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IN THE HIGH COURT OF JUSTICE IN NORTHERN IRELAND

QUEEN'S BENCH DIVISION (JUDICIAL REVIEW)

Norbrook Laboratories Limited's Application [2010] NIQB 44

AN APPLICATION FOR JUDICIAL REVIEW BY

NORBROOK LABORATORIES LIMITED

WEATHERUP J

NoroSeal

[1] This is an application for judicial review of a decision of the Veterinary Medicines Directorate made on 21 September 2009 whereby it determined that a product of the applicant named NoroSeal is a 'veterinary medicinal product by presentation' and therefore requires a marketing authorisation under the Veterinary Medicines Regulations 2008. Mr Vaughan QC, Mr Larkin QC, Mr Scoffield and Ms Gray appeared for the applicant and Dr McGleenan appeared for the respondent.

[2] The grounding affidavit of Edward Enda Haughey, Baron Ballyedmond, Chairman of the applicant company, states that the applicant desired to place a product on the market which would perform the function of a teat seal for cattle. It was decided to include an anti infective at a concentrated level below that regarded as medicinal by the UK regulatory authorities. The product consists principally of a heavy metal known as bismuth in the form of a paste which is administered into the orifice of the teat by a small plastic applicator.

[3] The label for NoroSeal states –

> "Udder Care from Norbrook Laboratories Limited.
> Ready-to-use

> NoroSeal
> Contents: 4g paste containing Bismuth subnitrate.
> NoroSeal provides a barrier in heifers and cows to promote and maintain healthy teats by forming a seal at the orifice of the teat. This seal is readily removed by milking the teat at the time of calving.
> Wear gloves while using.
> Wash hands after use."

[4] The product information leaflet offers the advice to users that it is essential that cleanliness be maintained when administering NoroSeal. It is stated that in order to prevent infection being introduced to the teat orifice during the application of NoroSeal it is vital that aseptic techniques are used prior to and during the application of NoroSeal. Warnings are issued that NoroSeal is approved for use in cattle as a non medicinal product and as such no meat or milk withdrawal periods apply and NoroSeal should not be used in cows with mastitis.

The Veterinary Medicines Directive and Regulations

[5] Directive 2001/82/EC, the Veterinary Medicines Directive, as amended by Directive 2004/28/EC sets out the community code relating to veterinary medicinal products. Recital 4 states that the main purpose of any regulation on the manufacture and distribution of veterinary medicinal products should be to safeguard animal health and welfare as well as public health.

Article 1.2 defines veterinary medicinal product as –

> "(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or
>
> (b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological immunological or metabolic action or to making a medical diagnosis."

Category (a) above is known as 'medicinal by presentation' and category (b) above is known as 'medicinal by function'. There is no other category of veterinary medicinal product.

Article 5 provides that no veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been

granted by the competent authorities of that Member State in accordance with the Directive or a marketing authorisation has been granted in accordance with Regulation (EC) No 726/2004.

[6] The Veterinary Medicines Directive was transposed by the Veterinary Medicines Regulations. For the purposes of the decision in the present case the relevant regulations were the Veterinary Medicines Regulations 2008.

Regulation 2(1) defines "veterinary medicinal product" in accordance with the Directive.

Regulation 4(1) provides that it is an offence to place a veterinary medicinal product on the market unless that product has been granted a marketing authorisation by the Secretary of State or the European Medicines Agency. For present purposes the relevant authorisation agency is the Veterinary Medicines Directorate (VMD) which is an Executive Agency within the Department of Environment Food and Rural Affairs based in England.

The assessment of NoroSeal by the VMD

[7] On 12 December 2008 the applicant forwarded to the VMD information on a proposed product described as "Norbrook Teat Seal" for consideration as a non medicinal product. By reply dated 5 January 2009 VMD stated that on looking at the formulation of the product it was not considered to be 'medicinal by function' and various particulars were requested. On 12 May 2009 the applicant furnished further information to the VMD and by letter dated 18 May 2009 VMD confirmed that on the description provided and the proposed labelling it was not considered that the product was medicinal. However by letter dated 30 July 2009 VMD stated that on reviewing the product it was considered that "…. it is in fact an intramammary product, not just an external teat sealant. Because of the means of administration all intramammary products are regarded as medicinal products and require a marketing authorisation."

[8] The applicant disputed the VMD conclusion and by letter dated 21 September 2009 VMD provided a note of reasons for the conclusion that NoroSeal required a market authorisation. The reasons stated that NoroSeal was considered to be a "substance" for the purposes of the Directive; that while NoroSeal prevented infection (mastitis) by forming a physical barrier to infection it did not prevent infection by exerting a pharmacological, immunological or metabolic action and therefore was not a veterinary medicinal product by function; however it was a veterinary medicinal product by presentation despite the lack of specific medicinal claims in respect of the product, as presentation in a manner or in a context that gives

rise to a reasonable inference on the part of a consumer that the product's purpose is to prevent disease is sufficient for it to fall within the first limb of the definition.

[9] The applicant sought a statement of the basis on which NoroSeal was considered to be a veterinary medicinal product by presentation and by reply dated 25 September 2009 VMD stated that the presentation of NoroSeal gave rise to a reasonable inference that the product's purpose was to prevent disease. VMD referred to the August 2009 Newsletter of the Market Veterinary Centre and an article dealing with 'Preventing Early Lactation Mastitis' which recommended the use of an internal teat sealant which had been shown to reduce intramammary infections. The Newsletter referred to the availability of a new internal teat sealant, namely NoroSeal. The applicant disputed that the purpose of NoroSeal was to prevent disease and pointed out that no such claim was made. The purpose of the product was stated to be, as appears on the label, to assist in the maintenance of udder health.

The Applicant's Grounds for Judicial Review

[10] The applicant's grounds for judicial review are as follows –

(a) VMD misdirected itself in law or has failed to take relevant considerations into account by –

(i) failing to acknowledge that NoroSeal is a device as it is made up of an inert heavy metal Bismuth and not a substance within the meaning of the Regulations;

(ii) failing to consider and apply the ECJ decision in Commission v Germany [2007];

(iii) failing to acknowledge that for a substance to be registered as medicinal on the presentational ground the presentation must in the context of this case be that of the applicant itself;

(iv) failing to consider adequately the view of the average well informed consumer, in particular who would be expected to read the warnings in the data sheet accompanying NoroSeal that it is not a medicinal product;

(v) failing to address its mind sufficiently to the express indications and recommendations on NoroSeal's packaging.

(b) VMD has taken irrelevant considerations into account or if relevant considerations has given them manifestly excessive weight namely –

(i) the fact that another product on the market OrbeSeal is treated as a veterinary medicinal product when either (1) that product by itself ought not to be considered as a veterinary medicinal product or in the alternative (2) if it is properly considered a veterinary medicinal product then it is materially presentationally different from NoroSeal in that OrbeSeal (a) describes itself as an intramammary (b) is to be used in conjunction with antibiotics and (c) can only be supplied on veterinary prescription;

(ii) reference is made to NoroSeal on a website by persons completely unconnected to Norbrook.

(c) VMD has reached a conclusion on presentation which is clearly wrong and Wednesbury unreasonable.

(d) Having considered that NoroSeal was not a veterinary medicinal product and having decided that NoroSeal was not a medicinal product and having unambiguously represented to Norbrook that NoroSeal was not a veterinary medicinal product and Norbrook having acted on the basis of that representation Norbrook has a substantive legitimate expectation that NoroSeal would continue to be treated in that way and in all the circumstances it was an abuse of power for VMD to change its approach.

(e) It is disproportionate for VMD to require Norbrook to obtain the marketing authorisation under the regulations and/or to withdraw NoroSeal from the market in circumstances where –

(i) it had originally taken the decision that NoroSeal was not a veterinary medicinal product and Norbrook acted on the basis of that decision;

(ii) VMD has refused to accept Norbrook's offer to adjust NoroSeal's presentational material to assuage any legitimate concern that the VMD might have.

(f) VMD's decision was taken in a procedurally unfair manner in that representations made to VMD by others relating to the classification of NoroSeal which were not available to Norbrook in order that it may make informed representations about them.

(g) VMD's decision is in breach of the applicant's property rights under Article 1 of the First Protocol of the European Convention since the restriction placed on the marketing of the applicant's property are –

(i) not in accordance with law for the reasons given above;
(ii) disproportionate to the legitimate purpose being pursued.

(h) VMD failed to give adequate reasons for its decision.

Veterinary Medicinal Products by Presentation

[11] The first category of veterinary medicinal product, namely by presentation, requires (i) a substance (ii) presented (iii) as having properties (iv) either for treating disease in animals (v) or for preventing disease in animals. The nature of a medicinal product has been considered by the European Court of Justice on a number of occasions. There are policy reasons for not having too broad or too narrow an interpretation of medicinal products. It is recognised that there may be some overlap between a medicinal product by presentation and a medicinal product by function. A medicinal product by presentation may arise -

(a) Where the product is "indicated or recommended" for treating or preventing disease;

(b) Where the average well informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, regard being had to its presentation, have the properties of treating or preventing disease.

(c) In particular the external form of the product (eg tablet, pill or capsule) may serve as strong evidence of the intention to market the product as a medicinal product (but cannot be the sole or conclusive evidence).

(d) Not only the form of product but the form of packaging may be strong evidence of intention to market the product as a medicinal product, which may for reasons of marketing policy tend to make it resemble a medicinal product.

(e) Particular regard may be had to the form of packaging and product information which makes reference to medical endorsement of the product.

(f) A statement that a product is not a medicinal product is persuasive evidence which may be taken into consideration but it is not in itself conclusive.

[12] Leentert van Bennekom (ECJ 30 Nov 1983) concerned a prosecution in the Netherlands for possession for the purposes of resale of vitamins in the form of tablets, pills and capsules. A medicinal product by presentation under the Human Medicines Directive was defined as "any substance or combination of substances presented for treating or preventing disease in human beings or animals". The ECJ stated that the first community definition of a medicinal product based on presentation was designed to cover not only medicinal products having a genuine therapeutic or medical effect but also those which were not sufficiently effective or which did not have the effect which consumers would be entitled to expect in view of their presentation. Thus the Directive sought to preserve consumers not only from harmful or toxic medicinal products as such but also from a variety of products used instead of the proper remedies. For that reason the concept of 'presentation' of a product had to be broadly construed. Accordingly the ECJ concluded that substances such as vitamin preparations which were not indicated or recommended expressly as being suitable for curing, treating or preventing an infection might nonetheless constitute substances "presented for treating or preventing disease in human beings or animals" within the meaning of the community definition of medicinal products contained in the Directive.

[13] In Jean Marie Delattre (ECJ 21 March 1991) the French authorities instituted criminal proceedings in respect of the marketing of products that included items relating to slimming, digestion, blood circulation and tiredness. The applicant classified the products as foodstuffs or food supplements or cosmetic products and they were presented in the form of tablets or creams or gels. All products carried a statement to the effect that they were not medicinal products. The ECJ concluded that a product may be regarded as being presented as being a medicinal product if its form and the manner in which it was packaged rendered it sufficiently similar to a medicinal product and in particular if on its packing and in the information provided, reference was made to research by pharmaceutical laboratories or to methods or substances developed by medical practitioners or even to testimonials from medical practitioners commending the qualities of the product. A statement that the product was not medicinal was persuasive evidence which the national court may take into consideration but was not in itself conclusive.

[14] In Commission of the European Communities v Federal Republic of Germany (ECJ 15 Nov 2007) a garlic preparation in capsule form was considered. The Federal Republic of Germany relied on the large number of products containing active substances such as garlic bulb powder or oil on the German market packaged in a similar fashion and classified as medicinal

products but that was not sufficient to confer the status of medicinal by presentation. The State had not provided any specific evidence in support of that argument. The only aspect of packaging which tended to make the product resemble a medicinal product was a photograph of a head of garlic on the product's external packaging, as this also featured on a number of medicinal products in Germany. However this was considered not sufficient to inspire, in a reasonably well informed consumer, confidence like that usually inspired by medical medicinal products. The capsule form of the product was the only aspect likely to suggest classification of the product as a medicinal product by presentation and although that served as strong evidence of intention to market that product as a medicinal product it could not be the sole or conclusive evidence since otherwise certain food product s which were traditionally presented in a similar form would be covered. The capsule form, being the only indicator, was not exclusive to medicinal products.

[15] Johann Stephanis Wilhelmus Tervoort (ECJ 28 Oct 1992) concerned herbal teas being marketed without any indication of any therapeutic property. However a foundation in the Netherlands sent customers on request brochures describing the therapeutic and prophylactic properties of the herbal teas. The issue arose as to whether the product which in general was regarded as a foodstuff and did not possess any known pharmacological property should be regarded as a medicinal product by presentation if it presented as having therapeutic or prophylactic properties. The ECJ held that the product recommended or indicated as having prophylactic or therapeutic properties was a medicinal product even if it was generally regarded as a foodstuff and even if in the current state of scientific knowledge it had no known therapeutic effect.

Whether the product is a 'substance'

[16] The applicant contends that the product is not a "substance" for the purposes of the Directive and therefore cannot be a veterinary medicinal product. Article 1.4 of the Directive defines "substance" as -

> "Any matter irrespective of origin which may be
>
> - human eg human blood and human blood products
>
> - animal eg micro organisms whole animals, parts of organs, animal secretions, toxins extracts blood products

> - vegetable eg micro organisms plants, parts of plants, vegetable secretions, extracts
>
> - chemical eg elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis."

[17] Mr Hillan on behalf of the applicant described NoroSeal as a 'device' rather than a 'substance'. He made a comparison with other teat inserts that do not require marketing authorisation. For example Columbus Teat Plugs are a solid form device that penetrate through the teat canal into the teat cistern. They are used when the teat is injured and the plug keeps the teat canal open during the healing process. A similar device designed for teat cistern insertion is Dr Nailers Teat Dilator. A further product is the Wax Teat Insert which has a soft but solid wax form with a plastic end to assist removal and is presented in sterile blister packs. In addition there are teat cannulae made from solid plastic but with a hollow tube-like design to allow removal of milk from the udder.

[18] This teat sealant comprises bismuth subnitrate as a malleable paste which fills the internal contours of the teat canal and teat cistern and effectively prevent the passage of microbes into the udder. The Shorter Oxford English Dictionary includes in the definitions of 'device' – 'A thing designed for a particular function or adapted for a purpose; an invention, a contrivance, *esp* a (simple) mechanical contrivance'. The applicator could be described as a device. NoroSeal could not be described as a device. The malleable paste is clearly 'matter' and it is 'chemical' matter and NoroSeal is clearly a 'substance' for the purposes of the Directive.

Whether the product is intramammary

[19] There was much debate on whether NoroSeal is an intramammary product. John Fitzgerald, Director of Operations at VMD, at paragraph 11 of his affidavit referred to NoroSeal as "an intramammary product and not just an external teat sealant". The udder of a cow comprises four mammary glands or "quarters". Within each quarter is a gland cistern which has a mean volume ranging from 100ml to 1890ml. Below the gland cistern is the teat cistern which has a volume of 30-40ml. The gland cistern and the teat cistern are separated by cells known as Furstenberg's Rosette. Below the teat cistern is the teat canal leading to the orifice from which the milk is expelled.

[20] Mr Fitzgerald had first considered NoroSeal to be a product that was applied externally and this was based on its description as "forming a seal at the orifice of the teat". However on further review VMD concluded that there was every likelihood that NoroSeal would be deposited in the teat cistern.

Andrew Hillan, Head of Veterinary Services with the applicant, described NoroSeal as "a semi solid teat seal that, much like a thick liquid poured into a mould, takes on the shape and form of the internal teat canal and distal teat cistern to help maintain a healthy teat." He stated that this was not an intramammary product and that use of the term "intramammary" suggested that the product defused into the mammary gland. Similarly Professor Peter Lees, Emeritus Professor of Veterinary Pharmacology at the Royal Veterinary College University of London, stated that NoroSeal was not an intramammary product and because of its contents and design it should not and could not enter the mammary gland.

[21] This debate was properly described in the course of the exchanges between the parties as a red herring. NoroSeal is not an intramammary product in that it does not enter the mammary gland. However it is not an external product as it does enter the teat canal and the distal teat cistern. That a product is not only used externally but is used internally may be relevant to its presentation and function.

The VMD Guidance on Marketing Authorisation

[22] VMD issued a guidance document entitled "Veterinary Medicines – Do you need a Marketing Authorisation?" The guidance refers to products that are medicinal by presentation and medicinal by function. Under the heading 'Medicinal by Function' the term 'route of administration' appears. The guidance states "Products can also be considered medicinal due to their route of administration. For example a vitamin supplement administered in an injectable form would be considered medicinal."

Annex B of the guidance includes reference to eyedrops as being medicinal by function due to 'route of administration'.

Specific topics in the guidance include "Teat and Udder Products". This states that teat dips are considered to be medicinal by presentation since they are used as aids for the prevention of mastitis. It is further stated that products applied to teats and udders which contain more than 0.3% iodine are considered medicinal by function. In addition products other than teat dips which do not contain medicinal ingredients and make no medicinal claims, such as udder washes for use before milking, may be marketed without a marketing authorisation.

Means of Administration

[23] The applicant contends that VMD introduced, improperly, a third category of veterinary medicinal product namely 'medicinal by

administration'. The VMD letter of 30 July 2009, issued after the review of the product, noted that the product was not just an external teat sealant and "because of the means of administration all intramammary products are regarded as medicinal products and require marketing authorisation". The applicant regarded the VMD reference to the means of administration as creating a new unauthorised category of veterinary medicinal product or, having regard to the wording of the guidance, as representing a finding that the product was medicinal by function. Those conclusions having been disavowed by the VMD on the basis that the product was considered to be medicinal by presentation, the applicant regarded this as a change of approach.

[24] The use of the language has caused confusion. I am satisfied that the VMD did not introduce a third category of veterinary medicinal product relating to the means of administration. It would appear that when the VMD was referring to the means of administration it was inclined to regard the product as being medicinal by function. However by the time the VMD came to produce the statement of reasons for its decision on 21 September 2009 I am satisfied that VMD regarded and continues to regard NoroSeal as being a veterinary medicinal product by presentation. The means of administration of the product is an aspect of the presentation.

[25] The VMD must have given consideration to whether the product was medicinal by function. The VMD letter of 29 July 2009 referring to the means of administration for intramammary products reflects the language of the guidance on the route of administration and medicinal products by function. A VMD email of 3 September 2009 stated that certain routes of administration had always been considered by VMD to be medicinal, with injections and eyedrops being given as examples. It was stated that such products are associated with the risks of introducing contaminants such as bacteria into parts of the body that are usually sterile. Such routes of administration were stated to be distinct from oral, intra-vaginal and rectal which tend to have heavy bacterial loads as the norm.

[26] Orthica BV v Bundes Republik Deutschland (ECJ 9 June 2005) concerned products marketed as food supplements. The ECJ considered the meaning of 'pharmacological' effect for the purposes of a medicinal product by function and also whether the requirement that there be a health risk formed an integral part of the definition. The pharmacological properties of a product were stated to concern whether it may be administered with a view to restoring, correcting or modifying physiological functions. Risk to health was stated to be an autonomous factor that must also be taken into consideration in the context of the classification of the product as a medicinal product by function.

[27] The applicant states that NoroSeal contains an anti-infective agent at a concentrated level below that regarded as medicinal by the regulatory authorities. The anti-infective agent is iodine at a concentration of 0.1%. The VMD guidance states that products applied to teats and udders which contain more than 0.3% iodine will be considered medicinal by function. Mr Fitzgerald raised concerns about the level of iodine in NoroSeal as it is used internally. The use of iodine may be having a pharmacological effect which would render the product medicinal by function.

[28] However, while giving consideration to whether the product might be medicinal by function, this was not the basis on which the VMD reached its decision on the status of the product. The conclusion was that the product was medicinal by presentation. It is this conclusion that will be examined.

Medicinal by Presentation

[29] A product may be medicinal by presentation if it is "indicated or recommended" for treating or preventing disease. The applicant does not intend there to be any such indication or recommendation in the present case. A product may be medicinal by presentation where the average well informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, regard being had to its presentation, have the properties of treating or preventing disease. The dispute in the present case is whether this objective test has been satisfied by NoroSeal.

[30] Counsel for the VMD relied on a number of factors that were said to indicate that NoroSeal was a veterinary medicinal product by presentation. There is the use of the applicator, which is the means by which the substance is inserted into the teat canal. The applicator is described by VMD as a syringe although this description is disputed by the applicant on the basis that a syringe has the capacity to withdraw a substance and that is not a feature of the NoroSeal applicator. I accept that the manner of administration of a substance may be evidence that it is medicinal by presentation. The form of the product, be it tablet, pill or capsule, creams, gels or paste, may be such evidence. The manner of administration, whether by injection or applicator may be such evidence. There is the related matter of the external packaging showing the introduction of the solution by the applicator. There is the claim in relation to the maintenance of healthy teats by the creation of a seal. The route of administration may provide such evidence. NoroSeal is applied to a sterile area. It carries the risk of bacteria being introduced into sterile cavities. It may require an anti infective agent to safeguard against that risk. It clearly requires warnings in relation to such a risk arising on the administration of the product. There is the related matter of the anti infective agent being used in the solution to create a barrier. Further there is the product leaflet

emphasising the need for aseptic techniques. Counsel for the VMD asks what purpose the product would have other than the appearance of properties that prevent mastitis.

[31] VMD must make a judgment case by case in relation to the requirement for a marketing authorisation. A product may be a medicinal product by presentation based on the objective test of the average well informed consumer. The product is judged on its presentation. Does the presentation of NoroSeal give the impression that it should have the properties for treating or preventing disease? In the present case that question relates to whether the presentation gives the impression that the product should have properties that prevent mastitis. The average well informed consumer must be taken to know how NoroSeal will actually apply to the animal. That knowledge will inform the consumer that the substance will be placed through the teat orifice into the teat canal and the distal teat cistern. The average well informed consumer must also be taken to be aware of the nature of mastitis.

[32] The indicators of properties for disease prevention are the manner of application by the use of the applicator, the nature of the substance in the form of a paste, the use of a substance that is applied internally through the teat orifice to the teat cistern and canal, the packaging and product literature showing the use of the applicator to apply the substance to the teat, the inclusion in the ingredients of the anti infective iodine and the warnings about the need for aseptic measures. The contra-indicators are the statements that the product is concerned with udder care, that the product is non medicinal and the absence of any claims in relation medicinal properties. I am satisfied that the average well-informed consumer would gain the impression that NoroSeal should have properties for preventing mastitis.

[33] The presentation will be that of the applicant. However that is not limited to the terms by which or the manner in which the producer elects to package or describe or classify the product. Regard will be had to the warnings and express indications and recommendations but they are not conclusive of the position. Nor can the claims of third parties fix a product as being medicinal by presentation but those claims, if from a competent authority, may provide some indication of the views of an average well informed consumer.

[34] It is not possible to categorise the conclusion of the VMD that NoroSeal is a veterinary medicinal product by presentation as being clearly wrong or Wednesbury unreasonable. In so far as it is for the Court to reach a conclusion on the issue, I am satisfied, on the basis of the matters referred to above, that NoroSeal is a veterinary medicinal product by presentation.

Comparisons with OrbeSeal

[35] NoroSeal has been compared and contrasted with another product known as "OrbeSeal" made by Pfizer Limited which the VMD has found to be a veterinary medicinal product. The product literature refers to OrbeSeal as a veterinary medicinal product and states that it is indicated for the prevention of new intramammary infections and for mastitis control and refers to dry cow intramammary treatments and antibiotic therapy. By contrast the NoroSeal product literature makes no claims in relation to the treatment or prevention of disease and according to Mr Hillan it is simply offered as a teat seal, a mere device.

[36] NoroSeal and OrbeSeal have minor formulation differences but both contain 65% Bismuth sub nitrate in a mineral oil vehicle taking up the shape of the internal teat canal and the distal teat cistern and both are applied with an applicator. OrbeSeal was found to be medicinal by function. The applicant complains that OrbeSeal has unduly influenced the decision in relation to NoroSeal. It is said that OrbeSeal is materially presentationally different from NoroSeal in that OrbeSeal describes itself as an intramammary and is to be used in conjunction with antibiotics and can only be supplied on veterinary prescription. The consideration of the status of NoroSeal is an independent matter. There are comparisons and differences between the two products to be taken into account in the assessment of presentation. OrbeSeal is clearly a veterinary medicinal product and is clearly presentationally different to NoroSeal. This does not detract from the need for independent assessment of any requirement for marketing authorisation for NoroSeal. I am satisfied that a discrete decision was made on the status of NoroSeal and that the presentational differences were taken into account in an appropriate manner.

Additional grounds

[37] The applicant claims a legitimate expectation that NoroSeal will not require a market authorisation based on the early correspondence from the VMD. The initial response of the VMD of 5 January 2009 referred to the formulation of the product and stated that it would not be considered medicinal by function and asked for further information. Not all the requested information was provided but by its further response of 18 May 2009 VMD confirmed that "based on the description provided and the proposed labelling" the product could not be considered to be medicinal. By further letter of 30 July 2009 VMD referred to the description of the product as suggesting that NoroSeal would not enter the teat but that further review had revealed that NoroSeal was not just an external teat sealant. By letter of 31 July 2009 the applicant stated that NoroSeal is "deposited at the orifice of the teat and the packaging is designed accordingly". Such conclusions as were stated by VMD were based on an incomplete description and an incomplete

understanding of the operation of NoroSeal. The statements made by VMD in the circumstances could not amount to any irrevocable commitment to the exclusion of the product from the scheme for marketing authorisation.

[38] In any event the issue is whether NoroSeal is a veterinary medicinal product by presentation. VMD has concluded and I have concluded that NoroSeal is a veterinary medicinal product by presentation. The applicant cannot have any legitimate expectation other than that the VMD will make a decision in accordance with its statutory powers.

[39] Further, the applicant contends that the VMD conclusion was in breach of the applicant's right to property under Article 1 of Protocol 1 of the European Convention on Human Rights which provides -

> "Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one should be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.
>
> The preceding provisions shall not, however, in any way impair the right of the State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties."

[40] There are three rules in Article 1 of Protocol 1. The first rule, in the first sentence, is the general principle of peaceful possession of property. The second rule, in the second sentence, permits deprivation of property on certain conditions. The third rule, in the second paragraph, permits the State to control property for certain purposes. Deprivation under the second rule and control under the third rule are instances of interference with the first rule of peaceful possession. Any interference with the right to property must be justified as being in accordance with law and in the public or general interest and subject to the requirements of proportionality.

[41] Any interference with the applicant's property has been undertaken in furtherance of the legislative scheme. If there has been compliance with the legislative scheme then the interference is in accordance with law and undertaken for a legitimate purpose, which I am satisfied is the case. The applicant contends that the outcome is disproportionate to any legitimate purpose. The outcome is the result of the application of the legislative scheme. I am satisfied that reliance on Article 1 of Protocol 1 does not add to the grounds of challenge raised by the applicant.

[42] The applicant further contends that the outcome was disproportionate in that the applicant acted on foot of the initial VMD conclusion that the product was not medicinal. As stated above the initial statements by VMD were qualified and clearly provisional. The VMD had no alternative but to apply its judgment as to the requirement for a marketing authorisation as it became fully informed as to the details of the product. In addition the applicant contends that the outcome was disproportionate in light of the applicant's offer to adjust NoroSeal's presentational material. However the product was on the market and the VMD, as the regulatory authority, had a statutory duty to reach a conclusion on the application of the legislative scheme to the applicant's product.

[43] The applicant contends that the VMD did not give adequate reasons for the decision. The VMD furnished a statement of reasons in September 2009. The statement of reasons in essence expressed the judgment that the product was medicinal by presentation based on the objective approach of the average well informed consumer. This was not a judgment with which the applicant was in agreement but that is a different matter. The applicant was in a position to understand what had been decided and to consider what action was required in response.

[44] I do not consider that it adds to a consideration of the issues arising in this application for Judicial Review that the status of NoroSeal was reviewed by the VMD further to information furnished to the VMD by the applicant's commercial rival, Phizer Limited. Upon that review the applicant and the VMD entered into correspondence and meetings about the matter. The applicant had the opportunity to address the issues raised by the VMD.

[45] Nor do I consider that it adds to the present application to examine the circumstances in which the product known as 'Norbrook Teat Seal' required market authorisation from the regulatory authorities in the Republic of Ireland.

[46] I have not been satisfied on any of the applicant's grounds for Judicial Review. The application will be dismissed.