposed changes**: provide minimum general criteria to more precisely interpret the above definitions, similarly to what is done for the definition of 'serious adverse events' (283-287)	Partially accepted. The word 'serious' has been added to section 4.2 on Article 34(2). In what regards to the proposal for better clarity in section 4.3.2 (Art. 34[3][b]), it is already stated that risks should be relevant and that should lead to serious consequences to animals, users or to the environment. However, the word "relevance" at the beginning of section 4.3.2 has been changed by "severity" and "good tolerance" by "wide margin of safety".
215-217	4	**Comment**: With reference to Art. 34(3)(a) Regulation (EU)2019/6, the Draft Guideline states "*On the other hand, it is generally considered that pharmaceutical forms administered by injection require particular knowledge and skills. Injectables should therefore be subject to prescription*." This is correct for most of the VMPs administered by injection, but not for all (cf.	Not accepted. Please note that the current guideline text states that *a VMP subjected to prescription could sometimes be administered by a person different from the prescribing veterinarian*. Additionally, the text in Regulation (EU) 2019/6 refers to *pharmaceutical forms requiring no particular knowledge or skill in using the products*, with no distinction

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		BPI-comments on the Concept Paper on the elaboration of guidance for the application of Article 34 Regulation (EU) 2019/6, EMA/CVMP/65618/2022 of 29.04.2022). In several Member States (e.g. DE, BE, NL, FR, LT, DK) there are numerous VMPs with a good safety profile administered via the simple subcutaneous route, which are classified as not subject to veterinarian prescription since many years. This has been in line with the previous EU legislation i.e. Implementing Directive 2006/130 establishing the exemption criteria, which have been taken over basically unchanged by Art. 34(3) Regulation (EU) 2019/6. The exemption from the prescription requirement for VMPs with a good safety profile administered by the simple subcutaneous route should remain possible in the future. Art. 34(3) Regulation (EU) 2019/6 is – as was Art. 67(aa) of Directive 2001/82/EC as amended by Directive 2004/28/EC – a clear "may-provision", meaning that the granting of exemption to the prescription only principle as stipulated by Art. 34(1) Regulation (EU) 2019/6 lies in the discretion of the competent authorities. Consequently, when the competent authorities exercise this discretion applying the exemption criteria during initial marketing authorisations as well as variations should have the flexibility to take into account the existing differences in roles of veterinarians and farmers in the Member States. The fast access to VMPs especially in rural areas where the access to veterinarians is difficult	between routes of administration for the same pharmaceutical form.

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		should not be constrained. The farmers, especially organic farmers, and care givers for pet animals have gained a lot of experience through the long period of use of those VMPs. An inflexible interpretation of the exemption criteria may have unfavourable consequences regarding increasing costs, delays, and eventually animal welfare. For the sake of clarity this situation should also be depicted in the Draft Guideline, even if the guidance explicitly states that it is not intended to harmonise the prescription status for VMPs that are not authorised through the centralised procedure. **Proposed change:** "On the other hand, it is generally considered that pharmaceutical forms administered in particular by intramuscular or intravenous injection require particular knowledge and skills. These i~~I~~njectables should therefore be subject to prescription."	
221-222	5	**Proposed change**:… necessary instructions to ensure a correct and responsible administration.	Accepted.
230-231	5	**Proposed change**: …VMP is administered incorrectly, i.e. not according to the provisions in the SPC**,** or in case of accidental use in the same or other species.	Not accepted. An accidental use would also be not in line with SPC directions. No changes are required.
223-279	2	**Comment**: In this section, reference to SPC sections is made several times and seem incorrect: a lot of Sections 3.X of the SPC are referred to and seem to	Not accepted. Please note that the numbering of the SPC sections has recently changed. Please refer to version 9.0 of the QRD template.

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		actually be Sections 4 in SPCs, also a reference to Section 5.5 (Line 269) seems incorrect. Please check.	
238	2	**Comment**: Although not directly linked to this GL document on article 34, a clear definition of "contraindications" is not yet available in the SPC guideline or the annotated QRD template for SPC-PI. A clear definition in the appropriate guidance document would be highly appreciated.	Noted. As indicated by the stakeholder, the proposal is outside of the scope of this guideline.
244-247	3	**Comment**: additional example **Proposed change**: This could also include exposure to residues of the medications in the faeces or urine of the treated animal.	Not accepted. There current example suffices and there is no need to add additional ones.
256-257	1	**Comment**: The relevance of case of self-injection is questionable considering the Article 34 (3)(a) stating that injectables should be subject to prescription. **Proposed change**: Regarding incorrect use, such risks for users should be related to relevant effects (e.g. in case of ~~self-injection~~ [alternative example(s) may be provided]) and/or the need for personal protective equipment (PPE).	Partially accepted. The self-injection example has been deleted. Additionally, the word 'relevant' has been changed to 'potential harmful', providing more clarity. Thus, no alternative examples are considered needed.
277-279	5	**Comment**: It is a good recommendation to restrict supply from large containers on veterinary prescriptions.	Noted.
290-293	2	**Comment**: Considering that VMP not subject to prescription are generally intended for animals in good/acceptable health conditions (prophylactic,	Partially accepted. Please note that expert judgement will always be needed for the assessment of this criterion, and that non-serious adverse events will not qualify to this

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		fleas/ticks, local antiseptics, diet supplements), it is considered not desirable to balance the definition of serious AE with the nature of the product indication/target population. Indeed, if the regulator introduces this balance, it opens to subjectivity the interpretation of the definition of "serious adverse event" as described in line 283-287, and the spirit of the law could be circumvented (e.g. not serious AE could thus be a reason for POM status because used in healthy animals, while the legal text states that it should be "warnings of potential serious adverse events")	criterion as per the definition provided. To avoid confusion, the second paragraph in section 4.3.3. has been slightly modified and the specific reference to the nature of the potential adverse events in relation to the intended use of the product is deleted.
294-314	2	**Section referred to: "**4.3.4. Article 34 (3)(d) (*d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent adverse event reporting)"* **Comment:** Some adverse events are frequent but with a very low seriousness, such as e.g. fur discoloration on the application site. Medicinal products with such frequent but non serious events should not be automatically subject to prescription.	Not accepted. The seriousness of the events is covered in Article 34(3)(c). This paragraph relates only to the frequency. No changes are required.
315	2	**Comment**: AnimalhealthEurope welcomes the clarity this section offers with respect to examples of current products not subject to prescription status. It is proposed that those examples are not limited to article 34 (3) € and satisfy also the other criteria of article 34 (3).	Not accepted. It is not considered that additional examples in other sections would improve the text, while there is a risk of adding uncertainties.

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319-320	5	**Comment**: Please clarify the scope of this document.	Not accepted. The scope has already been revised and it is considered sufficiently clear. No changes are required.
321	3	**Comment**: correction **Proposed change**: possible to set an exhaustive list of VMPs that are use	Accepted.
331	5	**Comment**: Please clarify if that applies also when this substance is used as an excipient in VMP, solvents, etc…	Accepted.
335	2	**Comment**: Presumably products intended for companion animals would not be concerned with the risk defined by article 34 (3) (f). It is proposed to add the following sentence: "Products intended for companion animals are not expected to present a risk for public health as regards residues in food obtained from treated animals even where the veterinary medicinal product is used incorrectly."	Not accepted. It is not considered necessary as companion animals will not be consumed.
335-343	4	**Comment:** In cases where the withdrawal period was determined solely on the basis of odour impairment of the food and not on the basis of toxicological relevance, it would be disproportionate to include the VMP in the prescription requirement. **Proposed change:** To add after line 343: "It should be noted that a withdrawal period may also be set for purely oleofactorial reasons for active substances with the status "No MRL required". Here, a case-by-case assessment for a possible exemption from the prescription requirement must be possible."	Not accepted. A withdrawal period set purely for such reasons will not be automatically considered a risk for public health as regards of residues in food. In addition, please note that expert judgement is needed on a case-by-case basis, and such scenario would thus be considered then.

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343	5	**Proposed change**: … health-based ~~reference~~ guidance value (HBGV)…	Accepted.
357	2	**Proposed change:** Please add "in general" after "Article 34(3)(g), to read: "For the interpretation of Article 34(3)(g), in general, the same principle should be followed..."	Accepted.
361	2	**Comment**: There may be a difference in VMPs which have been authorized for more than five years and for which in addition to art. 34 (1) f) not only contain actives approved for more than 5 years but for which long-term product specific information are available. For new active substances it may be more difficult to estimate a potential development of resistances because long term data are not yet available. For the interpretation therefore the data and facts available at the time of the assessment should be the basis of the risk assessment. **Proposed change:** After sentence ending "…one is aiming to treat." add the following sentence, "If the product in question has been approved for more than 5 years available surveillance and pharmacovigilance data linked to the product until the time of the respective assessment should be the basis of the risk assessment." And replace the sentence beginning "Regarding the likelihood of…" with "Products which have not been marketed for that long, any reported cases of resistance to the active substance in respect	Not accepted. The comment is appreciated, but it is not considered that changes are needed. It is true that substances marketed for several years might have information that could make the analysis suggested in the guideline more robust. But the current wording does not impede to use that information, when available. In fact, it is specifically mentioned that "any reported cases of resistance to the active substance in respect of parasites should be taken into account."

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		of parasites should be taken into account, considering however that the longer an active substance has been used for veterinary medicines, the more it can be assessed."	
368-371	4	**Comment:** There exists a large number of various non-prescription VMPs authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 which have been in the market for a very long time. Any evaluation of the prescription status should take due account of the application experience gained so far regarding the safety profile of those VMPs. This should be taken into account in all case-by-case decisions of the competent authorities. **Proposed change:** To add a new sentence in Line 371: "The obtained long-standing experience with the safety profile of medicinal products so far shall be adequately taken into account."	Not accepted. The resistance status is a dynamic factor that evolves with time. Linking the prescription to past experience tries to anchor this dynamic concept in a static set up for which no benefit can be found.
376	2	**Comment**: In order to better reflect the legal framework, it is recommended to modify line 376 in coherence with line 106. **Proposed change**: Please modify from "... but will ultimately be based on the provisions of Article 34(2)." by "... and will ~~ultimately~~ be based on the provisions of Article 34(2)."	Not accepted. The word "but" divides what is contingent (the justification provided by the applicant in line with Annex II requirement) and what is necessary (the provisions within Art. 34[2]).