Decision of the European Ombudsman closing his inquiry into complaint 1260/2010/RT against the European Commission

Decision
Case 1260/2010/RT - **Opened on** 10/08/2010 - **Recommendation on** 06/02/2012 - **Decision on** 12/12/2012 - **Institution concerned** European Commission (Draft recommendation partly accepted by the Institution) |

The complainant, a French farmers' association, complained to the European Commission that the French authorities failed to comply with the provisions of EU law concerning parallel imports of veterinary medicinal products (VMPs). It argued that France did not allow vets, farmers, pharmacists, and other retail distributors to have access to the simplified authorisation procedure for parallel imports of VMPs. In addition, the French authorities refused to grant access to the simplified procedure for parallel imports of VMPs to wholesale dealers authorised to distribute VMPs in other Member States.

The Commission opened infringement proceedings and sent a letter of formal notice to the French authorities. Subsequently, the French authorities modified the national legislation concerning the authorisation procedure for parallel imports of VMPs. The Commission therefore decided to close the case. The complainant alleged that the arguments provided by the Commission in its decision closing the infringement complaint were insufficient and unconvincing. It claimed that the Commission should either cancel its decision to close the infringement complaint, or open a new infringement proceeding against the French authorities.

In its opinion, the Commission first took the view that personal parallel imports of VMPs may not be authorised if the relevant provisions of Directive 2001/82/EC of the Community code relating to veterinary medicinal products are not complied with. The Commission noted, in sum, that parallel imports of VMPs are in general open to farmers, vets, and pharmacists or to wholesale dealers if they comply with specific provisions of that Directive relating to distribution, possession, and dispensing of VMPs and pharmacovigilance.

The Ombudsman considered that the Commission did not provide an appropriate justification for its decision to close the complainant's infringement complaint. He thus made a draft recommendation to the Commission. Following his draft recommendation, the Commission decided to open new infringement proceedings concerning the obstacles met by wholesale dealers who attempt to make parallel imports of VMPs. The Ombudsman therefore considered that the Commission had, so far, taken adequate measures to implement his draft

recommendation. He therefore decided to close the case.

The background to the complaint

1. Pursuant to the provisions of Directive 2001/82/EC [1] on the Community code relating to veterinary medicinal products (hereinafter 'the Directive'), a veterinary medicinal product (hereinafter 'VMP') cannot be put on the market of a Member State without a marketing authorisation, the primary purpose of which is to safeguard public health [2] .

2. Subsequently, once a VMP has obtained the marketing authorisation in a Member State, it can be placed on the market of that Member State through: (i) the distribution network that the manufacturers or original suppliers have established for their products in that Member State; or (ii) parallel imports. According to the European Commission's *Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted* [3] , 'parallel importation' takes place outside and – in most cases – in parallel with the distribution network that the manufacturers or original suppliers have established for their products in a Member State, although it concerns products which are in every respect similar to the ones marketed by the distribution networks. According to the Court of Justice case-law [4] , medicinal products imported by individuals (for instance, a patient) for their personal needs are considered 'personal parallel imports', without being subject to a prior authorisation procedure.

3. On 10 June 2005, the complainant, a French farmers' association, submitted an infringement complaint to the European Commission against the French authorities concerning the parallel imports and the personal parallel imports of veterinary medicinal products to France. It alleged that France did not allow veterinarians, farmers, pharmacists and other retail distributors to have access to the simplified authorisation procedure for parallel imports of VMPs. This would still be the case even if France had introduced a simplified procedure of authorisation for parallel imports of VMPs, as a result of the complainant's previous infringement complaint concerning parallel imports of VMPs in France.

4. On 2 July 2007, the Commission informed the complainant that, following his infringement complaint, it decided to open infringement proceedings against the French authorities. In this respect, the Commission sent a letter of formal notice to the French authorities. It took the view that the French authorities infringed the provisions of Article 28 EC Treaty (now Article 34 TFEU) by " *making the successive parallel importations and the personal parallel importations of VMP subject to excessive conditions* ".

5. On 6 May 2008, the French authorities modified the national legislation concerning the authorisation proceedings for imports of VMPs.

6. On 1 August 2008, the complainant forwarded to the Commission its comments concerning the above legislative modification.

7. On 24 October 2008, the Commission informed the complainant that it had sent a complementary letter of formal notice to the French authorities concerning the ongoing infringement proceedings. The Commission considered that the French authorities infringed the provisions of Article 28 EC Treaty (now Article 34 TFEU) by subjecting personal parallel imports of veterinary products to the exercise of an activity within an authorised establishment (that is, to the condition that the distributor holds an authorisation for wholesale distribution of VMPs) [5] .

8. On 30 July 2009, the Commission sent to the complainant a summary of the French authorities' reply to its letter of formal notice. It invited the complainant to submit comments on the position expressed by the French authorities.

9. On 19 August 2009, the complainant sent its comments.

10. On 11 January 2010, the Commission informed the complainant that it intended to close the infringement proceedings against the French authorities concerning the parallel imports of VMPs. It invited the complainant to submit its observations on its above intention.

11. On 29 January 2010, the complainant sent its observations.

12. On 22 February 2010, the Commission replied to the complainant's letter. It took the view that the complainant did not submit any new arguments in support of its allegations. Therefore, it decided to dismiss its infringement complaint.

13. Subsequently, the complainant and the Commission had an exchange of correspondence on the matter.

14. On 3 May 2010, the Commission informed the complainant that it decided to close the infringement case against the French authorities. It invited the complainant to submit a new complaint if it had new elements in support of its allegations.

15. The complainant was dissatisfied with the Commission's position and turned to the European Ombudsman.

The subject matter of the inquiry

16. In its original complaint, the complainant made the following allegation and claim, which were included in the inquiry:

Allegation:

The arguments provided by the Commission in its decision closing the infringement complaint were insufficient and unconvincing.

Claim:

The Commission should either cancel its decision to close the infringement complaint, or open a new infringement proceeding against the French authorities.

17. The Ombudsman opened an inquiry and asked the Commission to clarify certain aspects relating to the provisions of the French national legislation [6] .

The inquiry

18. On 10 August 2010, the Ombudsman opened an inquiry and sent the complaint to the Commission with a request for an opinion.

19. On 13 December 2010, the complainant sent the Ombudsman a further letter concerning its case.

20. On 14 December 2010, the Commission sent its opinion, which was forwarded to the complainant with an invitation to submit observations. The complainant sent its observations on 18 January 2011.

21. On 15 April 2011, the Ombudsman asked the Commission for further information regarding certain aspects of the case. The Commission replied to the Ombudsman's further inquiries on 1 August 2011.

22. In the meantime, on 8 June 2011, in accordance with Article 3(2) of the Ombudsman's Statute [7] , the Ombudsman's services carried out an inspection of the relevant documents on the Commission's file. The Commission considered the inspected documents to be confidential [8] . This meant that the public and the complainant could not have access to them.

23. The Commission's reply to the Ombudsman's request for further information and the report on the inspection of the files were forwarded to the complainant, which submitted its observations on the Commission's reply to the Ombudsman's request for further information on 12 September 2011.

24. On 6 February 2012, the Ombudsman made a draft recommendation to the Commission, in accordance with Article 3(6) of his Statute.

25. The Commission's reply to the draft recommendation was sent to the complainant with an invitation to submit observations. The complainant sent its observations on 11 July 2012.

26. On 4 October 2012, the complainant sent the Ombudsman a further letter concerning its case.

The Ombudsman's analysis and conclusions

A. Alleged failure to provide a sufficient and convincing explanation

Arguments presented to the Ombudsman

27. In its complaint to the Ombudsman, the complainant pointed out that it is particularly difficult to make parallel and, in particular, personal parallel imports of VMPs to France. Although such products may be similar to those VMPs which are already authorised on the French market, the parallel imports of VMPs are in fact only open to national wholesale dealers because only the latter may apply for the 'simplified authorisation procedure', that is to say, for a special procedure that is more rapid than the marketing authorisation procedure [9] . The parties entitled to the retail distribution such as pharmacies, independent veterinaries and farmers do not have access to the 'simplified authorisation procedure'. Moreover, they cannot import VMPs for their personal needs (for instance, farmers cannot import VMPs for the needs of their own farms), that is to say, to make personal parallel imports. In the complainant's view, the French legislation thus infringed the provisions of the EU law.

28. Furthermore, the complainant outlined that, in October 2008, the Commission sent a complementary letter of formal notice to the French authorities concerning the issue of personal parallel imports of VMPs. By doing so, the Commission appeared to have considered that: a) the EU provisions governing personal parallel imports also apply to VMPs; and b) the French legislation did not comply with the above EU provisions. The Commission failed to explain why it changed its position in 2010 and decided to close the infringement proceedings against the French authorities.

29. Finally, it referred to the specific case of a Spanish wholesale dealer that applied to the French authorities for parallel import authorisation for VMPs pursuant to the simplified procedure. The French authorities denied such authorisation because the dealer did not hold an authorisation for distribution delivered by the French authorities but only held an authorisation for distribution delivered by the Spanish authorities.

30. In its opinion, the Commission first took the view that the personal parallel imports of VMPs could not be authorised if the relevant provisions of the Directive are not complied with.

31. The fact that the complainant's allegations must, *inter alia* , be analysed in light of the provisions of the Treaty relating to the free movement of goods (Articles 34-36 TFEU) does not imply that the provisions of the Directive relating to importation, possession, distribution, delivery and pharmacovigilance do not apply. In this respect, Article 9 of the Directive provides that " *no veterinary medicinal product may be administered to animals unless the marketing authorization has been issued according to the national rules in force.* "

32. Furthermore, the Commission underlined that, when making personal parallel imports of

VMPs, a farmer would in fact be deciding on the treatment to be administered to animals used for the production of foodstuffs for human consumption. Such a situation cannot be compared to a situation involving a patient who makes personal parallel imports of medicine for his own use, as suggested by the complainant in its infringement complaint. The national authorisation for importing a VMP is indeed linked to both its marketing and its usage. The Directive provides for a more restrictive regime for the import of VMPs than for the regime of importations of plant protection products because the VMPs are used on animals for foodstuffs production. The link between the marketing authorisation and the use of the VMPs makes personal parallel imports of VMPs difficult, if not impossible. Moreover, the delivery of VMPs could be done solely on the basis of a prescription in order to protect human and animal health. Thus, before prescribing a VMP, a veterinarian should check the health condition of the animals. The role of guardian assigned to veterinarians could be jeopardised if, without their intervention, a farmer could possess significant quantities of VMPs imported from other Member States. The Commission thus took the view that it was misleading to use the word 'personal' when speaking about parallel imports of VMPs, given that these imports are ultimately made for a professional and not for a personal use.

33. As regards the parties entitled to apply for authorisation to import VMPs into France under a simplified procedure, the Commission explained that, according to Article 1(17) of the Directive, the importation of VMPs is a wholesale trade activity, for which an authorisation for distribution is required. Parallel imports are available to all economic operators, including farmers, if they fulfil the conditions of the Directive which do not relate to marketing authorisation [10] , but to pharmacovigilance and tracking of VMPs. Farmers who do not fulfil the above requirements are not authorised to make wholesale imports of VMPs. The Commission admitted however that, in practice, only the wholesale dealers could comply with the above Directive obligations. As regards veterinarians, Article 70 of the Directive allows veterinarians providing services in a Member State to take with them and administer to animals in another Member State small quantities of ready-made veterinary medicinal products not exceeding daily requirements.

34. With particular regard to the granting of authorisations (according to the simplified procedure) for parallel imports of VMPs solely to national wholesale dealers, the Commission stated that a distributor authorised to distribute VMPs in a Member State other than France could apply for and obtain authorisation (following the simplified procedure) to make parallel imports of VMPs already authorised on the French market, if it fulfils the conditions relating to freedom of services and establishment.

35. In its observations, the complainant pointed out that the Commission failed to put forward convincing arguments as to why, in January 2010, it had changed its position. It further outlined that, previously, the Commission had constantly argued that the provisions of the Directive did not concern the parallel imports which were covered by the provisions of the Treaty concerning the freedom of movement of goods. In the complainant's view, the three Directives covering imports of medicinal products (91/414/EC [11] , 2001/82/EC and 2001/83/EC [12]) pursue the same objective as the Directive, namely, the elimination of trade barriers for the medicinal products within the internal market. In this respect, in its written observations, submitted before

the Court of Justice in another case [13] , the Commission maintained that there was no distinction between the rules governing the parallel imports of VMPs and plant protection products. The Commission had also reaffirmed a similar view in its reasoned opinion sent to the French authorities in 2003 in the framework of the earlier infringement procedure concerning parallel imports of VMPs [14] . In the reasoned opinion it issued at the time, the Commission argued that the French legislation infringed the provisions of the Treaty relating to the free movement of goods with regard to both parallel imports and personal parallel imports of VMPs. In the complainant's view, directives 91/414/EC and 2001/82/EC impose similar obligations to the Directive, as regards the marketing authorisation and the usage of a VMP and of a plant protection product. Furthermore, the Court of Justice ruled that farmers could make personal parallel importations of plant protection products which have already been authorised in their Member States, subject to a prior (simplified) marketing authorisation [15] . Thus, the complainant refuted the Commission's argument that the use of the wording " *personal parallel imports* " for VMPs is misleading.

36. The complainant also outlined that the Commission wrongly appears " *to assimilate the personal parallel imports of VMPs with the self-prescription* ". In its view, the Commission wrongly assumes that a farmer who holds parallel import authorisations will try to stock up on veterinary medicines without prescription. According to the Court of Justice case-law, the risk of committing criminal offences should not hinder the functioning of the internal market. In addition, the Directive prohibits self-prescription.

37. In light of the above, the complainant emphasised that parallel imports should not be subject to a wholesale distribution authorisation and thus to the conditions applicable to the wholesale dealers.

38. Finally, the complainant pointed out that in its opinion, the Commission ignored the complainant's submission regarding the specific case of a Spanish wholesale dealer that applied before the French authorities for parallel import authorisation for VMPs (according to the simplified procedure). The French authorities denied such authorisation because the dealer did not hold an authorisation for distribution delivered by the French authorities but only held an authorisation for distribution delivered by the Spanish authorities. The complainant stressed that the above refusal by the French authorities constitutes a clear infringement of the EU law.

39. In its subsequent reply to the Ombudsman's specific questions concerning the Directive, the Commission clarified that the Directive does not provide for specific provisions concerning parallel imports. Therefore, the provisions of the Treaty relating to the free movement of goods (Articles 34-36 TFEU) are the only provisions applicable. These provisions endorse the rules on the basis of which a medicinal product can be imported to a Member State in parallel, after having obtained an authorisation in that Member State, granted according to the 'simplified procedure'.

40. In this respect, according to Articles 34-36 TFEU, the national authorities must check whether the imported product is essentially similar to a product that has already received marketing authorisation in the Member State of destination. If that is the case, the national

authorities will apply the provisions of the Treaty (instead of the Directive) and grant an authorisation for the concerned product according to a " *simplified* " procedure. Under this procedure, the applicant needs to provide less information than is required for an application for a " *normal* " marketing authorisation provided that: (i) the imported product has been granted a marketing authorisation in the Member State of origin; and (ii) the imported product is essentially similar to a product that has already received marketing authorisation in the Member State of importation.

41. However, the rules on the free movement of goods harmonised by the Directive do not limit themselves to the marketing authorisation. In the Commission's view, although the Directive's rules relating to marketing authorisation do not apply to parallel imports of VMPs (because a VMP may only be imported by parallel importation if it has been previously authorised on the market of the Member State of importation), the other provisions of the Directive relating to imports of VMPs (namely, possession, distribution, dispensing, fabrication or pharmacovigilance) are nevertheless applicable to parallel imports.

42. The Commission outlined that the provisions of Article 34 TFEU do not cover all aspects relating to importation, possession, distribution, dispensing and pharmacovigilance. The above-mentioned provisions of the Treaty cover only the non-harmonised aspects regarding imports of VMPs.

43. The Commission further took the view that the rules concerning the simplified authorisation procedure applicable to parallel imports of plant protection products could not be applied by analogy to parallel imports of VMPs. In this respect, it pointed out that the Court of Justice admitted that the rules governing plant protection products and medicinal products are different and these rules cannot be applied by analogy [16] . In the Commission's view it would be dangerous to apply for instance the rules concerning plant protection products to medicinal products for human use. The Directive provides for certain " *inviolable* " rules [17] , which apply even in the case of parallel imports of VMPs. Thus, any import of VMPs which is done by an undertaking for commercial purposes (re-sale) or by a farmer for the needs of his own farm, must comply with all the provisions of the Directive, except for those relating to the marketing authorisation. The whole trading chain (including the wholesalers, the pharmacists and the veterinarians) must comply with certain obligations, the purpose of which is to prevent the final consumer (for instance farmers) from buying these products in bulk. The Commission considered that a simplified procedure (which complies with the provisions of Articles 34-36 TFEU) is sufficient to verify whether a parallel import of VMPs is similar to a product that has already received marketing authorisation in the Member State of destination. However, in addition to this verification, the other conditions established by the Directive relating to distribution, possession and delivery of VMPs should also be complied with.

44. The Commission reiterated that the undertakings that make parallel imports of VMPs must hold an authorisation for distribution [18] . It is only in exceptional circumstances that the Directive allows derogations from the above rule [19] . Thus, the farmers cannot be placed in a privileged situation compared to other undertakings that make parallel imports of VMPs. It follows that the Commission cannot intervene with the national authorities further to simplify the

already simplified procedure for parallel imports, if the economic operator in question does not fulfil the criteria set down by the Directive (including those relating to keeping stocks of VMPs).

45. Moreover, every holder of an authorisation for parallel imports can obtain the product covered by the said authorisation. Thus, farmers would be able to stock up on VMPs, even in the absence of a prescription, if they were holders of such authorisations for parallel imports. In addition, there is always a risk relating to the conditions in which these products are stocked. For the above reasons, the Directive makes a clear distinction between undertakings trading in VMPs and those using such products.

46. Regarding the case of the Spanish wholesale dealer who was not authorised to make parallel imports into France, the Commission pointed out that " *it understood that the simplified authorisation procedure provided for by the French legislation is normally available to every wholesale dealer who is authorised to distribute VMPs in a Member State* " [20] .

47. In its observations on the Commission's reply to the Ombudsman's further inquiries, the complainant reiterated that the Commission had still not taken a clear position on the specific case referred to it, namely, that the French authorities had refused to grant access to the simplified procedure to a Spanish wholesale dealer who was authorised to distribute VMPs in Spain. In its view, if the wholesale dealers authorised to distribute VMPs in other Member States had access to the simplified procedure in France, the French farmers would be able to obtain VMPs distributed in these Member States, at better prices than those set by the national wholesale dealers. However, French legislation reserved access to the simplified procedure to national wholesale dealers only, and thus infringed the provisions of Articles 56 and 62 of the TFEU concerning freedom of services.

48. With regard to the prohibition preventing farmers, veterinarians and pharmacists from making parallel imports of VMPs (thus from having access to the simplified procedure), the complainant noted that the Commission merely reiterated its previous arguments. The complainant further stated that the Directive was mainly adopted to facilitate the trade of VMPs in the EU [21] . In its view, the objective of health protection is ensured because the Directive harmonised the " *inviolable* " rules referred to by the Commission in its additional opinion. However, the Commission failed to recognise that, under the Directive, each stakeholder assumes different responsibilities [22] .

49. The complainant reiterated its arguments that the EU rules [23] relating to parallel imports of plant protection products could be applied by analogy to parallel imports of VMPs. In its view, farmers who hold a permit for parallel trade (delivered according to a simplified authorisation procedure) could declare in advance, to the prefect of their region, the required quantities of VMPs and the date of their importation. The above procedure should be sufficient to safeguard human and animal health, given that it imposes strict requirements in terms of control and surveillance. In the complainant's view, the farmers who make parallel imports of VMPs should not have to comply with the same obligations established by the Directive for wholesale dealers.

50. Finally, the complainant requested that the Commission continue the infringement

procedure against the French authorities, " *at least* " as regards the access to the simplified procedure to wholesale dealers authorised to distribute VMPs in other Member States. In this respect, the complainant submitted that, even if its complaint could not lead to a favourable outcome as regards access to the simplified authorisation procedure for farmers, veterinarians or pharmacists, the Commission should at least ensure that wholesale dealers authorised to distribute VMPs in other Member States can make parallel imports of VMPs to France and have access to the above procedure.

The Ombudsman's assessment leading to a draft recommendation

51. At the outset, the Ombudsman pointed out that his assessment of the present case was going to be limited to the review of the Commission's explanation on the following three issues. First, whether (i) farmers could be allowed to make **personal** parallel imports of VMPs. Second, whether (ii) parallel imports of VMPs are in general open to farmers, veterinarians and pharmacists or to wholesale dealers only and, if so, under which conditions. Finally, (iii) the Commission's explanation provided as regards the case of the Spanish wholesale dealer to which the French authorities refused to grant an authorisation to make parallel imports of VMPs, according to the simplified procedure.

As regards issues (i) and (ii)

52. The Ombudsman first pointed out that, as rightly argued by the Commission, specific harmonised rules exist under EU law [24] , which apply to imports of each category of medicinal products, that is to say, to medicinal products for human use, to VMPs and to plant protection products.

53. In this respect, the different treatment afforded to the different specific imports could be justified by their distinct purposes. Consequently, the conditions under which a Member State may authorise parallel imports of VMPs determine *de facto* who is entitled to make such imports. It follows that, compared with parallel imports of medicinal products for human use, the parallel imports of plant protection products and of VMPs are made for a professional and not for personal use. Although a farmer will not necessarily import a VMP in order to resell it, such imports are certainly part of his/her commercial activity. It is reasonable to assume that the animals to which the VMP is administered could subsequently be intended for sale and for public consumption.

54. In these circumstances, the risks deriving from an improper use of imported VMPs for human and animal health are obvious. As the Commission rightly pointed out, in light of the public interest associated with the safeguarding of human and animal health, the national authorities must have the choice to check whether a VMP in question has already been authorised in the Member State of importation and thus could be treated as a parallel import. If that is the case, there could be parallel importation of the VMP in question on the basis of an official authorisation.

55. The Ombudsman went on to state that it is further reasonable to consider, as the Commission did, that the responsibility to carry out an assessment on the consequences of the import of a VMP (prior to an authorisation) must reside with the national authorities and cannot be exercised by individuals such as farmers. Indeed, the Directive establishes a mechanism of control for all VMPs placed on the market of a Member State [25] , which must be put in place by the national authorities.

56. As a result, it appears that all potential importers, including farmers, must comply with an obligation to undergo an authorisation procedure in the case of parallel imports of VMPs, including **personal** ones. Thus, the complainant's argument that veterinarians, farmers, pharmacists and other retail distributors should be allowed to make **personal** parallel imports of VMPs without undergoing **any** authorisation procedure (as is the case with personal parallel imports of medicinal products for human consumption) could not be upheld.

57. The further question arose as to whether or not the authorisation for parallel imports of VMPs should be granted following a simplified procedure.

58. According to the Commission's explanation, wholesale as well as retail dealers, such as farmers, in France have access to the simplified authorisation procedure [26] . In the complainant's view, this was not the case [27] . The Ombudsman noted in this respect the evidence submitted by the complainant, which was not contested by the Commission, on the basis of which it appears that the French legislation indeed **excludes** veterinarians, farmers, pharmacists and other retail distributors from the simplified authorisation procedure for parallel imports of VMPs, which is only available to wholesale dealers [28] .

59. In addition, the Ombudsman noted the Commission's subsequent view that, apart from " *a simplified authorisation* ", the farmers, veterinarians, pharmacists and other retail distributors need to comply with a number of specific provisions of the Directive in order to make parallel imports (including personal ones), namely, the provisions relating to distribution, possession or dispensing of VMPs and pharmacovigilance [29] . It would appear, therefore, that the Commission supports the French authorities' position that farmers, veterinarians, pharmacists and other retail distributors cannot make parallel imports of VMPs because it would be difficult for them to comply with the above specific provisions.

60. The Ombudsman was of the opinion that, in light of the aforementioned Commission's view and of the French position referred to above, which was apparently supported by the Commission, it is hard to understand why the Commission considers that, as a matter of principle, parallel imports of VMPs are open in France to **all** economic operators, including farmers, veterinarians, pharmacists and other retail distributors.

61. Moreover, the Commission's explanation did not appear to be coherent. On the one hand, the Commission stated that the Directive does not concern parallel imports but that the relevant articles of the Treaty apply instead. On the other hand, the Commission took the view that the specific provisions of the Directive, namely, those contained in articles 1(17), 9, 10, 67, 70 and

74 and relating to distribution, possession, dispensing of VMPs and pharmacovigilance, do apply to parallel imports of VMPs.

62. However, even if the Commission's view that some provisions of the Directive, which may be applicable to parallel imports, could be accepted, the Commission's enumeration of such applicable provisions [30] did not appear to be entirely convincing.

63. For instance, the exceptions provided for in (a) Article 10 of the Directive and which concern the conditions under which a veterinarian could administer to an animal a VMP that is not authorised in that Member State and (b) Article 70 of the same Directive and which concern the conditions under which veterinarians providing services in another Member State are allowed to take with them and administer to animals VMPs that are not authorised for use in that Member State, refer to VMPs **which are not authorised** for use in the Member State in which the veterinarian provides his services. Thus, the above provisions could not apply to parallel imports, which by definition concern products that, according to article 9 of the Directive, have already been authorised on the market of the Member State of importation.

64. Similarly, the obligation of pharmacovigilance provided for in Article 74 seems rather to concern the holder of the marketing authorisation rather than the importer in parallel.

65. In the Ombudsman's further view, the fact that the VMPs are in most cases administered on the basis of a prescription and under the supervision of a veterinarian (Article 67 of the Directive) does not lead to the conclusion that, subject to the conditions to be specified immediately below, these products should be necessarily purchased on the national market from official distributors and cannot be imported by parallel importation from another Member State by veterinarians, farmers, pharmacists and other retail distributors. These conditions are that (i) the products in question are parallel imports by reference to a product which already has a marketing authorisation in the Member State of importation; and (ii) in addition, the importer has applied for and obtained an authorisation from the Member State of importation.

66. Overall, the Ombudsman understood that the provisions of the Directive concern the conditions under which a VMP could be placed on the market of the Member States for the first time and refer mainly to the requirements that **the wholesale dealers** should fulfil in this respect [31] .

67. Furthermore, the Ombudsman added that, as the complainant rightly pointed out, the simple risk of an infraction such as the abusive usage of imported VMPs by farmers does not appear to be a proportionate means of achieving the objective pursued. Nor does it therefore justify the resulting restriction to trade between Member States. The Ombudsman agreed with the complainant that it is not sufficient for the Commission to assume that there would be an increased risk of fraud if farmers were allowed to import VMPs for the needs of their farms.

68. In support of its view, the Commission also argued that the regime of imports of VMPs set up by the Directive is more restrictive than the one governing the parallel imports of plant protection products (Directive 91/414/EC). In this respect, the same link as the link between

marketing authorisation and the usage of a VMP is imposed by the harmonised rules governing the imports of plant protection products [32] . EU legislation provides very specific and detailed rules for imports of both VMPs and plant protection products. These relate to possession, distribution and controls carried out by the Member States to verify whether the products placed on the **market and their use** comply with the provisions of the EU legislation.

69. Moreover, the Commission did not show or even try to explain why, in its view, the rules concerning parallel imports of plant protection products, and in particular the case-law of the Court of Justice relating to parallel imports of plant protection products, cannot, as the complainant argued, be applied by analogy to parallel imports of VMPs.

70. In this respect, the Ombudsman did not see why the Commission could not draw inspiration, for dealing with parallel imports of VMPs, from the regime of simplified authorisation procedure for plant protection products. As the complainant outlined, the simplified authorisation procedure could include adequate measures in order to reinforce the tracking of imported VMPs and their correct use. Such authorisation could be personal and the farmers could be under the obligation to indicate in advance the required quantities to be imported. In any event, as the Ombudsman argued above, the Commission's statement that farmers holding parallel import authorisations will try to stock up on veterinary medicines without a prescription was merely an assumption.

71. In light of the above, the Ombudsman was not satisfied with the explanations provided by the Commission in order to justify what the Ombudsman understood to be its position that, in addition to the simplified authorisation procedure for parallel imports of VMPs, all importers must comply with the provisions of the Directive relating to distribution, possession, dispensing of VMPs and pharmacovigilance.

As regards issue (iii)

72. The Ombudsman noted that the Commission stated that, under the French legislation, the simplified authorisation procedure is normally open to every wholesale dealer who is authorised to distribute VMPs in a Member State (third issue) [33] . However, the complainant submitted evidence to show that the French authorities had refused to grant an authorisation according to the simplified procedure to a Spanish wholesale dealer who fulfilled all the requirements of the Directive. In light of the Commission's above statement, it could appear that, as suggested by the complainant, the above refusal of the French authorities could indeed constitute an infringement of the EU legislation. However, the Commission omitted to inform the Ombudsman about the further steps taken in this respect, in spite of his specific question regarding this matter. If the Commission's position was due to the fact that issue (iii) was at the time pending before a French Court, this was not a reason for the Commission to remain silent about this matter [34] .

73. In light of the above, the Ombudsman found that the Commission's failure to provide an appropriate justification for its decision to close the complainant's infringement complaint concerning parallel imports of VMPs, despite the opportunity afforded to it by the Ombudsman's

inquiry and the Ombudsman's further specific question in this respect, constituted an instance of maladministration.

In light of the above finding of maladministration, the Ombudsman made the following draft recommendation, in accordance with Article 3(6) of the Statute of the European Ombudsman.

The Commission should deal appropriately with the arguments put forward by the complainant, continue to monitor the specific situation described by the complainant, and consider re-opening the infringement inquiry, if indeed the implementation of the EU law by the French authorities is not compatible with what appears to be the Commission's understanding of that same law.

The arguments presented to the Ombudsman after his draft recommendation

[35]

74. The Commission informed the Ombudsman that it was in the process of investigating further the case of wholesale dealers to whom the French authorities **refused** to grant authorisation to make parallel imports of VMPs pursuant to the simplified procedure. In this respect, the Commission noted that, if the French authorities indeed refused to recognise the distribution authorisations held by wholesale dealers and which were delivered by the competent authorities of other Member States certifying the origin of VMPs imported in parallel, this would constitute an infringement of EU law. The Commission has thus opened new infringement proceedings against the French authorities [36] .

75. The Commission also explained that it had not previously considered that grievance because the complainant informed it about this aspect shortly before lodging its complaint with the Ombudsman. In fact, the matter was not considered in the framework of the initial infringement proceedings against the French authorities. The complainant was duly informed of this fact. Initially, the Commission believed that the French authorities' wrong interpretation of the provisions of the Directive would subsequently be corrected by the national courts. Given that, in his draft recommendation, the Ombudsman informed the Commission that the French courts had rejected the complainant's appeal against the decision of the French authorities to refuse a Spanish wholesale dealer an authorisation for parallel imports of VMPs pursuant to the simplified procedure, the Commission decided to request more information from the French authorities on the matter. The infringement proceedings are thus ongoing.

76. In its reply, the Commission also noted that its legal analysis as regards the conditions under which an economic operator may make parallel imports of VMPs is very similar to that of the Ombudsman. It however considered useful to clarify certain aspects of its position as follows.

77. The Commission noted that the provisions of the Directive on the marketing of VMPs are not applicable to parallel imports. Those provisions are replaced by national simplified authorisation procedures, which have to comply with the provisions of Article 34 TFEU.

However, this does not mean that the other provisions of the Directive should be set aside. In the Commission's view, if the economic operators comply with the relevant provisions of the Directive, they can benefit from the simplified authorisation procedure and make parallel imports. The parallel importation of VMPs remains a wholesale activity corresponding to the definition provided in Article 1(17) of the Directive. If a farmer intends to make parallel imports of VMPs, he must first obtain an authorisation for wholesale distribution.

78. The Commission further noted that, Articles 11 (and not 10, as the complainant argued) and 70 of the Directive lay down strict conditions under which a veterinarian may use imported VMPs in a Member State where they are not authorised. Similarly to a farmer, if a veterinarian intends to make parallel imports of VMPs (which constitutes a commercial activity), he must first obtain an authorisation for wholesale distribution.

79. In the Commission's view, the obligation of pharmacovigilance provided for in Article 74 of the Directive, which concerns holders of marketing authorisations, applies *mutatis mutandis* to holders of authorisations for parallel imports. The holder of a marketing authorisation assumes the obligation of pharmacovigilance for the medicine he or she places on the market but he or she cannot assume responsibility for all VMPs with regard to which an authorisation for parallel imports has been issued on the basis of their similarities with his or her medicine. Similarly, the holder of a marketing authorisation cannot assume the obligation of pharmacovigilance for VMPs which are distributed in another Member State on the basis of an authorisation for parallel imports. Thus, Member States must ensure that the holder of a parallel import authorisation assumes the same obligation of pharmacovigilance as the holder of a marketing authorisation.

80. The Commission reiterated that, in its view, the differences between plant protection products and VMPs prevent the case-law of the Court of Justice relating to parallel imports of plant protection products from being applied by analogy to VMPs. However, the interpretation of EU law can only be decided by the Court. The Commission also noted that the complainant itself submitted in its observations that, if its complaint cannot lead to a favourable outcome as regards access to the simplified authorisation procedure for farmers, veterinarians or pharmacists, the Commission should at least ensure that wholesale dealers authorised to distribute VMPs in other Member States can make parallel imports of VMPs to France and have access to the above-mentioned procedure.

81. In light of foregoing, the Commission reiterated that it will not reopen the infringement inquiry against the French authorities as regards the issue of access to the simplified authorisation procedure for farmers, veterinarians or pharmacists.

82. In its observations, the complainant, in sum, contested the Commission's views that, except for the simplified authorisation procedure, all the requirements of the Directive apply equally to holders of a marketing authorisation and to holders of a parallel import authorisation, especially as regards the obligation of pharmacovigilance. The complainant further maintained that the rules concerning parallel imports of plant protection products may be applied by analogy to parallel imports of VMPs. However, it noted that the issue of access to the simplified authorisation procedure for parallel imports of VMPs by farmers, veterinarians and pharmacists

could be 'suspended' pending a future decision of the Court of Justice.

83. The complainant outlined that, should wholesale dealers have access to the simplified authorisation procedure and be able to distribute VMPs in France, a satisfactory settlement of its complaint will have been attained. It also emphasised that the Commission did not initially include the above matter in the infringement proceedings which led to its complaint to the Ombudsman. The matter is now being dealt with by the Commission in the new infringement proceedings which it opened following the Ombudsman's draft recommendation.

84. The complainant further stated that, on 29 June 2012, it informed the Commission that, at present, the French authorities apparently recognise authorisations for distribution issued to wholesale dealers by the competent authorities of another Member State. However, it appears that the French authorities still require wholesale dealers to possess a French document called an ' *autorisation d'exploitation* ' for parallel imports of VMPs. The complainant challenged before the Commission the requirement to hold such an authorisation. Thus, on 29 June 2012 [37] , it submitted a new infringement complaint to the Commission concerning the above matter.

85. In its communication of 4 October 2012, the complainant informed the Ombudsman about the subsequent steps taken by the Commission with regard to its new infringement complaint against the French authorities. In this respect, the complainant referred to two infringement proceedings opened by the Commission: (i) the first one, to which the Commission referred in its reply to the draft recommendation, concerns the French authorities' failure to recognise the distribution authorisations delivered to wholesale dealers by the competent authorities of other Member States certifying the origin of VMPs imported in parallel; (ii) the second one concerns the requirement that wholesale dealers from other Member States must also be in possession of an ' *autorisation d'exploitation* ' in order to make parallel imports of VMPs in France. The Commission has already closed the first infringement complaint because it concluded that the French legislation in question complies with EU law as regards the recognition of distribution authorisations delivered to wholesale dealers by the competent authorities of other Member States certifying the origin of VMPs imported in parallel .The complainant did not oppose such action. However, the Commission is still investigating the requirement that wholesale dealers have to hold the said ' *authorisation d'exploitation* ' in order to be able to make parallel imports of VMPs in France. The complainant presented detailed arguments to demonstrate that the requirement of an ' *authorisation d'exploitation* ' breaches EU legislation.

The Ombudsman's assessment after his draft recommendation

86. The Ombudsman first points out that, following his draft recommendation, the Commission decided to open infringement proceedings with regard to the French authorities' refusal to recognise the distribution authorisations delivered to wholesale dealers by other Member States. According to the complainant, these proceedings are now closed and it did not challenge this closure in its observations. The Ombudsman is pleased to note that the Commission did not abandon the issue but followed up the complainant's subsequent complaint

concerning specific national obstacles to the parallel importation of VMPs by wholesale dealers, namely, the requirement to possess an ' *autorisation d'exploitation* '. This shows that the Commission has acted diligently and is carefully monitoring the situation. The Ombudsman therefore considers that, to date, the Commission has taken adequate measures to implement his draft recommendation. He has therefore decided to close the case.

87. As regards the Commission's handling of the complainant's new infringement complaint, should the complainant be dissatisfied with the outcome of these infringement proceedings, it could submit a new complaint to the Ombudsman.

B. Conclusions

On the basis of his inquiry into this complaint, the Ombudsman closes it with the following conclusion:

The Commission has taken adequate measures to implement the Ombudsman's draft recommendation.

The complainant and the Commission will be informed of this decision.

P. Nikiforos Diamandouros

Done in Strasbourg on 12 December 2012

[1] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, OJ L311, 28.11.2001, p.1, as amended by Directive 2004/28/EC of the European Parliament and the Council of the 31 March 2004, OJ L 136, 30.04.2004, p. 58.

[2] Articles 5 and 12 of Directive 2001/82/EC.

[3] COM(2003) 839 final.

[4] Case C-62/90 *Commission v Germany* ,[1992] ECR I-2575 and Case C-212/03 *Commission v France* [2005] ECR I-4213.

[5] In French : " *En soumettant les importations personnelles parallèles des médicaments vétérinaires a l'exercice d'une activité dans le cadre d'un établissement autorisé (c'est à dire lorsque l'operateur dispose légalement de la qualité de distributeur en gros de médicaments vétérinaires), la France avait manqué aux obligations qui lui incombait en vertu de l'article 28 du traite CE (34 TFEU).* "

[6] The Ombudsman's questions were as follows:

" *(1) Who is entitled ('les ayants droit'), according to French legislation, to apply for authorisation under a simplified procedure (as opposed to a marketing authorisation procedure) to import into France veterinary medicinal products ('VMPs') authorised for marketing in the Member State of origin, where the product to be imported is essentially similar to a product already authorised for marketing on the French market?*

Could independent veterinarians, farmers, pharmacists, or other retail distributors apply for authorisation using the simplified procedure?

(2) Could a wholesale distributor, authorised to distribute VMPs in a Member State other than France, apply for and obtain authorisation (following the simplified procedure) to make parallel imports of VMPs already authorised for marketing on the French market?

(3) Could independent veterinarians, pharmacists, or private individuals make their own parallel imports of authorised VMPs, namely, VMPs authorised for marketing in the Member State of origin, where the product to be imported is essentially similar to a product already authorised for marketing on the French market? "

[7] Article 3(2) of the Ombudsman's Statute reads as follows: " *The Community institutions and bodies shall be obliged to supply the Ombudsman with any information he has requested from them and give him access to the files concerned. Access to classified information or documents, in particular to sensitive documents within the meaning of Article 9 of Regulation (EC) No 1049/2001, shall be subject to compliance with the rules on security of the Community institution or body concerned.* "

[8] The documents inspected were the following: (i) exchange of correspondence between the Commission and the French authorities - (a) note de service (DGAL/SDSPS/N2005-8160) du Ministère de l'Agriculture et de la pêche, dated 20 June 2005, (b) note (N°2942), dated 17 October 2005, (c) note (N° 2910-T07OP309/RH; AGRAP - RP 783/07), dated 15 October 2007, (d) note (N° 3784-T08OP388/RH; AGRAP - RP/1045/08) dated 23 December 2008, (e) letter to the French Representation, dated 29 June 2007, (f) letter to the French Representation, dated 17 October 2008); (ii) exchange of correspondence between the Commission's services - (a) note to ENTR/F2 (D(2005)33211, dated 11 November 2005, (b) note to the Legal Service, DG AGRI and DG SANCO (D(2008)25520), dated 13 August 2008, (c) note to the Legal Service, DG AGRI and DG SANCO (D(2009)9936), dated 31 March 2009, (d) note to ENTR/F2 (D(2009)26287), dated 11 August 2009, (e) note to ENTR/F2(D(2009)38760), dated 4 December 2009, (f) ten internal notes (" *fiches NIF* ") drafted from 2007 to 2010, retracing the background of the complainant's complaint, (g) two internal notes entitled " *Document de travail* ", (h) exchange of e-mails between the Commission's services relating to the complainant's complaint, dated 28 August 2008, (i) exchange of e-mails between the Commission's services relating to the complainant's complaint, dated 19 January 2007, (j) exchange of e-mails between the Commission's services relating to the complainant's complaint, dated 27 April 2009, (k) exchange of e-mails between the Commission's services relating to the complainant's

complaint, dated 3 July 2009, (I) exchange of e-mails between the Commission's services relating to the complainant's complaint, dated 31 August 2010); and (iii) decision of the French Supreme Administrative Court (Conseil d'Etat) of 12 June 2006 (this document was not confidential).

[9] The simplified procedure is intended to check that the imported VMPs do indeed concern products which are very similar to VMPs that had been already authorised in France.

[10] In French: " *Les importations parallèles sont accessibles à l'ensemble des operateurs économiques, même aux éleveurs, mais a la condition que ces operateurs répondent aux exigences posées par la directive 2001/82/EC, autres que celles qui régissent l'autorisation de mise sur le marché* ".

[11] Directive 91/414/EC of 15 July 1991 concerning the placing of plant protection products on the market OJ *L 230, p. 1.*

[12] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.

[13] The complainant referred to Case C-260/06 *Escalier* and C-261/06 *Bonnarel* , [2007] ECR I-9717.

[14] The complainant referred to the reasoned opinion sent by the Commission to the French authorities in 2003 in the framework of the first infringement proceeding concerning parallel imports of VMPs .These were the first infringement proceedings against France (they started following another complaint presented by the complainant) which led to the French legislation being changed, namely, by introducing a simplified procedure of authorisation which did not exist at that time.

[15] See footnote 13 above.

[16] Case C-201/06, *Commission v France* , [2008] ECR I-735.

[17] In this respect, the Commission referred to the following provisions of the Directive: (i) Article 1(17) of the Directive, which provides that the importation of VMPs is a wholesale trade activity, for which an authorisation for distribution is required, according to Article 65; (ii) Article 9, which imposes the obligation to administer only VMPs for which a marketing authorisation has been issued, in accordance with the national rules in force; (iii) Article 67, which lays down that VMPs may be dispensed solely on the basis of a prescription under the strict control of a veterinarian; (iv) Article 70, which allows for the possibility that veterinarians providing services in another Member State be permitted to take with them and administer to animals small quantities of ready-made VMPs not exceeding daily requirements which are not authorized for use in the Member State in which the services are provided; (v) Article 10, which lays down that, only in exceptional cases, a veterinarian may be permitted to administer to an animal a VMP

which is not authorised in the Member State where the product is administered, although it has been authorized in another Member State; (vi) Article 74, which lays down the obligation of pharmacovigilance.

[18] Article 65 of Directive 2001/82/EC.

[19] In this respect, Article 70 of the Directive stipulates that veterinarians providing services in another Member State can take with them and administer to animals small quantities of ready-made veterinary medicinal products not exceeding daily requirements other than immunological veterinary medicinal products which are not authorized for use in the Member State in which the services are provided.

[20] In French: " *la Commission comprend que la procédure simplifiée en cause est normalement ouverte a tout operateur économique autorisé à distribuer en gros des médicaments vétérinaires dans un quelconque Etat membre* ".

[21] The complainant referred, in this respect, to recitals 3, 4, 5, 7, 9, 21 and 22 of the preamble of Directive 2001/82/EC.

[22] For instance, according to Article 74 of Directive 2001/82/EC, the obligation of pharmacovigilance applies only to the holders of the marketing authorisation and not to the wholesale dealers. In support of this interpretation of the provisions of the Directive 2001/82/EC, the complainant referred to Parliament's report of 8 October 2002 concerning the proposals of modification of Directive 2001/82/EC.

[23] The complainant referred both to the Court of Justice case-law and Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p 1.

[24] See footnotes 10 and 11 above.

[25] Article 69 of Directive 2001/82/EC.

[26] See footnote 10 above.

[27] In support of its views, the complainant submitted a document entitled " *Note de service DGAL/SDSPA/N2010-8310, 16 November 2010* ", issued by the French Ministry of Agriculture.

[28] See footnote 27 above, p.6. In French: " *un éleveur d'animaux, un vétérinaire, un pharmacien, ou un groupement agrée au titre de l'article L. 5143-6 ne peuvent pas effectuer pour leur compte des importations parallèles de médicaments vétérinaires* ".

[29] See footnote 17 above.

[30] See footnote 17 above.

[31] In this respect, (i) Article 1(17) of the Directive provides that the importation of VMPs is a wholesale trade activity, for which an authorisation for distribution is required, according to Article 65 and (ii) Article 9 imposes the obligation to administer only VMPs for which a marketing authorisation has been issued, in accordance with the national rules in force.

[32] Article 3(1) of Directive 91/414/EC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, p. 1) reads as follows: " *Member States shall prescribe that plant protection products may not be* **placed** *on the market and* **used** *in their territory unless they have authorized the product in accordance with this Directive* ".

[33] See footnote 20 above.

[34] On 10 January 2012, the complainant informed the Ombudsman's services that the French court of first instance rejected its appeal against the decision of the French authorities to refuse to a Spanish wholesale dealer an authorisation for parallel imports of VMPs, according to the simplified procedure.

[35] The Commission's and the complainant's arguments are summarised to the extent necessary for the purposes of this decision.

[36] Reference CHAP 2012(0901).

[37] Reference CHAP (2012)01882.