[2020] IEHC 16

THE HIGH COURT
JUDICIAL REVIEW

2018 No. 1080 J.R.

BETWEEN

ARTHROPHARM (EUROPE) LIMITED

APPLICANT

AND

THE HEALTH PRODUCTS REGULATORY AUTHORITY

RESPONDENT

CHANELLE PHARMACEUTICALS MANUFACTURING LIMITED

NOTICE PARTY

JUDGMENT of Mr Justice Garrett Simons delivered on 14 January 2020

INTRODUCTION

1. The within judicial review proceedings seek to challenge a decision to grant a marketing authorisation in respect of a veterinary medicinal product. The proceedings have the potential to be a complex piece of litigation, and it is now estimated that the substantive hearing of same will take some ten to twelve days before the High Court. The proceedings have been subject to case management, and a number of procedural issues have been identified in respect of which the parties have sought rulings in advance of the substantive hearing.

2. The first procedural issue concerns the question of whether the proceedings were issued within the three month time-limit prescribed under Order 84, rule 21 of the Rules of the Superior Courts (as amended in 2011), and, if not, whether an extension of time should be granted.

3. The determination of this issue turns largely on whether the applicant for judicial review was justified in deferring the institution of proceedings until such time as it secured a sample of the product on the open market and arranged to have same analysed. It will also be necessary to consider whether a subsequent communication on behalf of the regulatory authority on 6 March 2019, which is to the effect that nothing raised by the applicant in correspondence provided a basis for the regulatory authority to "withdraw" the marketing authorisation, represents a *fresh* decision which reset the clock for the purposes of the three month time-limit.

OVERVIEW OF FACTUAL BACKGROUND

4. The applicant for judicial review, Arthropharm (Europe) Ltd., has been authorised to market a particular veterinary medicinal product in Ireland since 1991. The product is known as "Cartrophen Vet 100 mg/ml Solution for Injection" ("*Cartrophen*"), and is used for the treatment of osteoarthritis and related musculoskeletal disorders in dogs.

5. The notice party to these proceedings, Chanelle Pharmaceuticals Manufacturing Ltd., applied for and obtained a marketing authorisation in respect of what it says is a "generic" of Cartrophen. As explained in more detail under the next heading below, EU law prescribes a streamlined procedure for the grant of marketing authorisation for the sale of generic medicinal products. The concept of a "generic" medicinal product in the present context refers to a veterinary medicinal product which has the same qualitative and

quantitative composition and active substances in the same pharmaceutical form as a "reference" product which is already authorised. A marketing authorisation can be issued for a generic medicinal product without any requirement for the applicant to provide the results of safety and residue tests or of pre-clinical and clinical trials. Put otherwise, an applicant for marketing authorisation can "piggyback" on the earlier authorisation of the reference product to obtain its own marketing authorisation. The proprietary rights of the producer of the reference product are protected to the extent that an authorisation for a generic product may only be granted once ten years have elapsed from the initial authorisation of the reference product. The grant of a marketing authorisation is stated to be without prejudice to the Patents Act 1992 (as amended).

6. The marketing authorisation impugned in these proceedings was granted to Chanelle Pharmaceuticals Manufacturing Ltd. by the Health Products Regulatory Authority on 20 July 2018. The authorised generic product is known as "Osteopen 100 mg/ml Solution for injection for dogs" ("*Osteopen*").

7. Arthropharm (Europe) Ltd. has sought to challenge the grant of the marketing authorisation on a number of grounds. It will be necessary to consider these in more detail presently in order to address the question of whether the delay in instituting the proceedings was justified. For introductory purposes, however, the grounds might be summarised as entailing an allegation that the manufacturing processes for the two products are not the same, and that Osteopen does not have the same qualitative and quantitative composition as Cartrophen.

8. Where convenient, the following shorthand will be employed in this judgment to describe the parties: (i) Arthropharm (Europe) Ltd. will be referred to as "*the Objector*"; (ii) Chanelle Pharmaceuticals Manufacturing Ltd. as "*the Authorisation Holder*"; and (iii) the Health Products Regulatory Authority as "*the Authority".*

9. The legislative regime governing the grant of marketing authorisations is discussed in detail under the next heading below. It might be helpful, however, to flag one surprising feature of the legislative regime from the outset. The holder of the marketing authorisation in respect of the reference product, i.e. the original producer of the product, is not afforded any special status in respect of an application for the authorisation of a generic product. There is no requirement to put the original producer on notice of either the making of the application or of the grant of the marketing authorisation. Instead, the original producer has to rely on the public notification of the decision.

10. The Authority has gone so far as to plead that the original producer in these proceedings, Arthropharm (Europe) Ltd., does not even have a "sufficient interest" or locus standi to maintain an application for judicial review. It is not necessary to determine this issue for the purposes of the preliminary ruling on the time-limit point.

11. These proceedings were instituted by way of an *ex parte* application for leave to apply for judicial review on 20 December 2018. The decision to grant the marketing authorisation had been made on 20 July 2018, and thus the application was made some five months

after that decision. At first blush, the proceedings would appear to have been instituted well outside the three month time-limit prescribed under Order 84, rule 21. The Objector contends, however, that the legal position is more nuanced, and emphasises that it had been proactive in the period between its first learning of the decision and the institution of these proceedings. Reliance is placed, in particular, on the fact that it had engaged in correspondence with the Authority. It is also said that part of the alleged delay is explicable by reference to the fact that time was needed to obtain a sample of the generic product on the open market and to have same analysed. In order to determine whether these submissions are well founded, it will be necessary to consider the chronology of events over this period in some detail. This consideration commences at paragraph 26 below. Before turning to that task, however, it may be helpful first to set the context by providing an overview of the legislative regime.

LEGISLATIVE REGIME

12. The grant of marketing authorisation for veterinary medicinal products is governed principally by Directive 2001/82/EC ("*the Directive*"). The Directive has been transposed into domestic law principally by the European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007) *("the 2007 Regulations")*. There are certain curiosities in the manner in which the Directive has been transposed, and these will be identified in context in the discussion below.

13. Given that this judgment is concerned solely with the time-limit point, it is not necessary to engage in a detailed examination of the legislation at this stage. It is sufficient for the purposes of this judgment to identify in broad terms the nature of the decision-making being challenged.

14. Article 5 of the Directive provides that no veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been granted. The general procedure for obtaining a marketing authorisation is prescribed under article 12. An application must include all the administrative information and scientific documentation necessary for demonstrating the quality, safety and efficacy of the veterinary medicinal product in question. In particular, the following test and trial results must be provided. (See article 12(3)(j)).

> (j) results of:
>
> — pharmaceutical (physico-chemical, biological or microbiological) tests,
> — safety tests and residue tests,
> — pre-clinical and clinical trials;
> — tests assessing the potential risks posed by the medicinal product for the environment. This impact shall be studied and consideration shall be given on a case-by-case basis to specific provisions seeking to limit it.

15. A more streamlined application procedure is available in the case of generic medicinal products. This is provided for under article 13 of the Directive, and is stated to be a "derogation" from the general procedure under article 12. An applicant who relies on the streamlined procedure is not required to provide results of safety and residue tests or of

pre-clinical and clinical trials if he or she can demonstrate that the medicinal product is a generic of a reference medicinal product which has been authorised for not less than eight years in a Member State or the European Union. Provided that the product to be authorised fulfils the definition of "generic medicinal product", it will be unnecessary for an applicant to provide the results of tests and trials.

16. The concept of a "generic medicinal product" is defined as follows at article 13(2) of the Directive.

> 'generic medicinal product' shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information intended to provide proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

17. Given the nature of one of the principal objections made to the authorisation of the generic product in the present case, namely that the product is a *biological* veterinary medicinal product and that there is a difference in *the manufacturing process* as between the two products, it is relevant to note the provisions of article 13(4) of the Directive as follows.

> 4. Where a biological veterinary medicinal product* which is similar to a reference biological veterinary medicinal product does not meet the conditions in the definition of generic medicinal products, *owing to, in particular, differences relating to raw materials or in manufacturing processes** of the biological veterinary medicinal product and the reference biological veterinary medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.
>
> *Emphasis (italics) added.

18. As appears, this provision is only applicable to a biological veterinary medicinal product: there is a dispute between the parties as to whether the generic product does, in fact, constitute a biological product.

19. The statement of grounds invokes these various provisions of the Directive in support of an argument that the application for marketing authorisation should not have been dealt with by the Authority pursuant to the streamlined procedure under article 13. The correctness or otherwise of this argument is something which could only be properly determined following a substantive hearing of the judicial review proceedings. For the purposes of the preliminary issue currently before the court, namely whether there has been compliance with the time-limit under Order 84, rule 21, it is sufficient to note that certain of the grounds of challenge now pleaded had already crystallised by 12 October 2018, i.e. within the three month period. I will return to discuss the implications of this at paragraph 83 below.

20. Of more immediate relevance to the time-limit point are the legislative provisions governing the publication of a decision. Article 25 of the Directive provides as follows.

> Article 25
>
> 1. When granting a marketing authorisation, the competent authority shall inform the holder of the summary of product characteristics that it has approved.
> 2. The competent authority shall take all necessary measures to ensure that information concerning the veterinary medicinal product, and in particular the labelling and package leaflet, is in conformity with the summary of product characteristics approved when the marketing authorisation was granted or subsequently.
> 3. The competent authority shall make the marketing authorisation publicly available without delay, together with the summary of product characteristics for each veterinary medicinal product that it has authorised.
> 4. The competent authority shall draw up an assessment report and comments on the file as regards the results of the pharmaceutical, safety and residue tests and the pre-clinical and clinical trials of the veterinary medicinal product concerned. The assessment report shall be updated whenever new information becomes available which is of importance for the evaluation of the quality, safety or efficacy of the veterinary medicinal product concerned. The competent authority shall make the assessment report and its reasons for the opinion publicly available without delay, after deleting any information of a commercially confidential nature.

21. The requirement for public notification is reiterated under article 94 of the Directive as follows.

> Article 94
>
> Any decision referred to in this Directive, taken by the competent authorities of the Member States, may only be taken on the grounds set out in this Directive and shall state in detail the reasons on which it is based.

Such a decision shall be notified to the party concerned who shall at the same time be informed of the remedies available to him under current legislation and the time allowed for seeking such remedies.
Decisions to grant or revoke a marketing authorisation shall be made publicly available.

22. The manner in which the public notification requirements have been transposed into domestic law is somewhat curious. Whereas the 2007 Regulations do contain a provision equivalent to article 94 of the Directive, there is no provision directly equivalent to article 25. Instead, the decision-maker, now the Authority, is to "have regard to" article 25 of the Directive. The two relevant provisions of the 2007 Regulations are set out below.

23. Regulation 46 of the 2007 Regulations reads as follows.

> 46. [The Authority] shall publish notice of the grant or revocation of a veterinary product authorisation in Iris Oifigiúil.

24. Regulation 9(4) of the 2007 Regulations reads as follows.

> (4) [The Authority], except in the case of a homeopathic animal remedy referred to in Regulation 7(2), shall have regard to Article 25 of the Directive.

25. It will be necessary to consider whether public notification of a decision is a prerequisite to the commencement of the running of time for the purposes of the three month time-limit under Order 84, rule 21. In particular, it will be necessary to consider whether time only runs from the date of publication in Iris Oifigiúil. I will return to these issues at paragraph 49 below.

CHRONOLOGY OF EVENTS POST-DECISION

26. The impugned decision to grant a marketing authorisation for the generic product, i.e. Osteopen, was made by the Authority on 20 July 2018. Shortly thereafter, on 23 July 2018, the Authority posted the decision and a number of documents associated with the grant of marketing authorisation on its website. In particular, it posted a document described as a "product authorisation assessment". These various documents are publicly accessible on the Authority's website, i.e. access to same is not confined to any class of person nor is registration required.

27. The decision to grant the marketing authorisation was not published in Iris Oifigiúil until 8 January 2019.

28. The affidavit evidence filed on behalf of the Objector indicates that its officers first became aware of the grant of the marketing authorisation on 23 August 2018. It seems that this information came to the attention of the managing director of the company when he was contacted by a distributor in the United Kingdom.

29. The first communication from the Objector to the Authority was by way of email dated 12 October 2018. (There is some confusion as to the precise date of this email: the letter attached to the email bears the date 10 October 2018, but the email itself does not seem

to have been sent until 12 October 2018. Nothing turns on this discrepancy of two days, as both dates fall within the three month period, and for the sake of consistency the date 12 October 2018 will be used throughout this judgment when referring to this communication).

30. The only explanation offered for the lapse of time between the date upon which the company first learnt of the grant of the marketing authorisation (23 August 2018), and the date upon which the email was sent (12 October 2018), is that set out as follows in the first affidavit of Mr (Sydney) David Cullis-Hill.

> "30. The date specified for grant of the authorisation on the HPRA website is 20 July 2018. The Applicant first became aware that a veterinary marketing authorisation had been granted in respect of Osteopen as a generic of Cartrophen on or about 23 August 2018, when I was contacted by a distributor of Cartrophen in the United Kingdom. On becoming aware of this, I carried out investigations in relation to Osteopen with a view to identifying the manufacturer and finding out as much information as possible about the product. The Applicant also carried out significant research of the available scientific literature on the potential impact of difference in the manufacturing process on Pentosan Polysulfate Sodium ("PPS"), the active ingredient of Cartrophen and Osteopen."

31. The email communication of 12 October 2018 consisted of a covering email, and a number of attachments containing a detailed objection to the marketing authorisation.

32. Relevantly, one of the principal complaints being made as of 12 October 2018 was that the active ingredient in Osteopen, i.e. pentosan polysulfate sodium or PPS, is produced in a different factory and by a different process than that for the reference product, i.e. Cartrophen. As discussed presently, precisely the same complaint features prominently in the statement of grounds in these proceedings.

33. This complaint is summarised as follows in the covering email of 12 October 2018.

> "From: Info Arthropharm
>
> Sent: 12 October 2018 07:10
>
> To: HPRA Customer Service
>
> Subject: Objection to registration of Osteopen MA no. VPA10987/131/001
>
> Dear Sir/Madam,
>
> Please see attached our objection of a generic product registration (Osteopen) using Cartrophen Vet as a comparator.
>
> In summary we believe the registration process has been flawed for the reasons outlined in the accompanying objection including;

- A generic product registration has been approved for a country where the comparator product is not registered
- Differences in manufacturing processes for the API were not taken into account
- the biological activity of the API from different manufacturers is known to have wide varying biological activity and potency
- consideration to different structures and molecular weights and sulfation patterns from different manufacturing processes was not evaluated

We have attached a link the accompanying letter to Cartrophen Vet Dossier (2014) which will be available for a short time, please advise if you cannot gain access. There are links to the references available also.

We appreciate a review of the registration process.

Please acknowledge receipt of email and attachments."

34. The complaint as to the difference in manufacturing processes is repeated in the substantive objection which had been attached to the email. See, for example, the following extracts.

"'Not all PPS or PSPS the same' – A literature review.

Although batches of PPS from the same manufacturer should be structurally similar in size and sulfation, PPS batches from different manufacturing facilities are demonstrably not structurally identical and hence each batch may have very different biological properties."

35. This theme is returned to a number of pages later.

"Alternate manufacturing processes can result in batches of PPS which are more or less potent in many different mechanistic actions. There is thus a necessary requirement to perform dose response studies on every alternative PPS preparation to ensure it has similar treatment potency and efficacy to Bene PPS. If a PPS preparation is more potent, there is a risk of toxicity and a higher incidence of sides effects. If the PPS preparation is less potent, it could be ineffective for the treated condition."

36. The objection concluded as follows.

"Conclusion

For the above reasons I believe the generic application approval be suspended pending a review of the facts and a review of the decision to register with the present limited data be reviewed."

37. The Authority sent an email dated 16 October 2018 confirming safe receipt of the email of 12 October 2018. The Authority's email indicated that it (the Authority) would consider

the comments/submission and provide a response as soon as possible once the concerns raised in the communication had been carefully considered. True to its word, the Authority subsequently sent a detailed substantive response by email dated 30 October 2018.

38. Unfortunately, it seems that, due to an error within the Objector's own offices, the email from the Authority containing its substantive response was deleted. Notwithstanding that the managing director of the company thought (mistakenly) that no substantive response had been received from the Authority to the email of 12 October 2018, no further steps were taken by the Objector to contact the Authority until 13 December 2018. On that date, a firm of solicitors acting on behalf of the Objector wrote to the Authority. The solicitors' letter refers to the objection made on 12 October 2018. The letter goes on to indicate that the Objector had since obtained a sample of Osteopen, and alleges that there are major structural differences between the generic product, Osteopen, and the reference product, Cartrophen.

39. By email dated 14 December 2018, the Authority explained that a substantive response to the email of 12 October 2018 had, in fact, been sent by email on 30 October 2018. The solicitors for the Objector replied indicating that their client had advised that he did not receive the response, and asking that a copy of the email of 30 October 2018 be provided. This was done by email dated 17 December 2018. The solicitors for the Objector responded by letter dated 18 December 2018, which indicated an intention to make an application for leave to apply for judicial review. Following further correspondence, the *ex parte* application for leave to apply was ultimately made to the High Court (O'Regan J.) on 20 December 2018.

40. The leave application had been made some five months after the date of the decision (20 July 2018). The position adopted by the Authority and the Authorisation Holder is that time runs from the date of the publication of the decision and associated material on the Authority's website (23 July 2018). It is submitted, therefore, that the proceedings have been brought out of time. Conversely, the Objector submits that the time-limit did not begin to run against it until 30 October 2018, i.e. the date upon which the substantive response from the Authority to the objection of 12 October 2018 had been sent. (It will be recalled that this email had been mistakenly deleted by the Objector). See paragraph 49 of the affidavit grounding the application for judicial review as follows.

> "49. I am advised by my legal advisers and so believe that the within proceedings have been commenced with (*sic*) the time limits prescribed for the commencement of judicial review proceedings in circumstances where the Applicant did not receive a substantive response from the HPRA to its objection until 17 December 2018, when the HPRA attached a PDF of an email dated 30 October 2018 from the HPRA to the Applicant. The Applicant has been unable to locate a copy of the email dated 30 October 2018 and does not appear to have received same. *Even had this email been received on 30 October 2018, the within application for leave to bring judicial*

review proceedings is been moved within three months of the HPRA's substantive response."

*Emphasis (italics) added.

41. Once Mr Cullis-Hill became aware of the true position within the company, a further affidavit was filed on 8 May 2019 explaining that the email had been deleted in error.

HISTORY OF PROCEEDINGS

42. It may be helpful to explain how precisely the time-limit point comes to be dealt with as a preliminary issue. The substantive application for judicial review had been listed for hearing, over four days, to commence on Tuesday, 3 December 2019. In the event, however, an application to adjourn the substantive hearing was made on Wednesday, 27 November 2019. The adjournment was sought in circumstances where the Objector indicated that it now intended to seek leave to cross-examine a number of expert witnesses, and it was apprehended that if cross-examination were to be allowed, then the time required for the substantive hearing would exceed the four days allocated. It was suggested that the hearing slot should, instead, be used to allow a number of procedural issues to be heard and determined.

43. This application was acceded to by the judge in charge of the Judicial Review List. Meenan J. directed that the procedural issues were to be determined prior to any hearing on the substantive application for judicial review. The procedural issues subsequently came on for hearing before me on 3 December 2019. Upon conclusion of argument on the time-limit point, I decided that consideration of the two other procedural issues should be deferred pending delivery of this reserved judgment on the time-limit point. Put otherwise, the time-limit point has been dealt with on a stand-alone basis, i.e. in advance of (i) the application for leave to cross-examine the expert witnesses, and (ii) the application for leave to amend the statement of grounds. This is because the time-limit point has the potential to be dispositive of the proceedings.

44. It seems that the question of whether there had been compliance with the time-limit had first been mooted at a direction's hearing on 22 January 2019. The Authority sought leave to issue a motion seeking an order setting aside the grant of leave on the grounds of delay. In response, counsel for the Objector had submitted that the most efficient use of court time would be for the Authority to plead the delay objection in its Statement of Opposition, and then possibly to have the time point dealt with as a preliminary issue. It was submitted that an application to set aside the grant of leave would not be appropriate.

45. The High Court (Noonan J.) refused the application for liberty to bring a motion to set aside the grant of leave. Noonan J. noted that no extension of time had been granted as part of the leave order, but that that issue had instead been left to the trial judge. The proceedings were taken into the Judicial Review List's case management list. The Authority was directed to file opposition papers, and the court ruled that the question of

whether the delay issue should be dealt with as a preliminary issue could be reviewed thereafter.

46. The matter was listed again for case management on 13 March 2019. On that occasion, it was indicated to the court that the parties were agreed that all matters should be dealt with at the substantive hearing. Counsel for the Authority did make it clear, however, that her clients stood over the merits of the time-limit point.

47. Prior to the adjournment application on 27 November 2019, the understanding seems to have been that the only procedural issues to be dealt with in advance of the substantive hearing were (i) an application to amend the Statement of Grounds, and (ii) an application for the discovery of documents. (The application for leave to amend was heard and determined in May 2019. The discovery application had been heard in July 2019 and a reserved judgment delivered in August 2019).

48. As explained above, the management of the case took a different course in light of the adjournment application.

DETAILED DISCUSSION

(1). THREE MONTH TIME-LIMIT

49. The first task for the court is to identify the date from which time began to run for the purposes of Order 84, rule 21. It is only if the proceedings are found to have been instituted *outside* the three month time-limit, that it will then become necessary to consider the separate question of whether an extension of time should be allowed.

50. Order 84, rule 21(1) provides that an application for leave to apply for judicial review shall be made within three months from "the date when grounds for the application first arose".

51. On the facts of the present case, the chronology of events can be summarised as follows.

20 July 2018	Decision to grant the marketing authorisation
23 July 2018	Decision posted on the Authority's website
23 August 2018	Objector first becomes aware of decision
12 October 2018	Objector's submission to the Authority
30 October 2018	Authority's substantive response
8 November 2018	Osteopen placed on market (Affidavit of Michael Burke)
20 December 2018	*Ex parte* application for leave
8 January 2019	Decision published in Iris Oifigiúil

52. The Directive mandates that both (i) a reasoned decision, and (ii) an assessment report be made publicly available *without delay* in the case of the grant of a marketing

authorisation. (See articles 25 and 94 of the Directive). A decision to grant a marketing authorisation is, in principle, justiciable. See, by analogy, Case C-104/13, *Olainfarm AS*.

53. It would undermine the purpose of the requirement for public notification and the right to effective judicial protection were the three month time-limit under Order 84, rule 20(1) to begin to run *prior* to the date of the publication of the decision. To interpret the rule otherwise could produce a scenario whereby the time-limit for judicial review proceedings would have already expired before the public were notified of the decision. The more difficult question, however, is whether the time-limit runs from the date of the *ad hoc* posting of the decision and associated documentation on the Authority's website, or, alternatively, from the date of the formal publication of the decision in Iris Oifigiúil.

54. As noted earlier, the manner in which the public notification requirements mandated by the Directive have been transposed into domestic law is curious. The requirements of article 25 have not been specifically transposed; instead, the Authority is directed under the 2007 Regulations to "have regard to" same. It seems that the Authority has adopted the pragmatic approach of posting decisions and associated documentation on its website.

55. This form of public notification is not, however, sanctioned by the 2007 Regulations. The only form of notification which is actually prescribed under the 2007 Regulations is that provided for under regulation 46, i.e. the publication of the decision in Iris Oifigiúil. This form of notification does not, on a literal reading at least, meet the requirements of the Directive in that it is confined to publication of the decision alone: there is no express requirement under regulation 46 to publish the assessment report.

56. The imposition of a time-limit on judicial review proceedings—which can only be extended in the very limited circumstances allowed for under Order 84, rule 21(3)—represents a potential restriction on the constitutional right of access to the courts. Whereas such restrictions are justified in the common good, it is at least arguable that such time-limits should only be applied in strict accordance with the relevant statutory regime. On this argument, the time-limit for challenging a marketing authorisation should only run from the date that the relevant decision has been published in the prescribed form, i.e. publication in Iris Oifigiúil.

57. Having carefully considered the matter, however, I have concluded that the three month time-limit should be calculated instead from the date of the *ad hoc* posting of the decision on the Authority's website. This conclusion is reached on the basis that the posting of the decision and associated documentation on the website represents an effective form of public notification, and that the wording of regulation 9(4) of the 2007 Regulations is flexible enough to authorise this form of public notification. The Directive mandates that the reasoned decision and assessment report be made publicly available without delay. The Authority is obliged, under regulation 9(4), to have regard to these requirements, and this obligation is satisfied by publication on the website. The formal publication of the decision alone in Iris Oifigiúil provides less rather than more information, and it would seem pedantic to defer the running of the time-limit until the date of this publication.

58. My conclusion is informed, in part at least, by the particular circumstances of this case whereby the Objector had actual knowledge of the making of the decision by 23 August 2018, i.e. well within three months of the date of the posting of the decision on the website. Given its actual knowledge, it is difficult for the Objector to argue convincingly that the running of time should have been postponed until the date of the subsequent publication in Iris Oifigiúil (8 January 2019). This is especially so where there is no suggestion that the Objector or its officers ever examined Iris Oifigiúil or relied on same as a source of information.

59. For the sake of completeness, I should also record that I do not accept the Objector's argument that the time-limit only began to run from the date of the Authority's substantive response of 30 October 2018. (This was the response to the submission made by the Objector on 12 October 2018). The nature and extent of the information which must be made publicly available is set out at article 25 of the Directive. On the facts of the present case, the requisite information was made available on the Authority's website on 23 July 2018. Once the legislative requirements had been complied with, time began to run. If and insofar as the Objector wishes to argue that further information was required in order to allow it to institute judicial review proceedings, this is a matter which goes towards the *separate* question of an extension of time. It does not affect the date upon which time begins to run.

60. In summary, therefore, I have concluded that the time-limit for the purposes of Order 84, rule 21 began to run from the date upon which the decision and associated documentation was first published on the Authority's website, i.e. 23 July 2018. This was the date upon which compliance with the requirements of articles 25 and 94 of the Directive had been achieved. The decision to grant a marketing authorisation had been published, together with a copy of the assessment report. A person inspecting the website would thus be aware of the nature of the decision, i.e. a decision to grant marketing authorisation, and would also understand the basis upon which the decision had been reached.

61. Whereas the hypothetical person inspecting the website might wish to argue that more expansive reasons should have been provided, or that certain information which had been omitted on the grounds of its "commercially confidential nature" by reference to article 25(4), should have been published, that person would nevertheless already be armed with sufficient material to allow proceedings to be prepared and drafted. This is borne out by the facts of the present case where, of course, the Objector had been in a position to put together a detailed objection to the decision by reference to the materials available as of 23 July 2018. It will be recalled that the detailed objection of 12 October 2018 had been prepared without any necessity for an analysis of a sample of the generic product.

62. The separate argument that the events of March 2019 gave rise to a *fresh* decision from which time begins to run again is addressed at paragraph 88 below.

(2). EXTENSION OF TIME

63. In light of the above finding that the proceedings were instituted outside the three month time-limit, it is necessary to move on to a consideration of whether an extension of time should be allowed.

64. Insofar as relevant, Order 84, rule 21 provides as follows.

> (3) Notwithstanding sub-rule (1), the Court may, on an application for that purpose, extend the period within which an application for leave to apply for judicial review may be made, but the Court shall only extend such period if it is satisfied that:
>
> (a) there is good and sufficient reason for doing so, and
> (b) the circumstances that resulted in the failure to make the application for leave within the period mentioned in sub-rule (1) either:
>
> (i) were outside the control of, or
> (ii) could not reasonably have been anticipated by the applicant for such extension.
>
> (4) In considering whether good and sufficient reason exists for the purposes of sub-rule (3), the court may have regard to the effect which an extension of the period referred to in that sub-rule might have on a respondent or third party.
>
> (5) An application for an extension referred to in sub-rule (3) shall be grounded upon an affidavit sworn by or on behalf of the applicant which shall set out the reasons for the applicant's failure to make the application for leave within the period prescribed by sub-rule (1) and shall verify any facts relied on in support of those reasons.

65. This form of the rule was introduced by way of amendment in 2011. See Rules of the Superior Court (Judicial Review) 2011 (S.I. No. 691 of 2011).

66. The principles governing the exercise of the discretion to grant an extension of time under the amended version of the rule have recently been considered by the Supreme Court in *O'S (M). v. The Residential Institutions Redress Board* [2018] IESC 61; [2019] 1 I.L.R.M. 149. The majority judgment summarises the nature of the onus upon an applicant who seeks an extension of time as follows.

> "54. The foregoing decisions clearly require an applicant who does not apply for leave to issue judicial review within the time specified in the Rules to furnish good reasons which explain and objectively justify the failure to make the application within the time limit and which would justify an extension of time up to the relevant date."

67. The judgment goes on to address the interpretation of sub-rule 21(3)(b) as follows.

> "95. In accordance with the ordinary meaning of the words used, sub-rule (3)(b) is only directed to 'the circumstances that resulted in the failure to make the application for leave within the [three month] period…'. It is not, by its words, directed to the entire period during which the time is sought to be extended as is the requirement

for good and sufficient reason in sub-rule (3)(a). However, it is to be applied in the context of an application for an extension of time and therefore, it is in a context where a person did not apply within the three month period but is now attempting to satisfy the Court that an extension should be granted up to the date of application.

96. The second feature of the words used to which I would draw attention is the phrase 'the circumstances that resulted in the failure to make…'. The court is not directed or confined to considering 'the reason for which' the application was not made within the three month period, notwithstanding that the Rules Committee have in sub-rule (a) used the term 'reason' in referring to the requirement of a good and sufficient reason. Their intent in using different words in sub-rules (a) and (b) should be given effect."

68. The judgment summarises the effect of the sub-rule as encompassing "all the relevant circumstances which resulted in the failure to apply within time", and states that it appears probable that in most instances where a court has been satisfied that there is a "good and sufficient" reason to extend time, it will also be in a position to make a positive finding under sub-rule (3)(b) in relation to the circumstances which resulted in the failure to apply within the three month period.

69. The Objector relies on two principal factors as justifying the delay in the institution of the within proceedings. The first is that it was necessary and/or appropriate to engage in correspondence with the Authority before having recourse to the courts. The second is that it was necessary to obtain a sample of the generic product, Osteopen, on the open market and to have same analysed before instituting proceedings. For the reasons which follow, I have concluded that neither of these factors fulfils the criteria under Order 84, rule 21(3).

(i). Engagement in correspondence prior to proceedings

70. In some instances, there may be a practical benefit to a putative litigant engaging in correspondence with a decision-maker prior to the institution of judicial review proceedings. For example, the correspondence may result in the clarification of some aspect of the decision and thereby address the concerns of the putative litigant, and thus obviate the necessity for proceedings. The case law is clear, however, that an applicant for judicial review must nevertheless comply with the time-limits, and cannot rely on their having engaged in correspondence as justifying a failure to make the application for leave within time. This principle is illustrated by the following two judgments. The first in time is *Irish Skydiving Club Ltd. v. An Bord Pleanála* [2016] IEHC 448. This judgment was delivered in the context of an application for an extension of time under section 50(8) of the Planning and Development Act 2000. The statutory test is in almost identical terms to Order 84, rule 21(3). The High Court (Baker J.) rejected an argument that an extension of time should be granted by reference *inter alia* to the fact that the applicant had been engaged in correspondence with the decision-maker. The judgment emphasises that time ran from the date of the decision, and that, prior to the expiration of the time-

limit, the applicant had been in possession of and had "control" of all of the relevant facts and information, and had sufficient information and knowledge to instruct solicitors to advise and to act on its behalf. The judgment also confirms that a decision-maker, in response to correspondence, is not obliged to state expressly that the time for seeking judicial review is short and fast approaching its statutory limit.

71. The second judgment is McCaffery v. Central Bank of Ireland [2017] IEHC 546. The High Court (Noonan J.) doubted whether engagement in correspondence with a decision-maker could ever ground an application for an extension of time by reference to Order 84, rule 21(3).

> "51. In essence then, the grounds upon which the applicants were given leave by the court to seek an extension of time were that their solicitor was corresponding with the Bank and it was reasonable to await the outcome before deciding to seek judicial review. It is difficult to see how this could ever form the basis for the court granting an extension of time even if it did amount to a good and sufficient reason, which is in itself doubtful, because it could not on any view be regarded as a circumstance which was either outside the control of or could not reasonably have been anticipated by, the applicant. The pursuit of such correspondence was of course directly controlled by the applicants. For the same reason, there could be no suggestion that the pursuit of such correspondence somehow could not have been anticipated by the applicants as they themselves were the instigators of it."

72. The principle set out in these two judgments applies with even greater force to the facts of the present case. The only conceivable basis upon which correspondence might be seen as necessary in advance of the institution of judicial review proceedings is where the information available in respect of a decision is so sparse that no meaningful steps can be taken towards the preparation of judicial review proceedings. By contrast, in the present case the Authority had posted detailed information in respect of the decision on its website. The published information included the assessment report. Indeed, this information was sufficiently detailed as to allow the Objector to formulate specific grounds of complaint in its submission of 12 October 2018. Many of these grounds of complaint ultimately found their way into the statement of grounds in these proceedings.

73. In truth, there is nothing in the initial correspondence which suggests that the Objector was seeking information in order to allow it to prepare judicial review proceedings. A reference to the possibility of taking judicial review proceedings only appears for the first time in the letter of 13 December 2018.

74. It is also telling that, for a period of more than two months, no attempt was made to chase up the Authority on its promise of a substantive response to the submission of 12 October 2018. It will be recalled that the Objector mistakenly thought that no response had been received: in fact, the response of 30 October 2018 had been deleted in error by an employee. Notwithstanding that the Objector was under the misapprehension that no substantive response was ever received, it made no further approach to the Authority until 13 December 2018. Against this factual background, it cannot realistically be said

that the Objector was actively engaged in correspondence or that it had reasonable grounds for thinking that the Authority was acquiescing in the delay in the institution of proceedings.

75. There is one further aspect of the correspondence which is also unsatisfactory, and which militates against its being relied upon as justifying an extension of time. None of the correspondence is addressed to the party who would be most immediately affected by any judicial review proceedings, namely the holder of the new marketing authorisation, Chanelle Pharmaceuticals Manufacturing Ltd. This is so notwithstanding that its postal address was readily available. (The address is set out in full in the documentation available on the Authority's website). One of the purposes of the tight three month time-limit is to protect the interests of affected third parties by ensuring that they are put on notice of a challenge to a decision. See, by analogy, *K.S.K. Enterprises Ltd. v. An Bord Pleanála* [1994] 2 I.R. 128 (at 135).

> "From these provisions, it is clear that the intention of the legislature was greatly to confine the opportunity of persons to impugn by way of judicial review decisions made by the planning authorities and in particular one must assume that it was intended that a person who has obtained a planning permission should, at a very short interval after the date of such decision, in the absence of a judicial review, be entirely legally protected against subsequent challenge to the decision that was made and therefore presumably left in a position to act with safety upon the basis of that decision."

76. The Objector should have notified the Authorisation Holder of the fact that the validity of the latter's marketing authorisation was being questioned. This could have been done by the simple expedient of furnishing it with copies of the correspondence which was being sent to the Authority. Had this been done, then the Authorisation Holder would at least have had an opportunity to consider whether it wished to hold off further investment pending the outcome of the dispute. (The relevant evidence is set out in the affidavit of Michael H. Burke sworn herein on 6 March 2019, at paragraphs 63 to 67).

77. No explanation has been provided on affidavit for the omission to notify the Authorisation Holder. Counsel for the Objector sought to suggest that it was a matter for the Authority to inform the Authorisation Holder of the existence of the objection of 12 October 2018. With respect, the onus is on the party seeking to challenge a decision to ensure that the affected party is put on notice of the intended proceedings within the three month time-limit.

(ii). Awaiting analysis of generic product

78. The second ground relied upon in support of the application for an extension of time is that it was necessary to obtain and analyse a sample of the generic product before instituting proceedings.

79. There is a consistent line of case law to the effect that a putative applicant is, generally, not entitled to delay the institution of judicial review proceedings in order to assemble all of the materials which it wishes to rely upon in its proceedings, including, for example, expert reports. See, for instance, *Talbotgrange Homes Ltd. v. Laois County Council* [2009] IEHC 535, [66] ("it would be a counsel of perfection for a party to obtain all relevant information from, say, a Government department before proceeding with an application"); *Irish Skydiving Club Ltd. v. An Bord Pleanála* [2016] IEHC 448, [41] ("applicant did not in my view need to engage engineering considerations before making a determination whether to challenge the decision of the Board by judicial review"); *SC SYM Fotovoltaic Energy SRL v. Mayo County Council (No. 1)* [2018] IEHC 20, [100] (not necessary to await receipt of response to request under Freedom of Information Acts); and A Foster Mother v. Child and Family Agency [2018] IEHC 762, [121] ("not entitled to await receipt of the psychologist report before making an *ex parte* application for judicial review").

80. Rather, the correct approach is to institute proceedings within time, and, if appropriate, to make an application thereafter to amend the statement of grounds once the additional awaited materials are to hand. The legal test for granting leave to amend is sufficiently flexible to allow for amendments on this basis. See, generally, *Keegan v. Garda Síochána Ombudsman Commission* [2012] IESC 29; [2012] 2 I.R. 570 and *Aquatechnologie Ltd. v. National Standards Authority of Ireland* [2000] IESC 64.

81. It is only in circumstances where it would be impracticable or unreasonable to institute judicial review proceedings in the absence of an expert report that it will be appropriate to defer the institution of proceedings. Such cases will be rare indeed. The determination of whether the deferral of proceedings was appropriate—and capable of justifying an extension of time—will have to be made by reference to the grounds of challenge ultimately put forward in the statement of grounds. It is only if legal proceedings could not have been formulated without an expert report that the deferral will be found to have been appropriate.

82. It is possible to envision a hypothetical scenario wherein the grounds of challenge to a decision to grant a marketing authorisation to a veterinary medicinal product are such that proceedings could not have been formulated without sight of an expert report analysing the product. There might, for example, be nothing in the publicly available documentation to indicate that there had been non-compliance with the requirements of article 13 of the Directive. The grounds of challenge might only be disclosed for the first time once the product had been analysed, and some discrepancy in the composition of same identified. In such a scenario, an applicant might be entitled to institute judicial review proceedings outside the three month time-limit on the basis that the grounds of challenge could not have been discoverable within time. It is important to emphasise, however, that a putative applicant would have to demonstrate diligence in obtaining and analysing a sample of the product. As reiterated by the Supreme Court in *O'S (M). v. The Residential Institutions Redress Board* [2018] IESC 61; [2019] 1 I.L.R.M. 149, there is an onus upon an applicant not only to justify the failure to have moved within the initial

three month period, but also to justify the lapse of time up and until the date of the institution of proceedings.

83. The facts of the present case are entirely different than the hypothetical scenario posited above. Here, it is evident from the detailed submission made to the Authority on behalf of the Objector on 12 October 2018 that many of the grounds of challenge had already crystallised at that stage. The Objector had identified—presumably on the basis of the publicly available documentation—what it alleges to be non-compliance with the requirements of article 13 of the Directive. All this was done at a time when the Objector had not yet had the benefit of an analysis of a sample of the generic product. Many of the complaints identified in the submission of 12 October 2018 are repeated verbatim in the statement of grounds as filed on 20 December 2018.

84. It is self-evident, therefore, that the Objector would have been in a position to formulate a detailed statement of grounds in advance of the expiration of the three month period on or about 23 October 2019. In particular, two of the three principal planks which form part of the case as ultimately pleaded could have been advanced prior to that date, namely (i) the contention that Pentosan Polysulfate Sodium ("PPS") is fundamentally unsuitable for approval as a generic given that it does not have a uniform composition; and (ii) the contention that the product is a *biological* veterinary medicinal product, and, accordingly, subject to the requirements of article 13(4) of the Directive. The separate grounds in relation to the alleged inadequacy of reasons could also have been advanced in October 2018.

85. The fact that the analysis of a sample of the generic product, which had been obtained subsequent to the expiration of the time-limit, allowed the Objector to formulate *additional* grounds of challenge did not relieve it of the obligation to institute proceedings within the three month time-limit. The correct approach would have been to institute proceedings within time, and then to apply subsequently to amend the statement of grounds so as to introduce the additional grounds. This approach would have ensured that one of the principal objectives underlying the time-limit, namely ensuring that affected parties are put on notice of a legal challenge in early course, would have been observed.

86. As noted earlier, one of the striking features of the correspondence in this case is that the Objector did not take any steps to notify the Authorised Holder that the validity of the latter's marketing authorisation was being questioned. It seems that the first that the Authorised Holder knew of the challenge was when the proceedings were instituted on 20 December 2018. The Objector should have put the Authorised Holder on notice earlier, and, further, should have taken the obvious step of requesting a sample of the generic product. Whereas the Authorised Holder would not have been under any legal obligation to provide such a sample, had it refused to do so, such a refusal would have been a significant factor which the court would take into account in the exercise of its discretion in the context of either (i) an application to amend existing proceedings, or (ii) an application for an extension of time. Put otherwise, if a party's non co-operation

frustrated an applicant in bringing judicial review proceedings within time, then that party cannot assume that the time-limits will be enforced in its favour.

87. In summary, therefore, I am satisfied that on the particular facts of this case the Objector would have been in a position to formulate a meaningful statement of grounds within the three month time-limit. It was not necessary for it to await receipt of an analysis of a sample of the generic product before launching its legal challenge to the marketing authorisation.

DID AUTHORITY MAKE A FRESH DECISION ON 6 MARCH 2019?

88. One of the distinctive features of the legislative scheme for the authorisation of the marketing of veterinary medicinal products is that the Authority is under an express obligation to suspend, revoke, withdraw or vary marketing authorisations in certain circumstances. This feature distinguishes a marketing authorisation from many other types of licence, consent or permission. Given the particular reliance which has been placed in argument before this court upon case law decided under the planning legislation, it should be noted that a marketing authorisation is more precarious than a planning permission. The general position under the planning legislation is that a planning permission, which has not been the subject of judicial review proceedings brought within time, will, ordinarily, be immune from legal challenge thereafter. A planning permission can, generally, only be revoked in very limited circumstances, and such revocation will often entail the payment of statutory compensation. The existence of these points of distinction mean that some caution must be exercised when "reading across" the case law on the application of time-limits under the planning legislation to a decision to grant a marketing authorisation.

89. The Objector has sought to argue that certain correspondence issued on behalf of the Authority by its solicitors on 6 March 2019 represents a decision "not to withdraw" the marketing authorisation of 20 July 2018. It is further submitted that this represents a *fresh* decision in respect of which the three month time-limit only begins to run from 6 March 2019. It seems that an application to amend the statement of grounds to include additional grounds directed to these alleged "decisions" of 6 March 2019 was allowed by order of the High Court (Noonan J.) on 1 May 2019. As discussed below, however, although the relief sought at the amended paragraph d (6) of the statement of grounds refers to the events of 6 March 2019, the amended grounds of challenge pleaded at part (e) of the statement of grounds are, in truth, all directed to the *earlier* decision of 20 July 2018.

90. It *appears* to be accepted by all sides that the question of whether this aspect of the proceedings might also be out of time is something which I would have jurisdiction to address as part of my preliminary ruling on delay. Put otherwise, it does not appear to be seriously suggested that the making of the order on 1 May 2019 granting leave to amend involved conclusive findings to the effect that (i) the amendment had been made within time and that the time point could not be revisited, and (ii) the letters of 6 March 2019 represented fresh "decisions". Lest I am incorrect in this understanding, however, I will

hear further submissions from counsel before finalising an order on this aspect of the case.

91. In principle, a formal decision made pursuant to article 83 of the Directive and/or regulation 13 of the 2007 Regulations would be justiciable as a separate decision, i.e. a decision which is distinct from an initial decision to grant marketing authorisation. A putative applicant could argue, for example, that a veterinary medicinal product does not have any therapeutic effect on the species of animal for which the treatment is intended, and that the Authority is, therefore, obliged to revoke or withdraw the marketing authorisation in accordance with article 83(1)(b) of the Directive. If the Authority made a formal decision not to revoke or withdraw, then that decision would be justiciable. The three month time-limit would run from the date of public notification of the decision not to revoke or withdraw. It would be no answer to the proceedings to say that they involved a collateral challenge to the earlier decision to grant marketing authorisation. The precise point of article 83 is that it allows for the possibility of an authorisation being revoked or withdrawn. This regulatory power is not subject to any three month time-limit.

92. This is not, however, what has occurred in the present case. The letters of 6 March 2019 did no more than reiterate the decision of 20 July 2018, and to elaborate upon the reasoning underlying that decision. The correspondence does not disclose a formal decision pursuant to article 83 of the Directive. Indeed, it is telling that the principal deponent on behalf of the Objector, Mr Cullis Hill, appears to have fully understood that the letters of 6 March 2018 did no more than restate the basis of the decision to grant the marketing authorisation. See, paragraph 32 of his affidavit of 10 April 2019.

93. The reiteration of an earlier decision does not constitute a fresh decision for the purposes of the time-limit under Order 84, rule 21(3). See, by analogy, *Sfar v. Revenue Commissioners* [2016] IESC 15.

94. Moreover, the additional grounds of challenge inserted into the statement of grounds pursuant to the order granting leave to amend of 1 May 2019 are all directed to the validity of the decision of 20 July 2018. In brief, the additional grounds treat the letters of 6 March 2019 as the outcome of an "ongoing consultative process" in respect of the decision of 20 July 2018. There is no express plea at paragraphs (e) 42A to (e) 42F (inclusive) to the effect that the Authority failed to comply with article 83 of the Directive. Rather, all of the pleas are directed to alleged non-compliance with article 13 of the Directive, and in particular, article 13(4) thereof. These pleas are referable exclusively to the decision of 20 July 2018. There is nothing in the amended part (e) of the statement of grounds which asserts that there had been a breach of article 83 as a result of the letters of 6 March 2019.

95. In summary, therefore, the two letters of 6 March 2019 do not represent fresh decisions for the purposes of the calculation of the time-limit under Order 84, rule 21. The three month time-limit falls to be calculated from 23 July 2018 alone, i.e. the date of the publication of the decision of 20 July 2018 on the Authority's website, and not from any later date.

CONCLUSION AND PROPOSED FORM OF ORDER

96. For the reasons set out herein, I have concluded that the relevant date for the calculation of the three month time-limit under Order 84, rule 21 of the Rules of the Superior Courts is the date of the posting of the decision to grant the marketing authorisation on the Authority's website (23 July 2018). The proceedings were not instituted within three months of that date.

97. The Objector has failed to demonstrate "good and sufficient" reasons for the grant of an extension of time for the bringing of the proceedings. I am satisfied that, on the particular facts of this case, the Objector would have been in a position to formulate a meaningful statement of grounds within the three month time-limit. It was not necessary for it to await receipt of an analysis of a sample of the generic product before launching its legal challenge. The correct approach would have been to institute proceedings within time, and to apply thereafter to amend the statement of grounds in the event that the analysis disclosed *additional* grounds of challenge subsequently. This approach would have ensured that one of the principal objectives underlying the time-limit, namely ensuring that affected parties are put on notice of a legal challenge in early course, would have been observed.

98. The two letters of 6 March 2019 do not represent fresh decisions for the purposes of the calculation of the time-limit under Order 84, rule 21. Moreover, there is nothing in the amended part (e) of the statement of grounds which asserts that there had been a breach of article 83 as a result of the letters of 6 March 2019.

99. The judicial review proceedings will, therefore, be dismissed in their entirety. (This is subject to the caveat entered at paragraph 90 above that I will hear further submissions from counsel before finalising an order in respect of the amendments made pursuant to the order of 1 May 2019).

POSTSCRIPT

100. As appears from paragraph 99 above, the parties were invited to make further submissions on one issue, namely the implications of the order of 1 May 2019 granting leave to amend the statement of grounds. Following delivery of an unapproved copy of this judgment on 14 January 2020, the parties have since confirmed at a hearing on 21 January 2020 that the making of the order on 1 May 2019 did not entail any conclusive findings to the effect either (i) that the amendment had been made within time and that the time point could not be revisited, or (ii) that the letters of 6 March 2019 represented fresh "decisions". Accordingly, it was open to this court to determine these issues on the hearing of the preliminary application. Given the clarification of this jurisdictional issue, this court now makes the order proposed at paragraph 99 above, i.e. an order dismissing the judicial review proceedings in their entirety.

101. This court will also make an order in accordance with (i) sections 168 and 169 of the Legal Services Regulation Act 2015 ("*the LSRA 2015*"), and (ii) Order 99 of the Rules of the Superior Courts (as amended in 2019) directing that the Applicant for judicial review (Arthropharm (Europe) Ltd.) do pay the costs of the Respondent (the Health Products

Regulatory Authority) and of the Notice Party (Chanelle Pharmaceuticals Manufacturing Ltd.). Section 169(1) of the LSRA 2015 provides that a party who is entirely successful in civil proceedings is entitled to an award of costs against a party who is not successful in those proceedings, *unless* the court orders otherwise, having regard to the particular nature and circumstances of the case, and the conduct of the proceedings by the parties.

102. On the facts of the present case, the "event" went in favour of the Respondent and Notice Party. Whereas the event might be regarded as a narrow one, i.e. the time-limit point, the finding has been dispositive of the entire proceedings (subject always to the Applicant's right of appeal to the Court of Appeal). The judicial review proceedings have been dismissed in their entirety.

103. Costs orders are made in favour of both the Respondent and the Notice Party. Whereas a notice party will not always be entitled to an award of costs, I am satisfied that the Notice Party in the present case was a party directly affected by the proceedings, as the holder of the marketing authorisation impugned in the proceedings. It was entitled to defend its interests, and it was appropriate, therefore, that it participated in the proceedings and it should recover its costs from the unsuccessful party.

104. The costs order extends to include *all* of the costs of the proceedings to date, i.e. the award of costs is not confined to the costs of the preliminary action to strike out the proceedings on the grounds of delay. The costs order also includes all reserved costs.

105. The costs are to be measured by the Office of the Legal Costs Adjudicator in default of agreement.