THE HIGH COURT

COMMERCIAL

[2018 No. 102 J.R.]

[2018 No. 22 COM]

IN THE MATTER OF COUNCIL DIRECTIVE 2014/18/EC

AND IN THE MATTER OF THE EUROPEAN COMMUNITIES (AWARD OF PUBLIC AUTHORITIES' CONTRACTS) REGULATIONS (S.I. 284 OF 2016)

AND IN THE MATTER OF THE EUROPEAN COMMUNITIES PUBLIC AUTHORITIES' CONTRACTS) (REVIEW PROCEDURES) REGULATIONS 2010 (S.I. 130 OF 2010 AS AMENDED BY S.I. 192 OF 2015 AND S.I. 327 OF 2017)

BETWEEN

SANOFI AVENTIS IRELAND LTD TRADING AS SANOFI PASTEUR

APPLICANT

AND

HEALTH SERVICE EXECUTIVE

RESPONDENT

AND

GLAXOSMITHKLINE IRELAND LTD

NOTICE PARTY

JUDGMENT of Mr. Justice Denis McDonald delivered on the 12th day of October, 2018

Introduction

1. In these proceedings, the applicant ("Sanofi") seeks to challenge the decision by the respondent ("The HSE") to award to the notice party ("Glaxo") a contract for the supply of approximately one million doses of 6-in-1 Vaccine (Diphtheria, tetanus, acellular pertussis, Hepatitis B, inactivate polio vaccine, haemophilus influenza Type B conjugate) over a five-year period (approximately) together with a contingency of 200,000 doses. The contract was due to commence in January 2018.

2. The challenge by Sanofi to the decision of the HSE is pursued on three principal grounds: -

> (a) It is contended that the HSE failed to comply with its obligations to provide reasons for its decision and in particular (but not exclusively) in failing to set out the characteristics and relative advantages of the Glaxo tender;
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> (b) It is also contended that there has been a breach by the HSE of the principles of equal treatment and transparency. In this context, two broad complaints are made: -
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> > (i) it is alleged that there was a failure to formulate the award criteria in such a way that reasonably well-informed and normally diligent tenderers will interpret them in the same way; and
> >
> > (ii) there was a failure to disclose sub-criteria and/or weighting;
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> (c) Thirdly, it is contended that the HSE made a manifest error in the way in which it evaluated the tenders.

3. It will be necessary, in due course, to consider each of the grounds of challenge in detail. Before doing so, it may be helpful to set out some of the basic facts.

Background

4. According to Mr. Martin Dempsey (the deponent of the affidavits sworn on behalf of Sanofi) a broad range of high quality vaccines are manufactured by the Sanofi group, a multinational pharmaceutical company.

5. Mr. Dempsey was the person responsible for the overall coordination of the tenders submitted on behalf of Sanofi to the HSE. He has 29 years' experience in the pharmaceutical industry and has held senior positions in the Sanofi Vaccine Division for Ireland since 2005.

6. Insofar as the HSE is concerned, one of its functions is the administration of a comprehensive immunisation programme. For this purpose, the HSE National Immunisation Office ("NIO") was established in 2005 for the coordination of all publicly funded immunisation programmes including vaccine supply chain management. Since 2005, procurement of all vaccines for national programmes has been centralised and managed by the NIO. While the NIO currently has contracts of different durations for 23 vaccines, the 6-in-1 vaccine is supplied as part of the Primary Childhood Immunisation Programme under which children are required to have five visits to their general practitioner ("GP") to be fully vaccinated against thirteen infectious diseases. These vaccines are given in two or three injections to children at each of the five visits between the age of two months and thirteen months. All vaccines and their administration are funded by the HSE and provided free of charge by contracted GPs.

7. Glaxo is the supplier of the 6-in-1 vaccine to the HSE under the pre-existing contract which commenced in September 2013. Previously, it held a corresponding contract which commenced in June 2008 for the supply of the vaccine to the HSE.

8. The Sanofi vaccine is known as "Hexion". The Glaxo vaccine is known as "Infanrix Hexa". The Sanofi vaccine is a fully liquid ready

to use vaccine which is supplied in a pre-filled syringe. The Glaxo vaccine requires reconstitution. It is supplied in two parts, namely a pre-filled syringe together with a vial containing a single element of the vaccine described in the affidavit evidence before the court as the "lyophilised Hib component". As I understand it, the vial is added by the medical practitioner to the pre-filled syringe immediately before the vaccine is administered to the child.

The tender competition

9. On 17th August 2017, seven contractors (including both Sanofi and Glaxo) were appointed by the HSE to a Framework Agreement for the provision and supply of various vaccine products. The framework agreement was put in place pursuant to Regulation 33 of the European Union (Award of Public Authority Contracts) Regulations 2016 (S.I. 284 of 2016) ("The Procurement Regulations").

10. On 22 September 2017, the HSE published an "Invitation of Tender" (The "IOT") in relation to a Mini-Competition for the supply of the 6-in-1 vaccine ("the Mini Competition"). The Mini Competition was open to members of the Framework Agreement only. Included in the tender documents was a blank template Tender Response Document ("the Tender Response Document") which contained further information regarding the Mini Competition and included certain additional details relating to the technical and functional criteria. It will be necessary, in due course, to consider some of the provisions of the Tender Response Document and in particular to consider the sub-categories described in the document.

11. According to Mr. Dempsey's first affidavit, the Mini Competition presented a significant commercial opportunity for Sanofi. If Sanofi were successful in the Mini Competition, Mr. Dempsey says this would mean an increase by more than 180% of Sanofi's current sales forecasts for the next three years.

12. On 13 October 2017, Sanofi submitted the Tender Response Document (duly completed by it) together with various appendices. According to Mr. Dempsey, the Sanofi tender was designed to address the criteria identified in the template Tender Response Document. For the purposes of these proceedings, the relevant criteria are those relating to the functional and technical aspects of the tender. Mr. Dempsey says at para. 19 of his first affidavit: -

> *"I assumed that the tenders would be evaluated and assessed by reference to these factors only, and not by reference to other factors which were not disclosed in either the IOT or the Tender Response Document."*

13. In addition to the tender submitted by Sanofi, both Glaxo and Merck Sharp & Dohme ("MSD") also submitted tenders. The technical and functional aspects of the tenders were reviewed and evaluated by a Procurement Evaluation Group (the "PEG"), which was made up of the following: -

> (a) Dr. Brenda Corcoran MB, BCh, BAO (NUI), Diploma in Child Health (UCD); Master in Public Health (UCD) Fellow of the Faculty of Public Health Medicine (RCPI), Diploma in Leadership and Quality in Healthcare (RCPI). Dr. Corcoran is head of the NIO. She is also a member of the National Immunisation Advisory Committee, an expert committee of RCPI. According to the affidavit evidence before the court, she is one of only four people in Ireland to complete the Advanced Course of Vaccinology for Vaccine Decision Makers. She has worked in public health medicine for over twenty years in Ireland, Africa and Eastern Europe prior to establishing the NIO in 2005. She is also responsible for the coordination of high quality standardised implementation of publicly funded childhood and adult immunisation programmes;
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> (b) Mary Dowling, Diploma in Healthcare Management, Diploma in Quality and Leadership, RCPI. She has worked with the NIO as Business Manager since it was established in 2005. Even prior to the establishment of the NIO, she has formed part of the evaluation group for the procurement of vaccines since 2002. As explained by Dr. Corcoran in para. 13 of her affidavit sworn on 7 February 2018, four or five tender competitions for the award of contracts for various vaccines are evaluated annually. The NIO annual vaccine budget is of the order of €40 million.
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> (c) Cliona Kiersey, BSc. (Pharm.) (UCD), MBSI, Master in Pharmaceutical Medicine (UCD); Higher Diploma in Quality and Healthcare (RCSI), Diploma in Leadership and Quality in Healthcare (RCPI). According to the affidavit evidence before the court, Ms. Kiersey is also one of only four people in Ireland to complete the Advanced Course of Vaccinology mentioned at subpara. (a) above. She has worked in both retail and hospital pharmacies prior to joining the NIO in 2005. She is the chief pharmacist responsible for the centralising, purchasing, storage and distribution of all nationally funded vaccines (with an annual budget of €40 million). She has worked as part of a small multidisciplinary team (comprising nine members) to coordinate high quality standardised implementation of childhood and adult immunisation programmes. She represents the State on the EU-specific Procurement Procedure Steering Committee which will manage the vaccine procurement process on behalf of the Member States and the EU Commission. She also attends the EU Expert Group on Safety features for medicinal products for human use.
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> (d) Dr. Douglas Hamilton also attended the evaluation as an observer. However, according to the affidavit evidence before the court, he had no role in the evaluation of the tenders.

14. The PEG met by way of telephone conference on 19 October 2017. There are typed notes of that telephone conference which record that all three tenderers were deemed compliant with the mandatory requirements of the IOT and therefore qualified for evaluation. The notes also state that the evaluation of the technical and functional criteria "*was conducted and the scores are recorded on respective score sheets (attached)*". The notes also state that the evaluation was "*conducted as agreed*" and that the score in respect of technical and functional criteria was done "*using a Figure 1 – Figure 10 rating score system which would (sic) then converted into marks received on a pro rata basis*".

15. The scoring for the technical and functional criteria was then entered into a standard form document decribed as a "Decision Support Model" ("DSM"). The entries in the DSM are in very brief terms. The criteria which are most relevant for present purposes are those relating to "Presentation", "Compatibility & Interchangeability" and "Side Effects and Acceptability". For completeness, it should be noted that one of the entries was subsequently amended in December 2017. The original entry for "Compatibility & Interchangeability" for the Sanofi tender was described as: -

> *"8 Marks deducted for Interchangeability as data is based on 4 doses where 3 dose is in use".*

This was amended in December 2017 to read: -

> *"8 Marks deducted for Interchangeability as product only interchangeable if additional 4th dose given. NIAC recommended schedule is for 3 doses only".*

16. I should explain that the acronym "NIAC" is a reference to the National Immunisation Advisory Committee of RCPI mentioned in para. 13(a) above. The NIAC has published general immunisation procedures which, *inter alia*, recommend that the 6-in-1 vaccine should be administered in three doses over a period of time.

17. Following the scoring of each of the three tenders, the Glaxo tender achieved the highest overall score. The Sanofi tender was ranked third. However, it should be noted that Sanofi achieved more marks than Glaxo on the "Ultimate Cost" criterion. 60% of the total marks of 1,000 available was attributable to the "Ultimate Cost" criterion while 40% was attributable to the Technical and Functional criteria. The Marks awarded to Glaxo in relation to the Technical and Functional criteria is what made the difference in terms of the award of the contract.

18. On 3 November 2017, a draft of the contract approval request form was prepared for submission to the Head of Procurement of the HSE. This stated that the PEG had considered all proposals: -

> *"Using the Award Criteria and weightings published in the Mini-Competition Tender Response Document" and have conducted the evaluation using (inter alia) a 1- 10 rating score system in respect of the Technical and Functional Criteria".*

While the request form went through a number of different drafts, it was ultimately approved on 19 December 2017.

19. On 8 January 2018, the HSE wrote to Sanofi to say that its tender was unsuccessful and that the HSE intended not earlier than 23 January 2018, to award the contract to Glaxo. There are a number of errors in this letter which are not relevant for present purposes and therefore do not require to be addressed in this judgment. For example, the letter is written on the basis that a standstill period was applicable. This is not correct. No standstill period is applicable in the context of a contract awarded on the basis of a Framework Agreement.

20. The letter stated: -

> *"Following assessment for completeness and compliance of each of the Tenders . . . and following the evaluation of these Tenders, your submission was ranked as shown in the table attached as a schedule to this letter. This table comprises a summary of the reasons for the rejection of your Tender…"*

The table attached to the letter provided a record of the maximum marks available for each of the award criteria and individual sub-criteria. It also contained a column showing the marks awarded to Sanofi in respect of its tender in respect of each sub-criterion together with the corresponding marks awarded to Glaxo. The right-hand column of the table was headed "*Summary of Reasons (including details of the characteristics and relative advantages of the tender selected)*". In the right-hand column, the remarks given for each sub-criterion were in identical form to the entries in the DSM (subject to the amendment made in December 2017 as described in para. 15 above). There was, in fact, little or no information as to the characteristics and relative advantages of the Glaxo tender. In the course of her submissions on behalf of the HSE, Ms. Eileen Barrington S.C. suggested that, notwithstanding the heading of the right-hand column of this table, the letter of 8 January 2018 was not in fact intended to provide a summary of reasons or to provide details of the characteristics and relative advantages of the Glaxo tender. She submitted that the letter was therefore not deficient but in fact complied with the requirements of the Regulations (as set out below) in that it notified Sanofi of the decision to award the contract. For reasons which are discussed in more detail below, Ms. Barrington submitted that the obligation on a contracting authority to provide reasons (together with details of the characteristics and relative advantages of the successful tender) is not engaged until the contracting authority is requested to provide reasons. Here, Sanofi's request for reasons was made in a letter from its solicitors, Arthur Cox, on 16 January, 2018.

21. In the letter of 16 January 2018, Arthur Cox set out a number of specific complaints. The letter stated that Sanofi was "at a loss" to understand the outcome of the tender process, the methodology employed by the HSE in evaluating tenders and the marks awarded by the HSE in respect of a number of the award criteria including how sub-components of the award criteria were taken into account, assessed and weighted. The letter also complained that the HSE letter of 8 January 2018 did not provide any of the characteristics or relative advantages of the Glaxo tender. The Arthur Cox letter stated that Sanofi required a letter in a form which complied with the HSE's legal obligations. In due course, I will have to consider the terms of the correspondence in more detail. However, it is premature to do so at this point in the judgment.

22. A response was received by Byrne Wallace solicitors on behalf of the HSE by letter dated 22 January 2018. It stated that the information set out in the letter of 8 January 2018 was "more than adequate". Nonetheless, it provided more information in relation to some of the specific complaints made in the Arthur Cox letter of 16 January. In this context, it should be noted that the Arthur Cox letter had raised specific queries in relation to the sub-criteria (or more properly, sub-sub-criteria) in respect of "Presentation" "Shelf Life", "Side Effects and Acceptability" and "Compatibility and Interchangeability".

23. There was a further letter from Arthur Cox on 25 January 2018, taking issue with the approach taken by the HSE. In this letter it was contended that there was nothing in the previous correspondence from the HSE or Byrne Wallace which explained the characteristics or relative advantages of the Glaxo tender. The Arthur Cox letter reiterated Sanofi's request for a letter from the HSE in a form which complied with the HSE's legal obligations.

24. Byrne Wallace responded on 30 January 2018 providing some further detail. However, the letter also stated that the HSE was satisfied that it had complied with its obligations by means of the information and reasons provided to Sanofi in the letters of 8 and 22 January.

25. The approach taken by Byrne Wallace in their letter of 30 January 2018 was rejected by Arthur Cox in a further letter dated 1 February 2018. In that letter, Arthur Cox indicated that for the purposes of Regulation 8(4) of the European Communities (Public Authorities Contracts) (Review Procedures) Regulations 2010 (as amended) ("the Remedies Regulations") the complaints made in the Arthur Cox letters of 16 January 2018, 25 January 2018 and 1 February 2018 constitute the infringements alleged. It should be noted at this point that under Regulation 8(4) of the Remedies Regulations there is a requirement that a person intending to apply to the court under the Remedies Regulations must first notify the contracting authority in writing of the alleged infringement, the intention to make an application to the court, and the matters that are alleged to constitute the infringement of the procurement regulations. As the judgment of Haughton J. in *BAM PPP PGGM Infrastructure v. National Treasury Management Agency* [2016] IEHC 546 at paras. 104 – 105, makes clear, a failure to comply with Regulation 8(4) of the Remedies Regulations would have the result that a disappointed tenderer would not be entitled thereafter to pursue that particular complaint in judicial review proceedings.

26. These proceedings were subsequently commenced on 2 February 2018. On 12 February 2018, the proceedings were transferred to

the Commercial Court list, on the application of the HSE. In addition, the HSE sought to lift the automatic suspension. The latter application was listed for hearing on 23 February 2018 but was resolved on the basis that there would be an extension of the existing contract with Glaxo pending the determination of these proceedings.

27. On 5 March 2018, Glaxo applied to be joined as a notice party to the proceedings. By order of McGovern J. on that day, Glaxo was joined as a notice party but the court declined to grant leave to Glaxo to file opposition papers. Leave was given to Glaxo to file an affidavit to correct any alleged factual inaccuracies in the affidavits previously submitted in the proceedings.

28. On 17 May 2018, discovery was made by Sanofi. On 18 May 2018, discovery was made by the HSE. In the second schedule to the affidavit of discovery sworn on behalf of the HSE it was disclosed that handwritten notes were taken by members of the PEG during the conference call on 19 October 2017 but were no longer in the possession or power of the HSE. Subsequently on 31 May 2018, Arthur Cox raised a query in relation to the existence of notes by members of the PEG. In their response on 1 June 2018, Byrne Wallace stated: -

> *"The only notes . . .are those that were taken during the conference call... which were subsequently destroyed. These are referred to in the Second Schedule of the Affidavit of Discovery. No such documents were prepared by the members of the . . . PEG in advance of the meeting that took place on 19 October . . ." (Underlining in original).*

29. Arthur Cox did not pursue the matter any further in correspondence but in his third affidavit sworn on 11 June 2018 on behalf of Sanofi, Mr. Dempsey stated that there is a "*marked paucity of documents*" recording the evaluation of tenders by the PEG. His affidavit stated that he had assumed that the PEG would subject each tender to a "*thorough and rigorous analysis and would carefully document their deliberations . . .*" Mr. Dempsey also drew attention to the correspondence described above in which Byrne Wallace stated that the notes were destroyed. In para. 17 of his affidavit, Mr. Dempsey stated that, in the circumstances, it is: -

> *" …impossible to understand how the … PEG "considered all 3 tenders using the award criteria and weightings published in the tender documents" and how they assigned scores against Technical and Functional Criteria . . ."*

30. In the course of the first day of the hearing before me, an issue arose as to whether there was any complaint in the statement of grounds about the failure to keep records. Counsel for Sanofi, Mr. Declan McGrath S.C., made clear that Sanofi is not making the case that the failure to keep records or the destruction of records provides a basis "*in and of itself to quash the HSE decision*". However, he suggested that the issue is "*relevant to the consideration of whether the HSE has discharged its reason – giving obligation and whether it has complied with the principle of transparency in relation to the formulation of the award criteria and the non-disclosure of sub-criterion weighting and in relation to whether there has been manifest error or not…*". In response, I indicated that I would not make any ruling on that issue at that stage, but I made it clear that I have to decide this case on the basis of the issues pleaded in the statement of grounds. It should be noted that no application was made to amend or expand the statement of grounds following the making of discovery by the HSE.

31. At a later point on the first day of the hearing, it was suggested by Counsel on behalf of Sanofi that there was a breach of Regulation 84 of the Procurement Regulations which requires a contracting authority to maintain documentation to "*record the progress of all procurement procedures … and to justify the decisions taken at all stages of the …procedure, including the … selection and award of the contract*". In circumstances where no breach of Regulation 84 has been pleaded, I ruled that the court could not make any finding that Regulation 84 has been breached. I must bear in mind the approach taken by the Supreme Court in *A.P. v. D.P.P.* [2011] 1 IR 729 (dealt with further in paragraph 119 below) where Murray C.J. made clear at p. 732 that a party applying for relief by way of judicial review must set out clearly and precisely each and every ground upon which such relief is sought. In the same judgment, Murray C.J. deprecated the tendency for new arguments to emerge in the course of the hearing of judicial review proceedings which go beyond the scope of the grounds pleaded in the statement of grounds.

32. There was also a suggestion made in the course of the opening of the case that the plaintiff intended to rely on the principles set out in the judgment of Barrett J. in *Murtagh v. Kilrane* [2017] IEHC 384 where the court very helpfully summarised the applicable law relating to the duty of candour of public authorities in judicial review proceedings. However, I again made clear that in circumstances where this issue was never addressed in the affidavit evidence before the court and was not even canvassed in the written submissions, I could not permit the applicant (particularly in a commercial court case) to rely on a new argument of this kind in its opening oral presentation that had not been flagged in any way in advance to the respondents. I, therefore, did not permit the applicant to proceed further in relation to the duty of candour. In my view, if such a point was to be raised, it should have been properly ventilated in advance of the hearing so that the HSE would have had an opportunity to respond to it, and in particular, to place any relevant evidence before the court to seek to refute it.

The issues to be decided

33. As noted briefly in para. 2 above, the issues which arise for consideration are the following: -

> (a) In the first place, it is alleged that the HSE failed to comply with the duty to give reasons and in particular (but not exclusively) in allegedly failing to adequately set out the characteristics and the relevant advantages of the Glaxo tender.
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> (b) Secondly, it is alleged that there was a breach of the principles of equal treatment and transparency. As noted above, it is alleged that there was a failure to formulate the award criteria in such a way that reasonably well-informed and normally diligent tenderers ("RWIND tenderers") will interpret them in the same way. It is also alleged that there was a failure to disclose sub-criteria and/or weightings.
>
> (c) Thirdly, it was originally contended that there were a number of manifest errors in the way in which the HSE evaluated the Sanofi tender and the Glaxo tender. Ultimately only one alleged error was argued which centred on the score awarded to Glaxo in respect of the "Presentation" sub-sub-criterion. In this context, it should be noted that Sanofi scored full marks for this sub-criterion, while Glaxo was five marks behind. However, Sanofi maintains that Glaxo's marks should have been significantly lower in circumstances where, according to Sanofi, its vaccine has significant advantages over the Glaxo equivalent. In particular, the Sanofi vaccine is (as explained in para. 8 above) fully liquid and ready to use whereas the Glaxo vaccine requires to be reconstituted.

34. I now deal, in turn, with each of these issues.

The alleged failure to provide adequate reasons for the decision to award the contract to Glaxo

35. Before turning to the specific complaints made by Sanofi, it may be helpful at this point to draw attention to the relevant legal principles which are applicable.

36. In the first place, it is very important to bear in mind that under Regulation 55 of the Procurement Regulations, a number of specific obligations are imposed on a contracting authority. These include the obligations set out in Regulation 55(1)(b) to inform each tenderer as soon as possible of a decision reached concerning the award of a contract.

37. The obligation imposed by Regulation 55(1)(b) appears to me to be a free-standing obligation. It is, however, supplemented by the obligation imposed by Regulation 55(2) under which very specific information has to be provided to a tenderer, at least where the tenderer so requests in writing. Insofar as relevant, Regulation 55(2) provides as follows: -

> *"A contracting authority shall, as soon as possible but no later than 15 days following the receipt of a request in writing from the . . . tenderer concerned, inform:*
>
> *. . . (c) any tenderer that has made an admissible tender of the characteristics and relative advantages of the tender selected as well as the name of the successful tenderer . . ."*

38. In the course of her submissions on behalf of the HSE, Ms. Barrington S.C. suggested that the HSE letter of 8 January 2018 was provided in discharge of the HSE's obligations under Regulation 55(1) while the subsequent correspondence from Byrne Wallace of 22 and 30 January 2018 was provided in discharge of the more specific obligation imposed on the HSE by Regulation 55(2) following the written request for such information from Arthur Cox in the letter of 16 January 2018. This submission is made against the background that, as was conceded in the course of the hearing before the court, it was not until the Byrne Wallace correspondence of 22 and 30 January 2018, that any information was given to Sanofi about the characteristics and relative advantages of the Glaxo tender. Notwithstanding the heading of the right hand column in the table attached to the letter of 8 January 2018 from the HSE, no information was in fact provided in that column in relation to the characteristics and relative advantages of the Glaxo tender.

39. Ms. Barrington suggested that the obligation to supply information relating to the characteristics and relative advantages of the successful tender did not arise under Regulation 55(2) until after receipt of a request in writing from Sanofi. In other words, it was not until after receipt of the Arthur Cox letter of 16 January 2018, that the obligation to supply this information arose. Thus, she argued that there was no breach of Regulation 55(2) as a consequence of the way in which the letter of 8 January 2018 was framed. In essence, the case made by the HSE at the hearing was that the letter of 8 January 2018 was simply the notification required pursuant to Regulation 55(1)(b). Thereafter, the Arthur Cox letter of 16 January 2018 constituted a request for reasons and the relevant reasons (including the information in relation to the characteristics and relative advantages of the Glaxo tender) were supplied in the Byrne Wallace correspondence of 22 and 30 January 2018.

40. In response, Mr. McGrath suggested that there were two ways in which to interpret Regulation 55(2). It was possible to read it as a self – executing obligation to provide the information or it was possible to construe it as an obligation that was only triggered by a request in writing from the tenderer. In making that submission, Mr. McGrath very fairly drew my attention to the equivalent provision in the underlying directive (namely Directive 2014/24/EU) which provides in Article 55.2 as follows: -

> *"…on request from the tenderer concerned, the contracting authority as soon as possible but no later than 15 days following the receipt of a request in writing from the candidate or tenderer concerned, inform: . . .any tenderer that has made an admissible tender of the characteristics and relative advantages of the tender selected."*

41. The terms of Article 55.2 very clearly proceed on the basis that the obligation to provide details of the characteristics and relative advantages of the successful tender will only be triggered by a written request by a disappointed candidate. Mr. McGrath suggested that there was every reason to believe that the Irish legislature decided to impose a more onerous obligation on contracting authorities in Ireland having regard to the well-recognised principles applied in Ireland in relation to the giving of reasons by administrative bodies for their decisions. However, it seems to me to be more likely that Regulation 55 was intended to follow the approach taken in Article 55 of the Directive. In the first place, it is noteworthy that Regulation 55(1) imposes a self-standing obligation to inform each tenderer of a decision concerning the award of a contract. That is an obligation that must be performed "as soon as possible". If there was an obligation to provide information concerning the characteristics and relative advantages of the successful tender without any prior request in writing, it would seem very odd that this would not form part of the obligation imposed under Regulation 55(1). It is clear that the obligation imposed under Regulation 55(1) arises independently of any request made by a tenderer. If the obligation to provide the information required under Regulation 55(2) was also intended to operate irrespective of any request from a tenderer, one would expect that this would all form part of a single obligation under Regulation 55(1). It seems to me to be more probable that the legislature intended to follow the structure of Article 55 of the Directive. Regulation 55(1) in fact mirrors the provisions of Article 55.1 of the Directive which, in similar terms to Regulation 55(1) requires contracting authorities to notify the decision relating to the award of the contract "as soon as possible". As set out above, Article 55.2 imposes a separate obligation to provide precisely similar details to those set out in Regulation 55(2) within fifteen days from receipt of a written request. Thus, Regulation 55(2) seems to me to mirror the requirements of Article 55.2.

42. Given the structure of Regulation 55, (which, as noted above, mirrors very closely the provisions of Article 55 of the Directive) and given the principle that national regulations are to be read in light of the object and purpose of the underlying EU directive, it seems to me that the approach outlined in para. 41 above, is in fact the correct interpretation of Regulation 55. I will therefore proceed on that basis in this judgment. It therefore seems to me that the obligation on the HSE to provide the information and other material required under Regulation 55(2) was not engaged in this case until receipt of the Arthur Cox letter of 16 January 2018.

43. Insofar as the substantive obligation to provide reasons in concerned, both parties are agreed on the principles to be applied in relation to how that obligation is to be discharged. Those principles were very usefully and comprehensively summarised by Humphreys J. in *RPS Consulting Engineers Ltd. v. Kildare County Council* [2017] 3 IR 61 at p. 86 as follows: -

> *"(a) Where the award turns on quantitative criteria such as price . . . it may be sufficient to give the scores alone in relation to such. . . criteria.*
>
> *(b) Where the award turns on qualitative criteria, there is a heightened obligation to give reasons, particularly where the unsuccessful tenderer offered a more competitive price. In such situations, scores alone are insufficient.*
>
> *(c) The awarding authority must give reasons as to the relative advantages of the preferred tenderer. That involves a comparison between the preferred tenderer and the particular unsuccessful tenderer to whom the statement of reasons is addressed. To that extent there is a legal requirement for a bespoke statement of reasons.*
>
> *(d) While brief statements or succinct comments may be sufficient in particular circumstances, it does not follow that because a statement is succinct it will therefore be sufficient.*

(e) The contracting authority's comments must be sufficiently precise to enable the applicants to ascertain the matters of fact and law on the basis of which the contracting authority rejected their offer and accepted that of another tenderer.

(f) In order to set out the characteristics and relative advantages of the successful tender, the contracting authority must at least mention the matters which should have been included in the applicant's tender or the matters contained in the successful tenders. The statement of reasons must therefore be sufficiently detailed to explain how the preferred tender was advantageous by reference to particular matters, respects, examples or facts supporting a general assertion of relative advantage.

(g) Separately from the general requirement to give reasons, an unsuccessful tenderer may request additional information about the reasons for their rejection in writing. That request must be responded to positively unless specific listed exceptions apply."

44. In the course of his submissions, Mr. McGrath S.C. also helpfully drew attention to a recent decision of the Supreme Court in relation to the underlying rationale as to why reasons should be given. While the decision was given in the context of planning law rather than procurement law, I agree that the underlying principles are nonetheless helpful for present purposes in that they assist in understanding the rationale for the requirement to give reasons. In *Connelly v. An Bord Pleanala* [2018] IESC 31, Clarke C.J. said at para. 6.15: -

"Therefore . . .it is possible to identify two separate but closely related requirements regarding the adequacy of any reasons given by a decision maker. First, any person affected by a decision is at least entitled to know in general terms why the decision was made. This requirement derives from the obligation to be fair to individuals affected by binding decisions and also contributes to transparency. Second, a person is entitled to have enough information to consider whether they can or should seek to avail of any appeal or to bring judicial review . . .. Closely related to this latter requirement, it also appears from the case law that the reasons provided must be such as to allow a court . . . reviewing a decision to actually engage properly in such a… review."

45. The observations of Clarke C.J. in *Connelly* chime very closely with some of the observations made in the European case law dealing with the obligation to provide reasons in the context of a procurement processes. For example, as the General Court observed in Case T-89/07 *VIP Car Solutions v. Parliament*, at para. 60, the provision of reasons by a contracting authority in a procurement process is intended: -

". . . on the one hand, to make the persons concerned aware of the reasons for the measure and thereby enable them to defend their rights and, on the other, to enable the Court to exercise its supervisory jurisdiction"

46. It has also been observed by the General Court in Case T-299/11 *European Dynamics Luxembourg v. OHIM*, that the obligation to state reasons is an: -

"essential procedural requirement, which is distinct from the question whether the grounds given are correct".

47. Relying on a number of other propositions by the General Court in Case T-299/11 *European Dynamics Luxembourg SA v. Commission*, at para. 87, Case T-461/08 *Evro Paiki Dynamiki v. EIB* at para. 108 and Case T-165/12 *European Dynamics Luxembourg SA v. Commission* at para. 87, Sanofi also submits (in my view correctly) that: -

(a) The obligation to provide reasons presupposes that the contracting authority will take particular care to ensure that the grounds communicated to a disappointed tenderer, will set out the factors on which its decision is based. This seems to me to be entirely consistent with the approach taken by Humphreys J. in *RPS*.

(b) To ensure the requirement of effective judicial oversight, the statement of reasons must be sufficient in order to ensure that the unsuccessful tenderer (who so requests) will be given sufficient detail to enable a decision to be made as to whether there is any point in applying to the court. Without an adequate statement of reasons, the unsuccessful tenderer's right to an effective remedy will be undermined.

(c) Information on the "characteristics and relative advantages of the successful tender" will be all the more necessary when the price offered by the unsuccessful tenderer is lower than that offered by the successful tenderer. Again, this has been encapsulated in the decision of Humphreys J. in *RPS*.

(d) The adequacy of reasons can only be assessed on the basis of the reasons provided prior to the commencement of proceedings. This is clear from the decision of the General Court in the *VIP Car Solutions* case and, in a domestic context, from the decision of Kelly J. (as he then was) in *Deerland Construction Ltd. v. The Aquaculture Licenses Appeals Board* [2009] 1IR 673.

The complaint made by Sanofi in relation to reasons

48. The case made by Sanofi in its statement of grounds in relation to the adequacy of reasons is very clearly and succinctly stated. The case pleaded by Sanofi centres on the letter of 8 January 2018 and contends that the comments in the table attached to that letter do not provide any details of the characteristics and/or relative advantages of the Glaxo tender. In para. 13.25 of the statement of grounds, it is pleaded that: -

"No comments are given in respect of the Glaxo tender. Rather, the comments contained in the Table are limited to a commentary on why certain marks were deducted from the Sanofi tender."

49. Para. 13.26 of the statement of grounds then provides more specificity in relation to the complaints made about the Table to the 8 January letter. The following allegations are made in para. 13.26: -

(a) The table does not provide reasons for the rejection of the Sanofi tender;

(b) The table does not include details of the characteristics and/or relative advantages of the tender selected;

(c) The table does not include the principal specific facts and/or matters by reference to which each characteristic or relative advantage can be judged;

(d) The table does not enable Sanofi to understand why Glaxo's tender was deemed superior to the Sanofi tender;

(e) The table does not enable Sanofi to understand why greater marks were awarded to Glaxo in respect of the disputed criteria. It is not entirely clear to me what the statement of grounds means by the "disputed criteria". It may mean the specific criteria in respect of which complaint is made by Sanofi.

50. It will be seen that all of the complaints made in paras. 13.25 and 13.26 of the statement of grounds relate to the table attached to the HSE letter of 8 January 2018. In this context, it should be recalled that when the statement of grounds came to be pleaded, the HSE (as para. 24 above makes clear) had sought to rely on both the Byrne Wallace correspondence and on its own letter of 8 January 2018 as evidence of its compliance with the Regulation 55(2) requirements. They way in which the statement of grounds was drafted is understandable in circumstances where the argument made by Ms. Barrington (as summarised in paras. 38 and 39 above) had not been advanced at the time the statement was prepared.

51. The only remaining relevant allegations which are made in relation to the adequacy of reasons are contained in para. 13.27 and 13.28. In para. 13.27, there is a complaint made in respect of the Byrne Wallace letters of 22 and 30 January 2018 in the following terms: -

> *"While certain additional details regarding the rejection of the Sanofi Tender were provided in the 22 January Letter and the 30 January Letter, those additional details, when coupled with the comments contained in the Table, do not constitute or amount to adequate or sufficient reasons to enable Sanofi understand the reasons for the rejection of its tender and the characteristics and/or relative advantages of the tender selected".*

52. There is no attempt in the statement of grounds to specify why Sanofi contends that the letters of 22 January and 30 January fail to provide adequate or sufficient reasons to enable Sanofi to understand the reasons for the rejection of its tender and the relative advantages of the Glaxo tender.

53. The plea made in para. 13.28 is in very broad brush terms. It simply alleges that the HSE has failed to comply with the obligations that are imposed upon a contracting authority.

54. As noted above, Ms. Barrington on behalf of the HSE submitted that the letter of 8 January 2018 was nothing more than the notification of the decision and she makes the case that it is in the subsequent correspondence from Byrne Wallace of 22 and 30 January 2018 that the necessary detail is provided to enable Sanofi to understand the reasons why its tender was rejected and also to understand the characteristics and relative advantages of the Glaxo tender. It is therefore necessary to consider, in more detail, the correspondence between Arthur Cox and Byrne Wallace of January 2018. This is dealt with in paragraphs 69-96 below.

55. Before turning to the *inter-partes* correspondence, it is important to note, at this point, some of the terms of the IOT and of the tender response document form which together set out the principal terms applicable to the Mini Competition.

Relevant terms applicable to the Mini Competition

56. Clause 2.2 of the IOT set out the mandatory selection criteria. Unsurprisingly, among the mandatory selection criteria was a requirement that the supplier must confirm that the vaccine held an appropriate licence either from the Health Products Regulatory Authority or from the EU. It was also a mandatory requirement that the vaccines should comply with the NIAC Immunisation Guidelines for Ireland. In addition, it was indicated that suppliers must indicate and highlight any recent changes to the Summary of Product Characteristics ("SMPC") in respect of their vaccine.

57. Clause 2.3 then dealt with the Award Criteria. Tenderers were informed that those who passed the mandatory selection criteria would be evaluated to determine which tender represents the most economically advantageous tender. The first criterion was described as "Ultimate Cost" which had a weighting of 60% or 600 marks. The remaining criterion (which is the relevant one for present purposes) was "Technical and Functional" which was stated to have a weighting of 40% or 400 marks. The 400 marks available were derived from the individual scores for a range of sub-criteria (and in turn sub-sub-criteria). In order to arrive at a final mark for any tender one had to multiply each of the individual sub-criteria or sub-sub-criteria scores by a particular multiplier.

58. Clause 2.4 informed tenderers that the evaluation process would be conducted using a methodology which was set out in a series of numbered paragraphs. In para. 2, the following was stated in relation to the multiplier: -

> *"The tenders . . . will . . . be evaluated under each of the Technical and Functional sub-criteria listed above and a rating on a scale of 1- 10 will be awarded for each sub-criteria. These ratings will then be multiplied by the band multiplier for each sub-criteria which when totalled will give the overall mark for "Technical & Functional" criteria. [Please see scoring range table below]".*

59. On p. 7 of the IOT the relevant scoring range table was set out which gave a scoring range which ran from 0 to 10. A score of 0 would be the result where no response was received or the response was not deemed adequate to score. Scores of 1-2 were available in respect of "poor response". Under this heading, there was a panel which stated: - "*Significant deficiencies in the response leading to considerable cause for concern*". Beneath this there was a further panel which stated: - "*Very limited detail provided*". The final panel in this column stated: - "*Does not satisfy minimum requirements*".

60. There were similar panels beneath each of the other elements of the scoring range. A score of 3-4 was rated a "Fair Response". Beneath that rating, there were panels dealing with deficiencies in the response "leading to some cause for concern", details supplied at a high level, and a failure to fully satisfy all minimum requirements.

61. A "Good Response" score was 5-6, and again there were three panels in this column, the first of which dealt with "*Demonstrated capabilities and a good fit to the HSE requirement*", "*Good detail provided*" and "*May not fully satisfy all minimum requirements*".

62. In turn, a score of 7-8 was in respect of a "*Very Good Response*", the panels in this column referred to the following: -

(a) "Demonstrated capabilities and a very good fit to the HSE requirement";

(b) "Very good detail provided";

(c) "Satisfies all minimum requirements".

63. A score of 9-10 was in respect of an "Excellent Response". There were two columns here – one for a score of 9 and one for a score of 10.

64. In respect of the column dealing with a score of 9, there were three panels as follows: -

(a) "Clear demonstration and explanation of each factor"

(b) "Response provides confidence that the solution will fully meet requirements. Excellent fit to HSE requirements"; and

(c) "Capabilities and methodologies of operations set out in clear, unambiguous detail".

65. In the column referable to a score of 10, there were two panels as follows: -

(a) "Demonstrates a highly innovative approach to delivery of the required services" and

(b) "Have included additional innovation/functionality that exceed the minimum requirements as identified in the tender specifications without additional costs to the HSE". (Underlining in original).

66. When it came to the Tender Response Document, pp.7 – 14 provided more detail in relation to the Technical and Functional award criterion. The Tender Response Document effectively broke this criterion down, in turn, into two sub-criteria which were further broken down into a number of sub-sub-criteria. These were: -

(a) Continuity and security of supply for which there was 160 marks or 16% of the 40% available. In turn, this was broken down into a number of sub-sub-criteria as follows: -

(i) Delivery date/Lead time (4% or 40 marks);

(ii) Company contingency for supply in Ireland (6% or 60 marks);

(iii) Regularity of batch supply and expiry date management (3% or 30 marks); and

(iii) Shelf-life (3% or 30 marks).

(b) The next sub-criterion was in respect of "quality" for which there was 24% or 240 marks available. In turn, this was broken down into the following sub-sub-criteria: -

(i) Presentation, for which there was 5% or 50 marks available;

(ii) Side-effects and acceptability for which there was 3% or 30 marks available;

(iii) Compatibility and interchangeability in respect of which there was 5% or 50 marks available;

(iv) After sales service/technical backup for which there was 1% or 10 marks available;

(v) Stability data for temperature excursions for which there was 6% or 60 marks available; and

(vi) Packaging and labelling for which there was 2% or 20 marks available.

(vii) Added value, for which there was 1% or 10 marks available;

(viii) Falsified Medicines Directive for which there was 1% or 10 marks available.

67. Thus, although the two principal award criteria were "Ultimate Cost" and "Technical and Functional", the latter were broken down into the two sub-criteria described above and those sub-criteria were in turn (as a consequence of the detail in the tender response document) broken down into the sub-sub-criteria, all as described in para. 66 above.

68. Having set out the relevant terms applicable to the Mini Competition, it is now necessary to consider in more detail, the correspondence between the parties in January and February 2018.

The letter of 8 January 2018

69. As already noted above, the letter of 8 January 2018 informed Sanofi that a decision had been made to award the contract to Glaxo. The table attached to the letter identified the maximum marks available for each sub-criterion and this was further broken down into the marks available for each sub-sub-criterion. As against the maximum marks available in each case, the table provided the marks awarded to the Sanofi tender and, side by side with this, the marks for the successful tenderer were also given. However, in circumstances where these sub-sub-criteria were of a qualitative nature, it is clear from the decision of Humphreys J. in *RPS* that the provision of a score would not be sufficient in itself. Furthermore, insofar as any narrative was provided, the table did not explain the characteristics and relative advantages of the Glaxo tender. The summary of reasons given merely identified whether full marks were awarded in respect of any sub-sub-criterion and, if not, it provided very brief reasons as to why marks had been deducted from Sanofi.

The letter of complaint of 16 January 2018

70. As noted above, Arthur Cox wrote a letter of complaint on behalf of Sanofi to the HSE on 16 January 2018. During the course of the hearing a significant debate took place as to whether the Arthur Cox letter of 16 January 2008 called for reasons to be given in respect of each sub-sub-criterion or whether, when read as a whole, it effectively narrowed the request for reasons to a number of specific sub-sub-criteria. In this context, it should be noted that the bulk of the letter deals with four specific issues namely: -

(a) The score given in respect of shelf-life;

(b) The respective scores given to Glaxo and Sanofi in respect of "presentation";

(c) Side-effects and acceptability; and

(d) Compatibility and interchangeability.

71. However, in the course of the hearing, it was submitted by Mr. McGrath on behalf of Sanofi that the letter was not limited to seeking further information in relation to the four specific issues identified above but that, in fact, the letter called on Sanofi more generally to comply with its legal obligations and to provide reasons for the rejection of the Sanofi tender and of each of the characteristics and relative advantages of the Glaxo tender. The relevant section of the letter which, it was submitted, contained a more general request is contained in the first two pages of the letter. The relevant paragraphs are in the following terms: -

> *"We refer to . . .your letter dated 8 January 2018 to our client informing our client that it was unsuccessful in the above Mini-Competition. Our client is simply at a loss to understand the outcome of this tender process, the methodology employed by the HSE in evaluating the submitted tenders, and the marks awarded by the HSE in respect of a number of the award criteria including how sub-components of the award criteria were taken into account, assessed and weighted. Our client requires clarification in each of these respects as detailed further below.*
>
> *In the first instance; it is our client's contention that the quality of the information contained in your letter of 8 January . . .does not meet the legal standard . . .The 8 January . . .letter refers to it being issued in accordance [with] the Remedies Regulations . . . The comments provided in the letter of 8 January 2018 do not provide any characteristics or relative advantages of the tender selected. In fact, no comments are given in respect of the successful tender at all. There is no reference to the language used in the scoring range (Excellent, very good, etc.) in relation to either our client's tender or that of the preferred bidder. The comments provided are limited to setting out some reason for the deduction of marks of our client's tender. This does not constitute or satisfy the legal obligation to offer characteristics and relative advantages of the tender selected . . . In this respect, you have failed to comply with your legal obligations. Insofar as HSE argues that it is not compelled to meet the standard of the Remedies Regulations, then our client maintains that it has not been provided with sufficient information in order for it to understand on what basis it has been unsuccessful.*
>
> *Our client requires a letter in a form which complies with your legal obligations. Please provide.*
>
> *Based on the limited information provided in your letter, it appears to our client that there are a number of serious flaws in the award of marks in this tender process . . .*
>
> *The comments below are based on the limited information contained in the 8 January . . .letter and where no characteristics or relative advantages of the preferred tender have been disclosed to our client. Our client reserves the right to provide further commentary when a letter containing information which meets the legal standard with which HSE is bound to comply, is provided to our client. . . ."*

72. The letter then goes on to deal with the specific complaints in relation to shelf-life, presentation, side-effects and acceptability, and compatibility and interchangeability.

73. Although the passage highlighted in the above quotation might give the impression that the complaint is in relation to the specific issues addressed at length in the later part of the letter, I do not believe that the letter should be so narrowly construed. It seems to me that in the paragraphs quoted above, the author of the letter is in fact setting out a complaint that the HSE letter of 8 January 2018 does not provide any characteristics or relative advantages of the tender selected and that this information is required. This request does not appear to me to be limited in any way to the four specific issues mentioned above. In this context, the letter makes clear that Sanofi was reserving the right to make further observations (beyond the specific complaints dealt with in the bulk of the letter) once a letter "*containing information which meets the legal standard with which HSE is bound to comply*" had been furnished. In my view, the author of the letter was signalling that once full reasons were given, Sanofi may have more to say by way of complaint than is set out thereafter in relation to the four specific issues identified in para. 70 above.

74. At this point, however, it is important to note that there is, in fact, no obligation on a contracting authority to provide reasons to a disappointed tenderer in respect of any criterion where the tenderer scored a higher mark than the successful candidate. This is clear from the decision of the Court of Appeal in *Word Perfect Translation Services Limited v. Minister for Public Expenditure and Reform (No. 3)* [2018] IECA 156. Thus, in the present case, there was no requirement to provide any information in relation to the "*Presentation*" sub-criterion. Sanofi secured a higher mark than Glaxo in relation to presentation.

75. Although not expressly so decided in the *Word Perfect* case, it would seem to follow, as a matter of logic, that the same principle should apply where both the unsuccessful tenderer and the successful candidate scored the same marks. Furthermore, as p. 113 of the transcript of Day 1 of the hearing records, counsel for Sanofi very properly conceded (for the purposes of this High Court hearing) that in light of the *Word Perfect* decision, Sanofi is only entitled to advance its complaint relating to alleged inadequacy of reasons in respect of those sub-sub-criteria where Sanofi achieved a lower score than Glaxo. Thus, in the present case, there was no need, in my view, for the HSE to provide any additional information to Sanofi in respect of: -

(a) delivery date/lead time;

(b) company contingency for supply in Ireland;

(c) after sale service/technical backup;

(d) stability data for temperature excursions; and

(e) added value.

(f) Falsified Medicines Directive.

76. In each of these sub-sub-criteria, both Sanofi and Glaxo scored precisely similar marks. The only sub-sub-criteria where Sanofi scored a lower mark than Glaxo were: -

(a) regularity of batch supply and expiry date management;

(b) shelf life;

(c) side effects and acceptability;

(d) compatibility and interchangeability; and

(e) packaging and labelling.

77. Of these, the only categories that were not specifically canvassed in the letter from Byrne Wallace were: -

(a) regularity of batch supply and expiry date management (in respect which Sanofi achieved a score of 27 and Glaxo achieved a score of 28.5) ; and

(b) packaging and labelling (in respect of which Sanofi achieved a score of 12 while Glaxo achieved a score of 16).

78. It will be necessary, in due course, to consider the consequences that flow from the failure of the HSE to deal with these two sub-sub-criteria in the correspondence sent in response to the Arthur Cox letter of 16 January, 2018. Before considering those consequences, it seems to me that I should first address the reasons provided by the HSE in respect of the other sub-sub-criteria in issue. I should, however, note, at this point, the commentary that was provided by the HSE in the table attached to the letter of 8th January, 2018 in respect of both packaging and labelling and the regularity of batch supply and expiry date management.

79. Under the column headed "*summary of reasons (including details of the characteristics and relevant advantages of the tender selected)*". The following comments were provided in relation to regulatory of batch supply and expiry date management:

"marks deducted as the Tenderer is also endeavouring to ensure a minimum of 3-month longer expiry date that (sic) the previous delivery and marks deducted for only endeavouring to provide longer shelf life than that of previous batches."

80. The commentary in the same column in respect of packaging and labelling was in the following terms:

"marks deducted as no expiry date on peel off Label offered with a vaccine product and marks deducted in relation to the capacity of pack size offered".

81. I now turn to the specific issues canvassed in the Arthur Cox letter of 16 January, 2018. In light of the way in which the case was argued, it is only necessary to consider two of those issues namely:

(a) side effects and acceptability; and

(b) compatibility and interchangeability.

82. It is not necessary to address the debate which took place in the correspondence in relation to "*Shelf Life*". That issue was not pressed at the hearing before me. Nor is it necessary to address "*Presentation*". In light of the approach taken by the Court of Appeal in the *Word Perfect case* Counsel for Sanofi very properly conceded that I am bound by that decision. In circumstances where Sanofi scored a higher mark than Glaxo, it is not entitled to press for more information in relation to that sub-sub-criterion. For completeness, I should record that Counsel for Sanofi reserved the right to contest the approach taken by the Court of Appeal in the *Word Perfect* case in the event of an appeal from my decision.

83. Very specific complaints were made by Arthur Cox on behalf of Sanofi in the letter of 16 January, 2018 in relation to both side effects and acceptability and also compatibility and interchangeability. Insofar as the side effects and acceptability sub-sub-criterion is concerned, there were a total of 30 marks available. Glaxo secured a score of 24 marks while Sanofi achieved a score of 7.5 marks. In the table attached to the HSE letter of 8 January, 2018, the following commentary was provided in the column headed "*summary of reasons (including details of the characteristics and relative advantages of the tenders selected)"*: -

"marks deducted for the presence of all side effects and marks deducted for the presence of Aluminium, Formaldehyde and Thiomersal.

marks deducted as the vaccine offered cannot be administered to the total cohort".

84. In the Arthur Cox letter of 16 January, 2018, it was stated that Sanofi "is at a loss to understand the difference in marks…" the letter stated that the side effects of both the Glaxo vaccine and the Sanofi vaccine have a similar profile. The letter asked for details of the marks deducted for side effects in respect of both products and the letter requested that, to the extent that there is a difference in the marks deducted in respect of side effects, an explanation should be provided.

85. Insofar as the presence of Aluminium and Thiomersal is concerned, the letter stated that Aluminium is contained at higher concentrations in the Glaxo vaccine than in the Sanofi vaccine and that there are no more than trace elements of Thiomersal in the Sanofi vaccine. The letter asked for confirmation as to how marks were awarded for the presence of Aluminium in respect of both tenders and a specific request was made for the marks awarded to Glaxo and to Sanofi in respect of the presence of Aluminium. The letter also sought a specific confirmation that no deduction of marks was made in respect of the presence of Thiomersal.

86. In relation to the administration of the vaccine, the letter sought clarification as to what marks were deducted from the Sanofi tender in respect of the inability to administer the vaccines to the "*total cohort*" and the letter sought confirmation as to the cohort to which the Glaxo vaccine could be administered and the marks that were awarded to Glaxo in respect of administration to the total cohort. At this point, it might be noted that there is nothing in the letter which expresses any surprise or concern in relation to the reference to "*total cohort*" in the table attached to the HSE letter of 8 January 2018.

87. In relation to this sub-sub-criterion, the letter concluded by stating: -

"Please clarify how many marks attributed by HSE to each of the sub-criteria, side effects, presence of elements or administration cohort under this award criterion. Please clarify how many marks were deducted from our client's tender and that of the preferred bidder, under each of these elements and the rationale and factors taken into account by the

HSE in doing so."

88. In the response from Byrne Wallace of 22 January, 2018, attention was drawn to the provisions of s. 3.2.2.2 of the Tender Response Document which stated as follows: -

> *"Tenderers are required to provide details of any reported incidences of side effects for patients in using the product over the past three years. Information on cause of incident, remedial action and outcome/current situation should also be provided. Tenderers are required to provided details of use of thiomersal, aluminium, formaldehyde or latex in the manufacturing or packaging processes."*

89. The Byrne Wallace letter reiterated what had been said in the table attached to the letter of 8 January, 2018 – namely that Sanofi had marks deducted for the presence of all side effects, marks deducted for the presence of Aluminium, Formaldehyde and Thiomersal and marks deducted in circumstances where the vaccine cannot be administered to the total cohort. The letter then dealt with the way in which marks were deducted in respect of Glaxo's tender and Sanofi's tender. In relation to Glaxo's tender the letter stated that 1 mark was deducted for the presences of all side effects, 0.5 marks for the presence of Formaldehyde and 0.5 marks for the presence of Aluminium. The total deductions were 2 marks out of 10 which meant that the mark awarded was 8 out of 10 which, in turn, translated to a score of 24 out of 30. The letter also stated that the Glaxo vaccine can be administered to the total cohort and therefore no marks were deducted on this basis.

90. The Byrne Wallace letter then dealt with the Sanofi tender. It stated that 1 mark had been deducted for the presence of all side effects, 0.5 marks for the presence of Formaldehyde, 0.5 marks for the presence of Aluminium and 0.5 marks for the presence of Thiomersal. The letter also stated that 5 marks were deducted in circumstances where there was no data on vaccine administration to premature babies and it was therefore considered that the Sanofi vaccine cannot be administered to the total cohort of patients. In this context, it should be noted that the following was stated in the Sanofi SMPC (which had been submitted by Sanofi with its tender):

> *"No data are available for premature babies".*

91. The Byrne Wallace letter stated that the fact that the Sanofi vaccine cannot be administered to the total cohort had the consequence that the HSE would have to procure, maintain availability, fund and establish a distinct process with a different vaccine for the premature babies' cohort. The letter stated that the total deductions therefore amounted to 7.5 marks out of 10, this equated to a score of 2.5 out of 10 or 7.5 out of 30 (when one applied the multiplier mentioned in paras. 57-58 above).

92. In their subsequent letter of 25 January, 2018, Arthur Cox dealt at some length with side effects and acceptability. It is noteworthy that no specific complaint was made in this section of the letter in relation to the adequacy of reasons provided by Byrne Wallace in their letter of 22 January, 2018 on behalf of the HSE in relation to this sub – sub - criterion. Instead, this section of the Arthur Cox letter now concentrates on an alleged breach of the obligation of transparency (which I deal with below). This is in contrast to the section of the letter dealing with "*presentation*" where there is a specific complaint that the information provided in the letter of 22 January 2018 was not sufficient in that it provided no details as to the characteristics of the Glaxo tender that deserved a rating of "excellent". It is true to say that the letter commenced with a general complaint about the lack of reasons in which it was stated: -

> *"Neither in the HSE's letter of 8th January, 2018 nor in your letter of 22 January, 2018 are any characterises of relative advantages of GSK's tender provided. Our client reiterates its request for a letter in the form which discharges your client's legal obligations."*

However, that seems to me to relate to the ongoing failure of the HSE to provide reasons (including the characteristics and relative advantages of the Glaxo tender) in relation to all of the other sub-sub-criteria which are not specifically addressed in the Arthur Cox correspondence. It does not appear to me to be directed towards the side effects and acceptability sub-sub-criterion.

93. The complaint which is now made in this section of the 28 January letter (dealing with the side effects and acceptability sub-sub-criterion) relates to an alleged lack of transparency and it is suggested, for example, that the way in which marks were deducted in respect of the matters outlined above suggested that undisclosed weightings or sub-sub-criteria had been applied. This is the focus of the second part of Sanofi's case (dealt with below).

94. In their response of 30 January, 2018, Byrne Wallace responded to the general complaint about the alleged lack of reasons by reiterating that they were satisfied that the HSE had complied with its obligations. The letter also dealt with the specific allegation of lack of transparency in relation to side effects and acceptability and stated that the responses to s. 3.2.2.2 of the Tender Response Document were marked "*holistically and in their entirety*". This aspect of the letter is considered in more detail below when I deal with the second part of Sanofi's case.

95. In their concluding letter of 1 February, 2018, Arthur Cox suggested that the responses provided by Byrne Wallace in their letters of 22 and 30th January, 2018 were inconsistent and contradictory in that specified marks were stated in the letter of 22 January, 2018 to have been deducted in relation to the presence of side effects and certain additives while in the letter of 30 January, 2018 it was stated that the evaluation in relation to this sub-sub-criterion was carried out on a holistic basis. A complaint was also made that the deduction of 5 marks in respect of the cohort issue was "*disproportionate*". Ultimately, at the trial, the complaint in relation to proportionality was not pursued.

96. The Arthur Cox letter of 1 February concluded by setting out a summary of the complaints for the purposes of Regulation 8(4) of the Remedies Regulations. Insofar as the failure to provide reasons was concerned, the letter stated that Sanofi was of the view that the HSE: -

> *"has failed to observe its disclosure obligation of providing reasons in relation to why our client's tender was unsuccessful."*

Compatibility and Interchangeability

97. The maximum mark available for this sub-sub-criterion was a score of 50. Sanofi achieved ten marks for the category while Glaxo received full marks. In the "*summary of reasons*" column in the table attached to the HSE letter of 8 January, 2018, the following commentary was given: -

"Marks deducted for Interchangeability

As product only interchangeable if additional 4th dose given. NIAC recommended schedule is for 3 doses only."

98. In their letter of 16 January, 2019 Arthur Cox made the point that the difference in marks in respect of this category would only be justified in circumstances where one tender response is "*very materially inferior to that of another*". The letter states that the Sanofi vaccine can be administered at 2, 4 and 6 months and that a 4th dose is not required. Arthur Cox also made the point that the posology for both vaccines was "*also identical*". It was explained at the hearing that posology is concerned with dosage. Arthur Cox suggested that there was no basis for the deduction of marks in circumstances where no toddler booster dose is given. The letter continued as follows: -

"Please clarify on what basis HSE deducted marks from our client's tender and confirm why there is a reference to a NIAC recommended 3 dose issue when no such issue arises in respect of our client's tender."

99. In their response of 22 January, 2018, Byrne Wallace drew attention to the provisions of s. 3.2.2.3 of the Tender Response Document which stated: -

"The Supplier should demonstrate evidence of any compatibility with the current licenced vaccines and interchangeability with 6 in 1 vaccine currently in use."

100. Byrne Wallace stated that the Glaxo response was deemed to be "excellent" such that it achieved full marks for compatibility but that: -

"serious concerns arose as a consequence of the lack of interchangeability of your client's vaccine with the 6 in 1 vaccine currently in use and your client's tender was deducted 8 out of 10 marks on this basis."

101. The letter stated that no data had been provided in Sanofi's tender for interchangeability on a 2,4 and 6 months (i.e. 3 dose) schedule. The data provided by Sanofi in relation to interchangeability was based on a 4 dose basis only, therefore Sanofi's response was deemed to lack interchangeability. At this point, it should be noted that the question of interchangeability was addressed in Appendix 7 to the Sanofi Tender Response Document. According to Dr. Brenda Corcoran in para. 91 of her affidavit sworn on behalf of the HSE on 13 July 2018, p. 2 of that appendix shows that if the Sanofi vaccine was given as part of the NIAC recommended schedule with another 6-in-1 vaccine, this was equivalently effective when given at 2, 4, 6 and 15 – 18 months. As a consequence, this required a fourth dose to be administered. While Mr. Dempsey (in his affidavit sworn on behalf of Sanofi on 11 June 2018) has said in para. 38 that Appendix 7 did not state that the Sanofi vaccine could only be administered on the basis of a four dose schedule, Sanofi did not respond to the very specific evidence given by Dr. Corcoran about p. 2 of Appendix 7 in para. 91 of her affidavit (as described above). Obviously, the HSE could only consider the material that was submitted by Sanofi as part of the tender process. The contentions subsequently made in the correspondence from Arthur Cox (as summarised in para. 98 above) and in the affidavits sworn by Mr. Dempsey (as summarised earlier in this paragraph) were not available to the HSE at the time the PEG evaluated the tenders. The members of the PEG had to proceed on the basis of the information contained in Appendix 7.

102. The Byrne Wallace letter of 22 January continued: -

"Lack of interchangeability will result in two different vaccine products being in place for at least 12 months, placing an extra work load on our client as regards planning, education for health professionals and vaccine management. It would also create vaccine wastage as the introduction of a new product must coincide with babies born at the start of a quarter. All of the foregoing would result in significant additional costs for our client and your client's response contained no proposal to deal with these additional costs."

103. As in the case of side effects and acceptability, the subsequent letter from Arthur Cox of 25 January, 2018 did not raise any specific complaint in relation to the adequacy of the reasons given by Byrne Wallace on behalf of the HSE in relation to compatibility and interchangeability. The complaint that is made by Arthur Cox relates to an alleged lack of transparency and an alleged breach of the principle of equal treatment. There is also a complaint made that no indication was given in the invitation to tender that tenderers were required to provide information in relation to vaccine wash – out, planning and education for healthcare professionals, vaccine management or vaccine wastage. Nor is any specific complaint made in relation to the adequacy of reasons in relation to this sub-sub-criterion in the subsequent letter from Arthur Cox of 1 February, 2018. As noted in para. 92 above, that letter makes a general complaint that there has been a failure on the part of the HSE to observe its disclosure obligations in respect of providing reasons.

The case made at the hearing in relation to reasons

104. In a strongly made argument at the hearing, counsel for Sanofi submitted that, in light of the scoring range table set out in the IOT, the HSE, if it was to comply with its obligations under Regulation 55 (2), was required to provide reasons by reference to the various panels in the scoring range table (namely the panels described in paras. 59 – 65 above).

105. By way of illustration, counsel argued that insofar as the side effects and acceptability sub-sub-criterion was concerned, the mark achieved by Sanofi was 2.5 marks out of 10 while Glaxo got 8 marks out of 10. A mark of 2.5 was, as Mr. McGrath said, on the borderline between "*poor*" and "*fair*" on the scoring range table. As set out in para. 59 above, the scoring range table had three panels in the "*poor response*" column, namely: -

(a) Significant deficiencies in the response leading to considerable cause for concern;

(b) Very limited detail provided;

and

(c) Does not meet minimum requirements.

106. As decribed in para. 60 above, the relevant panels in respect of the "*fair response*" column were: -

(a) Deficiencies in the response leading to some cause for concern;

(b) Some detail provided but only at a high level response;

(c) Does not fully satisfy all minimum requirements.

107. Mr. McGrath submitted that in light of the structure of the scoring range table and the contents of the panels in both the "poor" and "fair" columns, the HSE, in response to Sanofi's request for reasons, was obliged to identify the following: -

(a) The deficiencies or significant deficiencies in the Sanofi tender leading to some or considerable cause for concern;

(b) The detail that was missing from the Sanofi tender;

and

(c) The minimum requirements which the Sanofi tender failed to satisfy.

108. Mr. McGrath submitted that, at minimum, the material set out in para. 107 above was the information that had to be supplied if Sanofi was to understand why its tender was unsuccessful.

109. Similarly, it was argued that, if Sanofi was to understand the characteristics and relevant advantages of the Glaxo tender, an explanation would have to be provided by reference to the panels in the scoring range table in relation to why Glaxo was awarded 8 marks out of 10. A score of 8 would come within the "*very good*" bracket in the scoring range table. As outlined in para. 62 above, the panels in the "*very good response*" column refer to the following: -

(a) Demonstrated capabilities and a very good fit to the HSE requirements;

(b) Very good detail provided;

and

(c) Satisfies all minimum requirements.

110. Mr. McGrath therefore submitted that for the HSE to discharge its obligation, it would have to explain to Sanofi: -

(a) The manner in which the Glaxo tender demonstrated capabilities and a very good fit to the HSE requirements;

(b) The basis on which the conclusion was reached that the Glaxo tender provided very good detail which was better than the detail provided by Sanofi;

and

(c) The minimum requirements that were satisfied by the Glaxo tender which were not satisfied by the Sanofi tender.

111. Mr. McGrath submitted that this was what was required, at minimum. He submitted that one could not even begin to understand the relative advantages of the Glaxo tender unless that information was provided.

112. An issue arose in the course of the hearing as to whether the case which I have just outlined at paras 104 to 111 above was pleaded by Sanofi in its statement of grounds. There is certainly nothing in the statement of grounds which is in the same level of detail as I have just set out. As described in paras. 49 – 50 above, paras 13.25 and 13.26 of the statement of grounds constitute an attack on the table attached to the HSE letter of 8 January 2018. No reference is made in those paragraphs to the scoring range table. Thus, these paragraphs do not specifically make the case that was made at the hearing (as summarised above). However, when those paragraphs are read in conjunction with para. 13.27, there is certainly a general complaint that there was a failure to provide reasons including details of the characteristics and relative advantages of the Glaxo tender. There is also an allegation that there was a failure to include the principal specific facts and matters by reference to which each characteristic or relative advantage can be assessed. That is as far as the statement of grounds could be said to go.

113. It is the case that in para. 40 of his affidavit sworn on 2 February 2018 verifying the statement of grounds, Mr. Martin Dempsey stated as follows: -

> *"I expected that the HSE would set out the rating on a scale of 1 – 10 which it awarded to each tenderer in respect of each of the technical and functional sub-criteria, so that I could understand, by reference to the Scoring Range, the basis for the rating awarded. This was not done. In fact, neither the 8 January Letter itself nor the Table make any reference to the Scoring Range. Based on the information provided by the HSE to date, it appears that the Tenders were not evaluated in accordance with the IOT and in particular in accordance with the Scoring Range".*

114. However, it is important to note that this averment by Mr. Dempsey in his verifying affidavit is directed towards a different issue raised in the statement of grounds. It is not concerned with the adequacy of reasons. Instead, it is concerned with the case made in paras. 13.29 – 13.32 where Sanofi alleges that the HSE failed to comply with the terms of the IOT and the Tender Competition Rules. In particular, in para. 13.30 it is alleged that the HSE failed to score tenders in accordance with the scoring range. The case is made, by reference to the table attached to the HSE letter of 8 January 2018, that it: -

> *"appears that the HSE scored the tenders without any reference to the scoring range".*

115. As I understand it, these allegations relate to the way in which the table to the letter of 8 January 2018 showed the final mark (calculated in the manner mentioned in paras. 57-58 above) rather than the score set out in the scoring range. Thus, for example, in the case of the side effects and acceptability sub-sub-criterion, the marks awarded to Sanofi are shown in the table attached to the 8th January letter as 7.5 which is a multiple of the scoring range mark of 2.5. However, as counsel for the HSE explained, the 2.5 mark was in fact set out in the DSM. In order to achieve the final mark, the scoring range in relation to this sub-sub-criterion (for which a total of 30 marks was available) was multiplied by three (to take account of the fact that the maximum mark available was a figure of 30 which is three times greater than the maximum score available in relation to this sub-sub-criterion under the scoring range).

116. Understandably, Sanofi did not ultimately pursue this ground at the hearing. By the time the hearing took place, Sanofi had, of course, been provided with the DSM as part of the HSE discovery and could therefore see for itself that the scoring range table in

fact provided the basis for the final mark awarded to Sanofi in respect of this sub-sub-criterion (which was achieved by applying the appropriate multiplier to the individual score).

117. In light of the matters discussed in paras 113 to 115 above, it is clear that para. 40 of Mr. Dempsey's affidavit is not relevant to the argument made by counsel for Sanofi as summarised in paras. 104 to 111 above. Nonetheless, counsel for Sanofi sought to make the case that the terms of para. 13.26 of the statement of grounds (at least when read in conjunction with para. 13. 27) were sufficient to cover the submission made by him (as summarised above). However, in my view, those paragraphs are in manifestly more general terms than the very specific and detailed contention advanced by counsel for Sanofi in his submissions at the hearing. There is in fact no reference anywhere in paras. 13.25 to 13.28 of the statement of grounds to the scoring range or to the scoring range table, or to any requirement that the reasons to be given by the HSE were required to be structured by reference to the panels in the various columns of the scoring range table. There was therefore nothing to put the HSE on notice that this formed part of Sanofi's case. In my view, counsel for the HSE was fully justified in her submission that the HSE's objection to this line of argument was not a formal pleading point.

118. In my view, an applicant for judicial review (and this is particularly important in a procurement context where very stringent time limits apply) is required to set out the case to be made in sufficient detail in the statement of grounds to enable a respondent to fully understand and know the case which is being made against it so that it can address all issues in its statement of opposition and replying affidavits. In the present case, Ms. Barrington, on behalf of the HSE, makes the very valid point that if the case made at the hearing had been spelled out in the statement of grounds, the HSE would have had an opportunity to address it in its statement of opposition and supporting affidavits. In the course of her submissions to the court, Ms. Barrington sought to suggest that the material in the panels in the scoring range were indicative only and were not intended to be prescriptive. That is not something that is said anywhere on affidavit. However, if the case made at the hearing had been spelled out in the statement of grounds, the HSE would have had an opportunity to address the issue and to explain (if this were truly the case) that the panels were indicative only and would be so understood by a RWIND tenderer. Counsel for Sanofi forcefully argued that it is not necessary to expressly plead such a case. He submitted that the HSE was, in effect, suggesting that an applicant has to plead its legal submissions. I fully accept that, as a general proposition, an applicant for judicial review does not have to plead its legal submissions in its statement of grounds. However, an applicant is required to set out the case in sufficient detail to enable a respondent to know the case which is being made against it. In my view, what is important in the present case is that the applicant is not simply arguing that the HSE failed in its duties under Regulation 55(2) but the applicant is going further and expressly contending that, if the HSE was to be in a position to fulfil its Regulation 55(2) obligation, it would have to provide the information required under that provision in the form suggested in paras. 107 and 110 above. That seems to me to go further than allege a mere failure to comply with the Regulation 55(2) obligation imposed on a contracting authority and to allege that the HSE here could only fulfil its obligation in a particular way. In my view, where an applicant seeks to make such a case – namely that a contracting authority is obliged to act in a particular way – such a case must be expressly pleaded so that the contracting authority will, in fairness to it, have an opportunity to know and understand the case made against it and to respond appropriately.

119. In these circumstances, and having regard to the approach taken by the Supreme Court in *A.P. v. D.P.P.* [2011] 1 IR 729, I am of the view that Sanofi is not entitled to make the case outlined in paras. 104 to 111 above, in circumstances where that case was not apparent from the very general case made in its statement of grounds. It seems to me that this approach should be taken in the interests of fairness and also in circumstances where, in a procurement case, there is an obligation on the applicant to bring any challenge within a strictly limited period of time. It would be contrary to the underlying rationale of that requirement, to allow an applicant to significantly extend the nature of the case made by it after the relevant time limits has expired. Quite apart from that consideration, it seems to me that this approach is required in light of the guidance given by the Supreme Court in *A.P. v. D.P.P.* [2011] IR 729. In that case, Murray C.J., at p. 732, said: -

> *"In the interests of the good administration of justice it is essential that a party applying for relief by way of judicial review sets out clearly and precisely each and every ground upon which such relief is sought.*
>
> *It is not uncommon in many such applications that some grounds . . . are expressed in the most general terms as to the alleged frailties of the decision or other act being impugned, rather in the nature of a rolled up plea, and alluding generally to want of legality, fairness or constitutionality. This can prove to be quite an unsatisfactory basis . . ., particularly when such a ground is invariably accompanied by a list of more specific grounds*
>
> *There has also been a tendency in some cases, at a hearing of the judicial review proceedings . . . for new arguments to emerge . . . that in reality either go well beyond the scope of a particular ground . . . or simply raise new grounds.*
>
> *The court of trial of course may, in the particular circumstances of the case, permit these matters to be argued, especially if the respondents consent, but in those circumstances the applicant should seek an order permitting any extended or new ground to be argued . . .. the respondents, if they object to any matter being argued at such a hearing because it goes beyond the scope of the grounds on which leave was granted, should raise the matter and make their objection clear. . ."*

120. It seems to me to follow from the approach taken by the Supreme Court in A.P., that, in proceedings of this kind, if any ground is to be extended or new ground argued, it is necessary for the applicant to seek an order permitting this. Of course, in a procurement case, the time limits are such that any application by Sanofi to amend or expand the grounds in its statement of grounds would, very likely, founder. In any event, no such application was made.

121. In these circumstances, I am of the view that Sanofi is not entitled to make the argument set out at paras. 104 to 111 above. Lest I am wrong in that view, I will nonetheless consider the argument made by Sanofi and I therefore set out my views in relation to it below.

122. In my view, the approach suggested by counsel for Sanofi (as outlined in paras. 104 – 111 above) is overly prescriptive. I can see nothing in the terms of Regulation 55(2) or in the case law summarised in paras. 43 – 47 above which requires that such a prescriptive approach should be taken. It seems to me that Article 55.2 of the Directive and Regulation 55(2) are deliberately couched in quite general terms. Furthermore, as I read the case law, the obligation is to ensure that the disappointed tenderer is given sufficient information to know why it achieved the score which it did and to ensure that such a tenderer is given the facts as to what the contracting authority considers were the characteristics and relative advantages of the successful tender. Once that level of information has been given, the Regulation 55(2) obligation will be discharged.

123. The extract from the judgment of Humphreys J. in the *RPS* case (quoted in para. 43 above) very succinctly and comprehensively sets out what is required. Thus, the contracting authority, in order to show the relative advantages of the successful tender, must

provide a bespoke statement of reasons that involves a comparison between the tenders of the successful and disappointed candidates respectively. Humphreys J. expressly acknowledges that (within limits), brief statements and succinct comments may suffice in particular circumstances. In order to pass muster, the reasons given must be sufficient to enable the disappointed candidate to ascertain the matters of fact and law on the basis of which the contracting authority rejected its offer and accepted that of the successful candidate. In order to show the relative advantages of the successful tender, the statement of reasons must be sufficiently detailed to explain how the preferred tender was advantageous by reference to particular matters, respects, examples or facts. Of course, the detail to be provided will be case – specific. The level of detail will depend on what actually motivated the contracting authority in any particular case. There may be some cases where it is necessary to provide a significant level of detail in order to understand the motivating factors but, in other cases, the motivating factors may well be capable of being stated quite succinctly. It is important to bear in mind that the obligation is not simply to describe the relative advantages of the successful tender – there is an obligation to provide reasons which also include the characteristics of the successful tender. Nonetheless, in many cases, there is likely to be an overlap between these requirements in that the important characteristics of the tender are likely to be those characteristics which were considered to be more advantageous and it is the more advantageous aspects of the tender that are likely to have underpinned the reasons why the contracting authority was minded to award a higher score to the successful tenderer.

124. I must therefore consider whether the reasons disclosed by the HSE in this case in the course of the correspondence in January 2018 were sufficient to meet its obligations under Regulation 55(2) and in particular to consider whether the reasons offered meet the standard set out in RPS. As explained above, I can see nothing in the case law cited to me which would require the court in this case to assess compliance with the Regulation 55(2) obligations by reference to the panels in the scoring range table. In this context, I note that in the correspondence from Arthur Cox on behalf of Sanofi in January and February 2018, no case was made at any stage that the reasons had to be provided by reference to the panels in question. I appreciate that there is no obligation on a disappointed tenderer to ask specific questions but the fact is that Arthur Cox, in their correspondence did raise a number of very specific questions. Yet, at no stage, was any reference made to the panels or any complaint or demand made that the reasons should be provided by reference to the criteria set out in paras. 107 and 110 above. Similarly, when Mr. Dempsey came to swear his affidavits in the proceedings, he likewise did not express any concern or complaint that the HSE had failed to provide the reasons in the form suggested at para. 107 and 110 above. The only complaint which Mr. Dempsey made in relation to the scoring range was that set out in para. 40 of his affidavit quoted in para. 113 above. While paras. 39 and 40 of Mr. Dempsey's affidavit refer to the scoring range table, Mr. Dempsey does not say that he had any expectation that the HSE would address the reasons to the particular concerns or issues set out in the panels in each of the column of the scoring range table. While this is, of course, not determinative, it is nonetheless significant that both Arthur Cox (a firm with considerable experience and expertise in procurement matters) and Mr. Dempsey (who also had significant personal experience of tendering – as para. 4 of his first affidavit makes clear) did not suggest that they had an expectation that the reasons to be provided by the HSE would address the material set out in the panels in the scoring range table.

125. Before attempting to assess the adequacy of the reasons given on behalf of the HSE in relation to the side effects and acceptability sub-sub-criterion, I should record that a very similar argument to that set out at paras. 104 - 111 was made by Mr. McGrath SC in relation to the other sub-sub-criteria at issue. In circumstances where I have formed the view that the approach suggested by Mr. McGrath is overly prescriptive, I do not propose in this judgment to record the argument made in relation to each of those sub-sub-criteria. Instead, I will now consider, by reference to the RPS principles, whether the response given on behalf of the HSE meets its obligations under Regulation 55(2) in relation to: -

(a) Side effects and acceptability;

and

(b) compatibility and interchangeability.

126. In my view, it is unnecessary to deal in detail with either of the sub-sub-criteria mentioned in para. 77 above – namely regularity of batch supply and expiry date management and also packaging and labelling. The only reasons provided in relation to these sub-sub-criteria were those described in the table to the 8 January letter (as summarised in paras. 79 and 80 above). As the HSE acknowledged in the course of the hearing, that table provided no information in relation to the characteristics or the relative advantages of the Glaxo tender. It therefore seems to me to follow that there was a manifest failure to comply with the Regulation 55(2) obligations in relation to those two sub-sub-criteria and it is unnecessary in the circumstances to spend time on them. I will address the consequences that flow from this once I have first considered the adequacy of the reasons given in relation to side effects and acceptability and in relation to compatibility and interchangeability.

The reasons given with regard to side effects and acceptability

127. The relevant exchanges between the parties in relation to this sub-sub-criterion are recorded at paras. 83 – 96 above. It is therefore unnecessary to repeat them here. The question which I have to consider is whether the reasons furnished by the HSE adequately explain why Glaxo secured a score of 24 marks while Sanofi achieved a score of 7.5 marks. In particular, I must consider whether the reasons given are sufficiently detailed to explain the characteristics of the Glaxo tender, the basis for the HSE's consideration that the Glaxo tender was advantageous, and also whether the reasons provided were sufficient to enable Sanofi to ascertain the matters of fact and law on the basis of which the HSE rejected the Sanofi tender and accepted the Glaxo tender. I must also consider whether the reasons were sufficient in order to ensure that Sanofi had adequate detail to enable a decision to be made as to whether there was a basis to challenge the decision of the HSE. I must also bear in mind that, in this case, the Sanofi tender was more advantageous than the Glaxo tender in terms of price. In RPS, Humphreys J. indicated that a heightened obligation to provide reasons applies in such circumstances.

128. I am of the view that the Byrne Wallace letter of 22 January 2018 did in fact provide sufficient reasons to Sanofi to enable it to understand why it was that the HSE considered that the Glaxo tender was considered to be more advantageous than the tender submitted by Sanofi insofar as this sub – sub – criterion is concerned. It seems to me that the letter of 22 January 2018 very clearly identifies a particular advantage which the Glaxo tender had over the Sanofi tender - namely that, in contrast to the Sanofi vaccine, the HSE considered that the Glaxo vaccine could be administered to the total cohort of patients. Sanofi was informed that the Glaxo vaccine can be administered to the total cohort, and that accordingly no marks were deducted on this basis in Glaxo's case. This was obviously a key characteristic of the Glaxo tender that was missing in the case of the Sanofi tender.

129. Sanofi was also given details of the deduction of marks from both Glaxo and Sanofi in respect of side effects and the presence of certain elements. Sanofi was informed in particular that both it and Glaxo were each deducted one mark for the presence of side effects. Sanofi was therefore made aware that, insofar as side effects are concerned, the Glaxo tender was not considered to have any advantages over its own tender. Sanofi was also made aware that one of the characteristics of the Glaxo tender was that its

vaccine was not without side-effects. Glaxo was also deducted a further 0.5 marks for the presence of formaldehyde and 0.5 marks for the presence of aluminium. The same deductions were made in relation to Sanofi. Thus, insofar as presence of formaldehyde and aluminium is concerned, Sanofi knew that the Glaxo tender was not considered to have any advantages over its own tender. Sanofi was also thereby made aware that, in common with its own tender, the Glaxo tender disclosed that its vaccine was characterised by the presence of formaldehyde and aluminium.

130. However, Sanofi was also deducted a further 0.5 marks for the presence of thiomersal. There was no corresponding deduction for Glaxo. To that extent, it was obvious to Sanofi that the Glaxo tender was considered to be more advantageous in so far as the absence of thiomersal is concerned. The letter further drew attention to the Sanofi Tender Response Document which stated that thiomersal was used during the Sanofi manufacturing process in respect of one of the ingredients in the vaccine, but this was reduced (by a purification process) to only trace amounts in the final product. While Sanofi may take the view that no adjustment should have been made to its score for the risk that there might be trace elements of thiomersal in the vaccine, the fact is that Sanofi knew from the letter of 22 January, the respects in which the Glaxo vaccine was considered by the HSE to be more advantageous than its own vaccine.

131. There were accordingly two reasons for the HSE's view that the Glaxo tender was more advantageous – namely the view of the HSE that the Sanofi vaccine cannot be administered to the total cohort of patients and the fact that, as disclosed by Sanofi in its tender, there could be trace elements of thiomersal present in the vaccine. This seems to me to have given Sanofi sufficient information to understand what the HSE considered to be the characteristics and relevant advantages of the Glaxo tender that persuaded the HSE to award higher marks to Glaxo than to Sanofi in respect of this sub-sub-criterion. It follows also that Sanofi was thereby made aware of the reasons why Glaxo achieved a higher score in respect of this sub-sub-criterion than Sanofi.

132. In addition, Sanofi had sufficient information to enable it to consider whether there was a basis for challenging the HSE's score in respect of this sub-sub-criterion. For example, if it considered that there was no rational basis for - or no material on which - the HSE could have formed the view that there was any perceptible presence of thiomersal in its vaccine, it could have sought to judicially review the decision of the HSE on irrationality grounds. Similarly, if Sanofi considered that the way in which marks were deducted had not been sufficiently disclosed to tenderers in advance, there was a basis on which Sanofi could seek to challenge the process on the grounds of infringement of the principles of transparency or equal treatment.

133. In all of the circumstances, it seems to me that, with regard to this sub-sub-criterion, the letter of 22 January 2018 does, in fact, satisfy the Regulation 55(2) obligation as explained in *RPS*. I see nothing in the subsequent correspondence which would alter this view. In expressing this view, I have borne in mind the heightened obligation that arises in cases where (as in this case) the unsuccessful tender scored better on price. However, it does not seem to me that the application of this heightened standard affects the conclusion which I have reached. This is for the simple reason that, as set out above, the information provided seems to me to have made it very clear to Sanofi as to why (insofar as this sub-sub-criterion is concerned) the Glaxo tender was awarded a significantly higher score. Furthermore, it seems to me that the letter of 22 January 2018 in fact answered each of the specific questions raised by Arthur Cox in their letter of 16 January 2018 in respect of this sub-sub-criterion. It is noteworthy that when Arthur Cox came to write again on 25 January 2018, no issue was raised that the reasons given in respect of this sub-sub-criterion were deficient in any way or that it was prevented from considering whether it had grounds for challenging the approach taken by the HSE. On the contrary, p. 3 of the Arthur Cox letter of 25 January 2018 sets out a whole series of additional arguments challenging the approach taken by the HSE on the basis that it had applied undisclosed sub-sub-criteria or weightings and that it had taken into account irrelevant considerations. It was also alleged that there was a breach of the principle of transparency. In many ways, the Arthur Cox response illustrates that Sanofi was now equipped with the relevant information that it needed in order to consider whether there were grounds for a challenge to the HSE decision insofar as the score given in respect of this sub-sub-criterion was concerned.

The reasons provided by the HSE in relation to compatibility and interchangeability

134. The relevant exchanges between the parties in relation to this sub-sub-criterion are summarised in paras. 97 – 103 above, and I will not repeat them here. What I have to consider is whether the reasons furnished by the HSE in relation to this sub-sub-criterion satisfy the Regulation 55(2) obligation as explained in *RPS*. Glaxo achieved a score of 50 (e.g. full marks) whereas Sanofi achieved only 10 marks.

135. In my view, it is clear from the Byrne Wallace letter of 22 January 2018 that the reason why the Glaxo tender was considered to be significantly superior in respect of this sub-sub-criterion related solely to interchangeability. The letter of 22 January expressly informed Sanofi that it had received full marks for compatibility. Thus there was no difference between the Glaxo tender and the Sanofi tender insofar as compatibility is concerned. The letter of 22 January makes clear that the difference between the two tenders arose in the context of interchangeability. The letter explained that this issue arose in circumstances where (in the view of the HSE) the interchangeability data provided by Sanofi was based on a four – dose basis only. The reasons why this created a difficulty for the HSE was explained very fully and the relevant extract from the letter providing this explanation has already been quoted in para. 102 above. While the letter does not expressly say that no such difficulty arises in relation to the Glaxo vaccine, this did not need to be said in circumstances where s. 3.2.2.3 of the Tender Response Document indicated that any tenderer should demonstrate interchangeability with the 6-in-1 vaccine "currently in use". The vaccine currently in use was the Glaxo vaccine. It was accordingly obvious that interchangeability was not a problem for Glaxo.

136. It was therefore obvious that the disadvantages described arising from lack of interchangeability in the case of the Sanofi vaccine did not arise in relation to the Glaxo vaccine. It follows that Sanofi was therefore made aware of the facts which gave rise to the advantage which Glaxo had over the Sanofi tender insofar as this sub-sub-criterion is concerned. It equally follows that Sanofi was aware of the characteristic of the Glaxo tender insofar as this sub-sub-criterion is concerned.

137. Furthermore, the information provided by Byrne Wallace in their letter of 22 January 2018 was also sufficient, in my view, to enable Sanofi to form a view as to whether the decision of the HSE could successfully be challenged as a consequence of the approach which it had taken in relation to this sub-sub-criterion. Thus, for example, Sanofi could consider whether there was a basis to challenge the decision on any of the grounds subsequently identified in the Arthur Cox response of 25 January 2018 where it was suggested that: -

> (a) nothing was disclosed in the tender documents to suggest that there were separate marks available for compatibility and interchangeability;
>
> (b) nothing was disclosed in the tenderers documents to require tenderers to address issues such as wastage, wash-out and education, which were all matters expressly mentioned in the letter of 22 January as the extract in para. 102 above makes clear.;

(c) there was a breach of the principle of equality of treatment between bidders since the approach taken by the HSE favoured the incumbent;

(d) that the HSE went beyond the confines of the subject matter of the tender process and therefore took into account irrelevant considerations.

138. In addition, if it was the case that Sanofi believed that there was no basis on which the HSE could have formed the view that the interchangeability data provided by Sanofi was based on four doses only, then Sanofi was in the position following receipt of the Byrne Wallace letter of 22 January 2018 to mount a challenge to the decision on the grounds of irrationality.

139. I have therefore come to the conclusion that, with regard to this sub-sub-criterion, the letter of 22 January 2018 provided Sanofi with a level of detail that met the requirements of Regulation 55(2). Again, I have borne in mind the heightened obligation that arises in a case such as this (where the Sanofi tender scored better on price). However, in circumstances where I am of the view that the information provided to Sanofi clearly explained the HSE's decision in relation to this sub-sub-criterion, I have come to the conclusion that the level of detail was sufficient even on the basis of this heightened obligation. While Sanofi may have profoundly disagreed with the reasons relied upon by the HSE as to why it considered the Glaxo vaccine to be superior in the context of this sub-sub-criterion, it now had sufficient information to form a view as to whether a legal challenge could be mounted in respect of the HSE decision. I do not see anything in the subsequent correspondence which alters my view. While Arthur Cox in the letter of 1 February 2018 complained that the responses received had been inconsistent and contradictory, the fact is that reasons were given which set out the HSE's approach and enabled Sanofi to see the factors which had influenced the HSE in the view which it had formed. If Sanofi considered the view to have been wrongly formed or if Sanofi considered that the HSE had acted in an unlawful manner, it now had the ammunition to bring any necessary challenge.

The failure to provide reasons in relation to the sub-sub-criteria described in para. 77 above

140. As noted in para. 77 above, there are two categories of sub-sub-criteria in which Sanofi achieved a score lower than the Glaxo score and in respect of which no reasons have been provided beyond what was stated in the table attached to the letter of 8 January 2018. These are: -

(a) regularity of batch supply and expiry date management;

and

(b) packaging and labelling.

141. Taking these two sub-sub-criteria together, the difference in points as between Glaxo and Sanofi amounts in total to 5.5 marks. That would not be sufficient in itself to change the outcome of the competition. The gap between the overall score awarded to Sanofi (853.5) and Glaxo (894.5) amounts to 41 marks.

142. I must now consider the consequences that flow from the failure to provide reasons in relation to these two sub-sub-criteria. It has been submitted to me by the HSE that if I come to the conclusion that there has been any failure to provide reasons, I should adopt the same approach as that taken by Humphreys J. in *RPS* and simply direct the HSE to provide reasons now in respect of these two categories. However, this is strongly contested by Sanofi on the basis that a failure to comply with mandatory procurement requirements should properly result in an order quashing the decision of the contracting authority.

143. I do not, however, consider that it would be appropriate or proportionate that the decision of the HSE should be quashed on this ground alone. I bear in mind that, of course, I must exercise the powers of the court under the Remedies Regulations and apply them in a manner which ensures effective judicial protection of European Union rights. As Finlay Geoghegan J. indicated in *Gaswise Ltd v. Dublin City Council* [2014] 3 IR 1, at p. 26, this follows from the decision in Case C-432/05 *Unibet (London) Ltd. v. Justitiekanslern* [2007] E.C.R. I-2271. On the other hand, as Finlay Geoghegan J. also observed in the same case (at the same page): -

> *"The remedy must also be proportionate and in considering what is proportionate, the court should take account of the position of [the contracting authority] and other participants in the tender process. . .."*

144. In my view, it would be disproportionate to set aside the decision of the HSE to award the contract to Glaxo by reason of its failure to provide reasons in relation to these two sub-sub-criteria. In expressing this view, I have not lost sight of the argument made by Mr. McGrath on behalf of Sanofi that Glaxo has already had the benefit of remaining *in situ* since the expiry of the previous contract. Mr. McGrath submitted that in those circumstances, it would not be in any way disproportionate for the court to decide to set aside the award. However, in my view, the difference in marks between Glaxo and Sanofi in relation to these two sub-sub-criteria would not justify the court taking such a course. As noted above, the divergence in marks as between Sanofi and Glaxo would not be sufficient to make a difference to the award of the contract. The difference in marks was 1.5 in relation to regularity of batch supply and expiry date management. The difference in relation to packaging and labelling was four. That could not have made a difference to the award given that the much larger gap of 41 marks between the final score for Sanofi and the final score for Glaxo. Even if Sanofi were awarded full marks for these two sub- sub –criteria that would only add 11 extra marks to its existing score. The only way in which the scoring could conceivably have made a difference is in the event that Glaxo was awarded a score of zero or close to zero and Sanofi was awarded full marks or close to full marks. However, it is fanciful to suggest that there was any such possibility. In the circumstances, it seems to me that it would plainly be disproportionate to annul the award of the contract on the basis of the failure to provide reasons in respect of these two sub-sub-criteria.

145. As mentioned above, I am mindful of the need to provide effective judicial protection to any tenderer in a procurement contest to ensure that the legal requirements are honoured by contracting authorities. However, it seems to me that this must be balanced against the requirement of proportionality identified by Finlay Geoghegan J. in *Gaswise*. It seems to me that the appropriate relief to be granted is, first, a declaration that Sanofi's rights have been infringed and, secondly, an order pursuant to Regulation 9(1)(c) of the Remedies Regulations directing the HSE to provide full reasons (including the characteristics and relative advantages of the Glaxo tender) to Sanofi within a period of time which I will fix after hearing from the parties. I am of the view that such relief will provide an appropriate, adequate and proportionate remedy to Sanofi in respect of these two sub-sub-criteria which will vindicate the infringement of its rights. In para. 38 of his first affidavit Mr. Dempsey stated (and significant emphasis was placed on this factor at the hearing) that it is essential that Sanofi is provided with sufficient information by contracting authorities so that it is in a position to know and properly understand why it won or lost a competition, as the case may be. The provision of proper reasons now in accordance with an order pursuant to Regulation 9(1)(c) will assist Sanofi in improving the overall quality of future tenders.

146. However, as Humphreys J. stressed in *RPS*, at p. 94, there can be no retrospective creation of reasons. The new letter of

reasons must be confined to the specific facts that existed in the minds of the PEG at the time of their evaluation of the tender. When furnishing the reasons, the HSE must confirm that the members of the PEG have themselves confirmed that these were the specific matters to which they had regard on the date of the evaluation. If any one or more of the members of the PEG is not prepared to make that statement, the HSE must also inform Sanofi of this when furnishing the new letter of reasons.

The principles of equal treatment and transparency
147. The second part of the case made by Sanofi is that there was a breach of the principles of equal treatment and transparency in the manner in which the award criteria were formulated by the HSE. It is alleged that there was a failure to disclose sub-criteria and/or weightings. This case is made by reference to the reasons provided by the HSE in the Byrne Wallace letters of 22 January 2018 and 30 January 2018 in respect of the side effects and acceptability and the compatibility and interchangeability sub-sub-criteria.

148. I now deal, in turn, with the case made in relation to each of these sub-sub-criteria.

Side effects and acceptability
149. The case made by Sanofi in relation to this issue is set out at paras. 13.44 to 13.51 of the statement of grounds. In those paragraphs, Sanofi draws attention to the way in which one mark was deducted for the presence of all side effects. 0.5 marks was deducted for the presence of formaldehyde, aluminium and thiomersal and 5 marks were deducted on the basis that the Sanofi vaccine could not be administered to the total cohort. It is alleged that the manner in which specific marks were deducted in respect of these considerations amounted in substance to the application of undisclosed sub-criteria and/or undisclosed weightings thereby infringing the principles of transparency and equal treatment.

150. In making this case, Sanofi relied on the decision in Case C-532/06 *Lianakis* where the Court of Justice, at para. 36, summarised the principle of equal treatment in the following terms: -

> *"According to the case-law, Article 36(2), read in the light of the principle of equal treatment of economic operators set out in Article 3(2) of Directive 92/50 and of the ensuing obligation of transparency, requires that potential tenderers should be aware of all the elements to be taken into account by the contracting authority in identifying the economically most advantageous offer, and their relative importance, when they prepare their tenders . . ."*

151. In that case, the court stressed that tenderers must be in a position to ascertain the existence and scope of each of the elements to be taken into account when preparing their tenders and the court stated at para. 38: -

> *"Therefore, a contracting authority cannot apply weighting rules or sub-criteria in respect of the award criteria which it has not previously brought to the tenderers' attention . . .."*

152. The court also stressed (at para. 40) that tenderers must be placed on an equal footing throughout the procedure which means that the criteria and conditions governing each contract must be adequately publicised by the contracting authorities. In the present case, Sanofi has argued that there was nothing in the IOT or in the tender conditions which gave any advance notice to the tenderers that any particular marks would be attributed to the presence of side effects or the presence of any of the elements described above or that it was a requirement to demonstrate (as part of satisfying this sub-sub-criterion) that the vaccine could be administered to the total cohort. Sanofi correctly says that there was no reference to "*total cohort*" in the Tender Response Document when it came to describe what was required of tenderers in respect of this sub-sub-criterion. Sanofi therefore argues that there was a clear breach of the principle described in *Lianakis* by not disclosing the weightings attached to the presence of side effects (1 mark), the presence of one of the three elements described above (0.5 marks each) or the deduction of 5 marks in relation to total cohort. In addition, Sanofi says that the total cohort requirement was not simply an undisclosed weighting but was, in fact, an undisclosed sub-sub-criterion.

153. There was a significant debate between the parties as to the effect of the *Lianakis* decision. In this context, it appears to be clear that the Court of Justice in *Lianakis* made a distinction between undisclosed criteria on the one hand and a decision by an evaluation body to ascribe weightings in respect of criteria which had been established in advance even though the weightings themselves had not been published in advance. In *Lianakis*, the court accepted that it is possible for a contracting authority, subject to certain conditions (dealt with below) to apply weighting factors in respect of individual aspects of sub-criteria where those sub-criteria had been established in advance.

154. In taking this approach, the court followed the earlier decision in Case C-331/04 *ATI* [2005] ECR I-10122. In order to understand the approach taken by the court in that case, it is necessary to consider some of the underlying facts in *ATI*. There, a contracting authority in Italy published a notice concerning a tender competition for a public contract for the provision of public transportation services. The tender documents specified four award criteria. One of those was: - "*organisational procedures and support structures*" for which a maximum of 25 points was available. The contract documents provided that the tender must contain a description of the proposed organisation of the transportation service which had to include information in relation to five different aspects of the organisation (namely depots, supervisory services, numbers of drivers, numbers of places of business, and numbers of employees engaged in organising drivers' shifts). There were therefore five different sub-headings (or sub-criteria) within this criterion for which 25 points were available. After the tenders were received, and just before the evaluation process commenced, the evaluation committee decided that the 25 points available for this criterion should be divided between the five sub-headings or sub-criteria which I have already mentioned. The number of points to be awarded for each of the sub-headings was broken down as follows, 8, 7 and 6 points for the first second and third sub-headings, and 2 points for each of the fourth and fifth sub-headings. That breakdown of the 25 points available had not been flagged in advance to any of the tenderers. An issue arose as to whether this constituted a breach of the principle of transparency. The Court of Justice held that the procurement rules do not preclude a contracting authority proceeding in that way, provided that (as set out in para. 32 of the judgment) three very specific conditions apply namely that:

> (a) the decision to apply weightings does not alter the criteria for the award of the contract set out in the tender documents;
>
> (b) the decision does not contain elements which, if they had been known at the time the tenders were prepared, could have affected that preparation;
>
> and
>
> (c) the decision was not adopted on the basis of matters likely to give rise to discrimination against one of the tenderers.

155. It is therefore clear that, provided the three conditions set out in the *ATI* case are satisfied, weightings can be applied by an evaluation body to individual aspects of previously announced criteria even where those weightings were not themselves published in advance.

156. In reliance on a decision of the General Court in Case T – 299/11 *European Dynamics Luxembourg SA v. OHIM,* Sanofi initially argued that even the allocation of weightings by the PEG would in itself infringe the principle of transparency as explained in *Lianakis* and that it was therefore not necessary to address the three ATI conditions. However, it subsequently emerged in the course of the hearing that the view of the General Court to that effect in the OHIM case was held to be erroneous by the Court of Justice. In that case, OHIM had published a contract notice calling for tenders in relation to the provision of information technology services. The ITT set out five award criteria. The first criterion related to "Methodology and experience". In respect of this criterion, tenderers were required to deal with seven topics including: -

(a) progress control;

(b) issue management process;

(c) change management process;

(d) escalations;

(e) lessons learnt programme;

(f) communications plan;

and

(g) deliverable acceptance procedures.

157. Tenderers were informed that there was a maximum of 40 points available for the "*methodology and experience*" criterion. However, in the course of evaluating the tenders, the evaluation committee of OHIM came to the conclusion that "*change management*" and "*communications plan*" were the two most essential tasks for the success of the project and they therefore gave them greater weight than the other sub-criteria within the "methodology and experience" sub-criterion. The General Court found that this was unlawful. In a paragraph on which Sanofi placed significant reliance, the court said (at para. 48) : -

> *". . . the Court finds that the applicants rightly argue that the contracting authority indeed gave to the sub-criteria 'change management' and 'communication' a more significant weight than the other criteria set out in the first award criterion. . . ... Given the case-law cited . . . above, the contracting authority cannot apply a weighting of sub-criteria which it has not previously brought to the tenderers' attention . . ."*

158. In making that finding, the General Court expressly sought to rely on the decision in *Lianakis*. The General Court continued at para. 49: -

> *". . . it should be noted that the 'change management' and 'communications plan' comprised only two sub-criteria among a set of seven sub-criteria which were listed at the same level . . . under the first award criterion, . . .and in respect of which the contracting authority intended to award a maximum number of 40 points (see paragraph 5 above). Nor is it apparent from the wording of that criterion . . . that the contracting authority intended, where appropriate and for specific undisclosed reasons, to afford a different weight to those sub-criteria. . .. That is particularly so, in respect of the sub-criteria 'change management' and 'communications plan', in respect of which it was not stated in the tender specifications that the contracting authority considered that they represented 'the two most essential tasks for the success of the project'."*

159. Critically, that aspect of the decision of the General Court in the *European Dynamics* case has been overturned by the Court of Justice in its decision in Case C-677/15 P *EUIPO v. European Dynamics Luxembourg SA*. Rather confusingly, in the intervening period between the decision of the General Court and the decision of the Court of Justice, OHIM had changed its name to EUIPO which is an acronym for the European Union Intellectual Property Office. The *EUIPO* case is in fact the appeal from the decision of the General Court in the *OHIM* case. In the *EUIPO* case, the Court of Justice came to the conclusion that the approach taken by the General Court was incorrect in that it did not take account of the approach taken in *ATI* and in *Lianakis* itself. The Court of Justice said (at para. 32 – 34): -

> *". . . a contracting authority cannot apply weighting rules or sub-criteria in respect of the award criteria which it has not previously brought to the tenderers' attention . . .*
>
> *33. Nevertheless, it is possible for a contracting authority to determine, after expiry of the time-limit for submitting tenders, weighting factors for sub-criteria which correspond in essence to the criteria previously brought to the tenderers' attention. That subsequent determination must, however, satisfy three conditions, namely, it must not: (i) alter the criteria for the award of the contract set out in the contract documents or contract notice; (ii) contain elements which, if they had been known at the time the tenders were prepared, could have affected that preparation; and (iii) have been adopted on the basis of matters likely to give rise to discrimination against one of the tenderers. . .*
>
> *34. In the present case, the disputed findings concern the introduction of weighting given to sub-criteria within one of the award criteria, which was not provided for in the tendering specifications or disclosed in advance to the tenderers, which EUIPO does not dispute. Thus, in the light of the foregoing, the General Court was not in a position to reach a valid finding that there had been a breach of the principles of equal opportunity and transparency without first examining whether it had been pleaded and established that those three conditions had not been met."*

160. Thus, in *EUIPO*, the Court of Justice has reiterated the approach taken in *ATI*. The effect of this line of authority therefore seems to be: -

(a) a contracting authority is not entitled to apply new criteria of any kind (whether that be criteria, sub-criteria, or sub-sub-criteria) in evaluating tenders where those criteria have not been published in advance. If it does so, this will vitiate the award and it is unnecessary to address the three ATI conditions;

(b) the same principle appears to apply to pre-ordained weightings (i.e. weightings which a contracting authority always intended to apply but did not publish in advance);

(c) however, a contracting authority is not precluded, after the time for submitting tenders has elapsed, from applying weightings to individual aspects of previously published criteria or sub – criteria or sub – sub – criteria where the three specific conditions set out in ATI (and reiterated in EUIPO) are satisfied.

161. In the present case, it will therefore be necessary, in due course, to consider on what side of the line the approach taken by the PEG falls. Did the PEG apply new sub-sub-sub-criteria which had not been previously published or did the PEG apply weightings which had not been pre-ordained? If the latter, are the *ATI* conditions met in the present case?

162. Before dealing with those questions, it is necessary to consider a number of other legal principles that apply in the court's consideration of this question.

163. It is clear from the decision of Finlay Geoghegan J. in *Gaswise Ltd. v. Dublin City Council* [2014] 3 IR 1 at pp. 9 – 10 and from the case law of the Court of Justice cited by her that all of the conditions and detailed rules of the award procedure must be drawn up in a clear and precise way in the relevant notice or the contract documents so that all RWIND tenderers exercising ordinary care can understand their significance and interpret them in the same way.

164. It is also clear from the *Gaswise* decision that, in considering this issue, the court should attempt to put itself in the shoes of the RWIND tenderer who would be responding to this particular IOT. In other words, the court should attempt to put itself in the shoes of a prospective supplier of vaccines to the HSE. As Finlay Geoghegan J. observed at p. 11, the court: - "*should not do so as a lawyer*."

165. Nonetheless, it is clear from the authorities, that the court is required to approach the matter quite rigorously. This can be seen, for example, in the judgment of Baker J. in *Somague v. Transport Infrastructure Ireland* [2016] IEHC 435 where she said at pp. 9 – 10: -

> *". . . there is . . .authority for the proposition that a degree of scrutiny not always found in judicial review is required, and while the court engaged in a judicial review is not competent to substitute its decision on the facts for that of the contracting authority, the court's scrutiny is more intense and engages with a review of the evidence of how the evaluation process in fact occurred, at a level of detail different from that found in other types of judicial review . . .*
>
> *What is also apparent from the authorities is that the court must look to whether an undisclosed or impermissible criterion could have, and not would have, made a difference to the end score, or whether to use the language of McCloskey J. [in Resource NI v. Northern Ireland Courts and Tribunal Service], it was "operative or material""*
>
> *This is apparent in ATI EAC [2005] E.C.R. 1-10109 Case C-331/04 at para. 28:*
>
> *"[I]t must be determined whether the decision contains elements which, if they had been known at the time the tenders were prepared, could have affected that preparation."*
>
> *However, there is no question of permitting a margin of discretion when there has been a failure to respect the principles of equality, transparency and objectivity . . ."".*

166. It was accepted by all parties before the court that, in considering the position of the RWIND tenderer the court may have regard to the responses from the other tenderers. This course was taken by Finlay Geoghegan J. in *Gaswise* at para. 24.

167. The HSE also stressed that there is an obligation on tenderers to use reasonable foresight when interpreting tender documents. For example, in *Healthcare at Home Ltd. v. The Common Services Agency* [2012] CSOH 75, Lord Hodge said at para. 27: -

> *"It is the task of the contracting authority to disclose to potential tenderers the existence and relative importance (or weighting) of the criteria which it will take into account in identifying the most economically advantageous tender. But that does not mean that a tenderer is not expected to use reasonable foresight in its analysis of what the stated criteria or sub-criteria entail. Indeed, that appears to me to be implicit in the ECJ's use of the hypothetical standard of " all reasonably well-informed and normally diligent tenderers". . .."*

168. In the same case, Lord Hodge stressed (at para. 26) that it is not realistic to require a contracting authority: -

> *" . . to frame its invitation to tender in such detail that two reasonable people could not reach different views on its interpretation without acting unreasonably."*

In the same paragraph Lord Hodge also said: -

> *"While this standard may possibly be achieved in very simple and straightforward contracts, it is one which is impracticable in complex agreements which are not uncommon in the field of public procurement. It is not in the nature of language for that degree of certainty to be achieved in such agreements. Further, in some circumstances, the obligation on the authority to give very precise and highly detailed descriptions of its requirements would both be very burdensome and also prevent tenderers from using their own initiative and experience to offer innovative approaches to meeting the authority's requirements".*

169. The HSE also relied on what was said by Peart J. in *Baxter Healthcare Ltd. v. Health Service Executive* [2013] IEHC 413. In that case, the applicant complained that it had received only 4 marks out of 10 in respect of a criterion dealing with a proposed building layout where the Contracting Authority had deducted 6 marks on the grounds that the plan proposed by the applicant would involve: -

> *"more noise and activity anticipated in a 40 station unit."*

The applicant complained that there was no reference to noise and activity in the criteria governing the award of tender. The applicant submitted that, had it known that noise and activity would be taken into account, it could have emphasised a number of factors which would have demonstrated that there would be less noise and activity in a 40 station unit than in a 20 station unit. However, this complaint was rejected by Peart J. who said at pp. 57 – 58: -

"I am satisfied that noise and activity have not become criteria which were not disclosed to the applicant. That is to read far too much into the brief comment on the score sheet in an effort to contrive a challenge to the tender result. Section 11.9 is a weighted section for which marks ranging between 0-10 could be awarded. Unless a contracting authority is expected to set out its requirements in the form of multiple choice questions with a box beside each to be ticked, so that the task of evaluation is reduced to a simple mathematical calculation, there must be scope within the tender evaluation process for the evaluation team to reach a score by means of applying its professional judgment to each question. That process avoids the mere adding of marks from ticked boxes, which would render pointless the experience and expertise available among members of a team such as the PEG in this case. Such bodies must be permitted to exercise a degree of discretion in how a section is scored. It must also be allowed to briefly comment on how or why a less than perfect score was considered appropriate. In my view, the applicant is being overly pedantic in attempting to establish fault on the part of the PEG by its use of the words "more noise and activity anticipated in a 40 station unit" on the score sheet. That is not the introduction of new criteria. There will always be some noise and activity in any area where people gather. The fact that the PEG was of the view that a 40 station unit would have more of such noise and activity that a unit half that size is not something which it had to announce in advance, particularly in circumstances where the applicant at no stage forewarned that it would put in a bid for two units in one location."

170. These arguments were rejected by Sanofi. While Sanofi's argument extended also to the marks deducted for side effects and the presence of the three elements described above, Mr. McGrath, in his submissions to the court emphasised in particular the issue which arises in relation to total cohort. He submitted that Sanofi (and by extension the RWIND tenderer) could not reasonably have been expected to foresee that the side effects and acceptability sub-criterion included a requirement that the vaccine should be capable of being administered to the total cohort or that half of the marks available in respect of this sub-criterion could be deducted for failure to satisfy that requirement. He argued that there was nothing in the material issued by the HSE in relation to this sub - sub-criterion that set out any clear or precise requirement that the vaccine be capable of administration to the total cohort.

171. The argument made on behalf of Sanofi is that the effect of the *Lianakis* decision (and of the other European case law discussed in paras. 150 to 160 above), is that if the total cohort requirement was not fairly disclosed in the context of the side effects and acceptability sub-criterion, that is sufficient for Sanofi to succeed on that ground. Mr. McGrath submitted (and I agree with this submission) that, in such circumstances, the *ATI* criteria (as summarised in para. 154 above) do not require to be addressed. A failure to disclose a requirement of the contracting authority attracts the operation of the principles set out in *Lianakis* (as summarised in para. 160(a) above). It would not be necessary in those circumstances to show that knowledge of the total cohort requirement would have affected the preparation of the tender by Sanofi.

172. It was submitted on behalf of the HSE that the effect of the *EUIPO* judgment was that the *ATI* test applies not only to weightings but also to an undisclosed sub-sub-criterion. This is what I understand the HSE to submit in paras. 97 – 101 of its written submissions. If that is the case which the HSE seeks to make, I believe it is mistaken. On my reading of the *EUIPO* judgment, the Court of Justice was simply reiterating the application of the *ATI* principles in cases where an evaluation body on behalf of a contracting authority decides, subsequent to the closing date for submission of tenders, that within any particular sub-criterion (or indeed sub-sub-criterion) more marks should be attributed to one aspect of the sub – sub – criterion than some other aspect or aspects of it. That is precisely what happened in the *EUIPO / OHIM* case. The evaluating committee on behalf of OHIM (as it then was) decided to give greatest weight to two out of 7 aspects of an individual sub-criterion – namely methodology and experience to which an overall maximum score of 40 marks was potentially available. I can see nothing in the *EUIPO* judgment which qualifies or overrides the distinction made in *Lianakis* between that type of case and a case where there has been a failure to disclose a particular requirement at all. In this context, I do not believe that any distinction can be made between criteria, sub-criteria, and sub-sub-criteria. They are all part of the requirements of a contracting authority and must accordingly be disclosed.

173. The first question which I must therefore consider is whether there was a failure on the part of the HSE to disclose that it was a requirement, in the context of side effects and acceptability, that the vaccine should be capable of being administered to the total cohort. In addressing this question I must place myself in the position of a supplier of vaccines. As *Gaswise* makes clear, I should not address this question from the perspective of a lawyer.

174. In considering the position of a supplier of vaccines, I should start with a consideration of s. 3.2.2.2 of the Tender Response Document. It describes the relevant sub-sub-criterion as "side effects and acceptability". This is followed by two short paragraphs, the first of which indicates that tenderers are required to provide details of any reported side effects, and the second of which indicates that tenderers are also required to provide details of the use of thiomersal, aluminium, formaldehyde or latex in the manufacturing or packaging process.

175. The first of those two paragraphs obviously deals with side effects. The second paragraph is concerned with the presence of certain agents in the manufacturing or packaging processes. However, it is clear from the response given by Sanofi in this section of the Tender Response Document, that Sanofi understood that it was required to provide much more by way of response to this section of the document than details of side effects or details of these agents. The response provides a significant amount of detail about the safety profile of Hexyon and gives details of the estimated number of "vaccinees" who received the vaccine. While that might be said to be principally concerned with side effects, the response also deals with risk-benefit and with the extent of the data available in relation to risk-benefit.

176. The response also gives information in relation to cumulative worldwide safety data and states that the "*safety profile of the vaccine is . . . accurately described in the relevant section of the [SMPC]*".

177. In addition, the response provides details of how widely used the vaccine is and the extent to which it has been licenced around the world. It also provides information about the extent to which the vaccine has been used in public immunisation programmes around the world. It then goes on to deal with the use of thiomersal and the other agents. In setting out the extent of the availability of the vaccine, the extent to which the vaccine has been licenced, and the extent to which the vaccine is used in public immunisation programmes, it seems to me that Sanofi was essentially addressing the extent to which the vaccine was acceptable. Thus, Sanofi appears to have well understood that s.3.2.2.2. required a response which provided this range of information. It is also potentially significant that express reference was made by Sanofi to the SMPC in its response to this section. As noted above, it was in the SMPC that it was stated that there is no data available in relation to the administration of the vaccine to premature babies. In the course of the hearing it was stressed on behalf of Sanofi that the obligation on it to provide the relevant SMPC was quite independent of this section of the Tender Response Document. Yet, when it came to providing its response to this section of the document, Sanofi chose to expressly cross refer to the SMPC.

178. It is also noteworthy that in an earlier draft of the Sanofi response to s. 3.2.2.2 of the Tender Response Document, Sanofi expressly stated: -

"Data in premature infants are still considered as missing information but more information is expected in Q 3 2017 . . .".

179. Although attention was drawn to the text of the draft response quoted above in para. 64 of the affidavit of Dr. Corcoran sworn on behalf of the HSE on 13 July 2018, no explanation has been given by Sanofi as to why, in this draft response, a specific reference was made in the context of the side effects and acceptability sub-criterion to the lack of data in respect of premature babies. While it is important to bear in mind that this was simply a draft document and was not the final document, and while it would be unsafe to draw any conclusions solely by reference to a draft document, it nonetheless has to be said that the entry in the draft document in relation to premature babies is consistent with an understanding that "*acceptability*" was concerned with the extent to which the vaccine could be used. In my view, it is of a piece with the information provided in relation to the extent of use of Hexyon around the world (as summarised on p. 11 of the final version of the Tender Response Document) and it is also consistent with the information given on p. 10 of the same document dealing with the worldwide safety data available in relation to the vaccine, (albeit that it identifies a gap in that data). Both of these pages are in response to s. 3.2.2.2.

180. Although Mr. Dempsey has sworn a number of affidavits on behalf of Sanofi, he has not explained what Sanofi understood by "acceptability". I do not wish to suggest that there was an obligation on Sanofi to provide such an explanation but it certainly would have been helpful for the court, in seeking to put itself in the shoes of the supplier of vaccines, to know what Sanofi understood by "acceptability". Nevertheless, the response provided by Sanofi (together with the draft response described above) throws some light on what Sanofi understood. What Mr. Dempsey does say in somewhat guarded language (in para. 51 of his first affidavit, and in para. 31 of his third affidavit) is that neither the IOT nor the Tender Response Document disclosed that marks were available (or available to be deducted) in respect of the total cohort issue under the side effects and acceptability criterion.

181. Although Mr. Dempsey has not provided any evidence to the court as to what Sanofi understood by "*acceptability*", there is evidence from the HSE and from Glaxo in relation to this issue. In particular, Ms. Kiersey in her affidavit sworn on behalf of the HSE on 9 March 2018 draws attention to the way in which Sanofi, in its response to s. 3.2.2.2 of the Tender Response Document expressly cross refers to the SMPC where, as mentioned previously, there is a specific acknowledgement that no data is available in respect of premature infants. Furthermore, Ms. Kiersey states in para. 95 of her affidavit that: -

> *". . . as Sanofi and any reasonably well-informed and normally diligent tenderer operating in this sector would have known, all Primary Childhood Immunisations ("PMI") vaccines administered by the HSE since 2005, when the NIO was established, have been contracted and procured for the total target cohort. There was no indication that the administration of the 6-in-1 vaccine . . . would be different."*

182. Importantly, while Mr. Dempsey, in para. 33 of his third affidavit takes issue with "*the accuracy of a number of statements made by Ms. Kiersey at paragraphs 95 to 105 inclusive of her affidavit*" he does not take issue with this averment. The only evidence as to what was known to operators in the vaccine sector is that contained in Ms. Kiersey's affidavit (as set out above) and in the affidavit of Grainne Farrell sworn on behalf of Glaxo on 28 June 2018 where she says, at para. 8 as follows: -

> *". . . this was a relatively obvious point which should have been apparent to the reasonably well – informed tenderer. The HSE has, since the introduction of the 6-in-1 vaccine into the National Immunisation Programme in 2008, procured one vaccine to administer to the total cohort. The invitation to tender and the Tender Response Documents relating to this Mini-Competition outlined the number of doses of 6-in-1 vaccine the HSE intended to procure and this information did not include a separation of the doses to include a second product for the pre-term group. . ."*

183. In light of these averments and in light of the material contained in the Sanofi response to s.3.2.2.2, when I place myself in the shoes of a vaccine manufacturer, it forcefully strikes me that the RWIND tenderer would be aware that the capability of any vaccine to be administered to the total cohort would be an important factor for the HSE in its evaluation of any tender. While the total cohort is not specifically identified in the "side effects and acceptability" sub-criterion, I am of the view that this is where one would expect it to be dealt with by the RWIND tenderer. In expressing that view, I draw attention to the matters set out in paras. 175 to 177 above where I describe the response actually provided by Sanofi to s.3.2.2.2. It seems to me that much of the response given by Sanofi was directed at the issue of the extent to which the vaccine can be administered. This is reinforced by a consideration of the draft response described in para, 178. As noted above, I would not consider the draft response to be determinative on its own. However, in conjunction with the response given in the final version of the document and in conjunction with the evidence of Ms. Kiersey and Ms. Farrell, all of this strongly supports the conclusion that the RWIND tenderer would understand "acceptability" to extend to the capacity of a vaccine to be administered to the population.

184. I fully appreciate that Mr. McGrath has argued that the court has been given no specific information in relation to the responses given by the other two tenderers to s. 3.2.2.2 of the Tender Response Document. Mr. McGrath has invited the court to draw an inference that in circumstances where it was expressly stated in the Byrne Wallace correspondence that the other tenderers did address the total cohort issue in this section of their Tender Response Document, and where the affidavit evidence is silent on this issue, I should draw an inference that the other tenders did not deal with total cohort in their respective tenders when they provided a response to s. 3.2.2.2. Mr. McGrath emphasised that in none of the affidavits before the court, filed on behalf of either the HSE or Glaxo, does the deponent specifically say that Glaxo dealt with total cohort in s. 3.2.2.2 of its tender. However, I do not believe that it would be appropriate to draw such an inference. In order to explain why this is so, it is necessary to have regard to the affidavit evidence before the court in relation to total cohort.

185. In the first place, it is important to bear in mind what was said by Mr. Dempsey in para. 51 of his first affidavit. The complaint made by him was very specific to Sanofi. He said: -

> *"Out of the ten available marks, half of those marks were deducted because the HSE considered that the Sanofi vaccine could not be administered to the total cohort. Nowhere in the IOT or the Tender Response Document did the HSE disclose that this criterion would be evaluated or weighted in this fashion. Had such information been disclosed, Sanofi could have, and indeed would have, provided significantly greater information regarding the total cohort to which Hexyon can be administered . . .."*

186. This complaint is made by Mr. Dempsey specifically in the course of dealing with the side effects and acceptability sub-sub-criterion. The HSE's position in relation to this issue is then dealt with quite comprehensively by Ms. Kiersey in paras. 69-105 of her affidavit sworn on 9 March 2018. The paragraphs dealing specifically with administration to the total cohort run from paras. 82-94. Ms. Kiersey deals with the responses given by Glaxo and by MSD in paras. 89-91. While it is true that Ms. Kiersey does not expressly say that the responses from Glaxo and MSD were specific to s. 3.2.2.2 of the Tender Response Document, she is responding in these paragraphs to what was said by Mr. Dempsey in para. 51 of his affidavit. She is also doing so in the specific section of her affidavit dealing with the side effects and acceptability sub-sub-criterion. What she says at paras. 89 – 91 is as follows: -

"89. Meanwhile, in its response, [Glaxo] addressed the safety and efficacy in infants up to 36 months of age, and prospective safety and efficacy data in preterm infants. . . . S. 4.4 of SMPC for Infanrix Hexa states clearly and unequivocally that "Clinical data indicate that Infanrix Hexa can be given to preterm infants".

90. S. 4.8 on "Safety in preterm infants" states: -

"Infanrix Hexa has been administered to more than 1,000 preterm infants (born after a gestation period of 24 – 36 weeks) in primary vaccination studies and in more than 200 preterm infants as a booster dose in the second year of life"".

91. S. 4.4 of the SMPC for [MSD's] product . . . states: -

"Special populations:

Premature infants: Limited data from 111 pre-term newborn infants in clinical trials indicate that Vaxelis can be given to premature infants" (My emphasis)".

187. Ms. Kiersey then goes on to refer in para. 92 to Sanofi's response in respect of this sub-sub-criterion which she describes as "*relatively terse*" and she draws attention to the way in which it referred in this section of its response to the safety profile of the vaccine as described in the SMPC for Hexyon. While it is true that Ms. Kiersey does not expressly say in paras. 96 – 98 of her affidavit that the information there highlighted by her was provided in the context of this sub-sub-criterion, I should have thought that on any straightforward reading of this section of her affidavit, this is what was intended. It is striking that, here, Ms. Kiersey refers - in the case of all three tenderers - to their respective SMPCs. That is unsurprising given the function of the SMPC which is to provide essential information in relation to the use of a medicine including qualitative and quantitative information on the benefits and the risks of a medicine. As discussed in paras. 175-177 above, risk benefit was specifically addressed by Sanofi in this section of its tender. As already outlined above, it seems to me that the references to the SMPC by Sanofi were not intended to deal solely with side effects but also with acceptability. In this regard, one does not need to look at a dictionary in order to understand the meaning of the word "*acceptability*". In my view, the meaning is clear. It relates to the quality of being acceptable. In order to form any view as to whether a particular medicine is acceptable, it seems to me to be a basic step to refer to its SMPC. It therefore seems to me to be probable that Sanofi was not the only tenderer who referred to its SMPC in response to this section of the Tender Response Document. On the contrary, it seems to me to be likely that all three tenderers did. I do not believe that it is necessary to make a formal finding to that effect. At this point in my judgment, I am simply addressing the issue as to whether an adverse inference should be drawn of the kind suggested by Mr. McGrath.

188. In the circumstances described in paras. 187 – 189 above, it seems to me that it would be unsafe to draw the inference suggested by Mr. McGrath. Furthermore, I must bear in mind that when Mr. Dempsey came to swear his third affidavit which was in response to (*inter alia*) Ms. Kiersey's affidavit, he did not raise any issue as to whether paras. 96 – 98 of Ms. Kiersey's affidavit could be said to specifically relate to s. 3.2.2.2 of the Tender Response Document. In my view, it would be inappropriate in those circumstances to draw an inference of the kind suggested by Mr. McGrath. If Mr. Dempsey had raised the point in his third affidavit, Ms. Kiersey would then have been in a position to clarify whether (as seems likely) paras. 96 – 98 of her affidavit deal with the responses from Glaxo and MSD to s. 3.2.2.2 of the Tender Response Document or whether there is in fact no reference to the SMPC in this section of their responses.

189. In these circumstances, I have formed the view that, from the perspective of the RWIND tenderer, the cohort to whom the vaccine could be administered fell within the ambit of "acceptability" and was therefore covered by this sub-sub-criterion. Thus, it could not be said, in my view, that in deducting marks in respect of "total cohort" the PEG was applying an undisclosed sub-sub-criterion. Accordingly, the *Lianakis* principle recorded in para. 150 above does not apply.

190. However, even if "total cohort" could not be said to constitute an undisclosed sub-sub-criterion, an issue still remains as to whether the deduction of 5 marks in relation to this issue represented the application by the PEG of an undisclosed weighting which fails to satisfy the *ATI* criteria summarised in para. 154 above. This is an issue which I address in greater detail below in paras 198-202 in the context of side-effects and the presence of thiomersal, formaldehyde and aluminium and I therefore believe that it is sufficient to briefly address the three limbs of the *ATI* criteria in the context of the total cohort issue. Mr Dempsey addresses one of those limbs in para. 51 of his affidavit (quoted in para. 185 above). In my view, there is a complete answer to Mr. Dempsey's contention in paras. 58 – 62 of Dr. Corcoran's affidavit sworn on 13 July 2018, where she refers to the contents of the Sanofi SMPC (described above) which made it very clear that no data is available in respect of premature babies. She then continues at paras. 60 – 63 as follows: -

"60. Moreover, at para. 33 of his affidavit, Mr. Dempsey accepts that "there is no data currently available in the SMPC in relation to the administration of Hexyon to pre-term infants" and that "studies of the issue are ongoing and the data will shortly be available" (my emphasis)

61. Thus – and without prejudice to the HSE's position, that the relevance of administration to the total cohort would have been entirely obvious to any reasonably well-informed and normally diligent tenderer – even on Sanofi's own case, Sanofi actually had no study/data available to it to address this issue of administration to pre-term infants.

62. Indeed, even as of 11 June 2018 (the date of swearing of Mr. Dempsey's Third Affidavit) it is still the case that such data will only "shortly be available". As such, I fail to understand the basis upon which Sanofi can continue to maintain its assertion that it could have provided "significantly greater information regarding the ability to administer Hexyon to the total cohort".

63. It is also notable that, while Mr. Dempsey makes this claim (at para. 31), he does not substantiate it with any specific or concrete examples of the information that he asserts could have been made available." (emphasis in original).

191. In my view, Sanofi has failed to rebut what is said by Dr. Corcoran in those paragraphs of her affidavit. There is simply no material before the court which substantiates the contention made by Mr. Dempsey in his first and in his third affidavits that Sanofi would have been in a position to plug the gap in information relating to preterm babies which was evident from its SMPC. I appreciate that Mr. Dempsey has sought to suggest that the vaccine has been administered to preterm infants in other jurisdictions. However, no details have been provided in relation to this and furthermore, it is difficult to see how this could, of itself, have overcome the obvious difficulty evident from the Sanofi SMPC which stated very clearly that there was no data available to substantiate the acceptability of the vaccine for preterm infants. Moreover, as Dr. Corcoran has stated, Mr. Dempsey fails to provide any specific or

concrete examples of any material, extant at the time of tender, that would be sufficient to substantiate the acceptability of the vaccine for pre-term babies. In these circumstances, I can see no basis on the evidence before the court to come to the conclusion that the decision of the PEG to deduct marks could have affected the preparation of tenders. For the reasons already discussed in paras. 174 – 191 above, I can see no basis upon which it could be said that the decision to deduct 5 marks in respect of the total cohort issue altered the criteria for the award of the contract. In my view, it was clear that this was relevant to the issue of acceptability and that, accordingly, the RWIND tenderer would be aware that if its vaccine was not capable of being administered to the total cohort, its score in respect of this sub-sub-criterion was likely to be lower than the score of a tenderer whose vaccine was not limited in this way. Nor can I see any basis upon which it could be said that the deduction of marks in respect of this issue was in any way discriminatory. Moreover, no case of discrimination has been argued. In those circumstances, I can see no basis upon which it could be said that the three conditions in *ATI* have not been satisfied.

The deduction of marks in respect of side effects and the presence of thiomersal and of formaldehyde and aluminium
192. Ultimately, this aspect of Sanofi's case did not feature strongly in the submissions made by the parties. Sanofi clearly cannot complain here that side-effects and the presence of these agents were not flagged in advance in the Tender Response Document. It is clear from s. 3.2.2.2 of the Tender Response Document that these were matters that would be considered by the HSE in evaluating this sub-sub-criterion. The complaint appears to be that no indication was given in advance as to how the overall mark would be broken down. In other words, the complaint is that the PEG applied an undisclosed weighting to these factors. In para. 52 of his first affidavit, Mr. Dempsey says: -

> *". . .it is not clear to me how the individual deduction of marks was arrived at. The award criterion was not broken down into individual sub-marks, but individual sub-marks were deducted in response to particular elements under this award sub-criterion. I do not understand how this is consistent with awarding marks on a "holistic" basis under the award sub-criterion."*

193. The explanation given by Ms. Kiersey is contained in paras. 76-80 of her affidavit sworn on 9 March 2018 where she said: -

> *"76. In order to ensure proportionality and equal treatment for all tenderers, 0.5 of a ratings mark was deducted for the presence of each of these in the manufacturing process. An additional ratings mark of 1 was deducted from all tenderers for the presence of all side effects.*
>
> *77. This scoring did not create undisclosed sub-weightings. Rather, these marks reflected, in the professional opinion of the . .. . PEG a score that ensured equal treatment across all tenderers. This scoring was also a proportionate response to the fact that the tendered vaccines would cause side effects. The consistency of scoring reflects the consistency of the . . . PEG in judging the impact of these side effects, rather than undeclared sub-weightings.*
>
> *78. I say that the HSE was also acting fairly by using a scoring system that ensured an even-handed approach as between all Tenderers in respect of the Side Effects and Acceptability Criterion.*
>
> *79. In addition, this scoring had no bearing whatsoever on the number of tenderers in the competition; did not alter the content or rating of the Side Effects and Acceptability Criterion; and did not alter the advertised criteria; did not alter the criteria for the award of the Contract set out in the IOT.*
>
> *80. Furthermore, the scoring did not contain elements which, if they had been known at the time the tenders were prepared, could have affected their preparation; and was not adopted on the basis of matters likely to give rise to discrimination against one of the tenderers."*

194. There was a response by Mr. Dempsey to this aspect of Ms. Kiersey's evidence when he came to swear his third affidavit where he simply reiterated in para. 30 of his affidavit that this suggests that a holistic approach was not taken and that the HSE applied undisclosed sub-criteria and/or undisclosed weighting.

195. For the reasons already set out in para 192 above, there is no basis to suggest that any undisclosed criteria were applied. The only issue is whether undisclosed weightings were applied and if so, whether the *ATI* test has been satisfied.

196. In the course of the hearing, Ms. Barrington strongly submitted that in fact no weightings were applied and there is no evidence on affidavit to the contrary. She submitted there is nothing in the DSM that suggests the application of any weightings; likewise, there is nothing in the memorandum of 19 October 2017 (described in para. 14 above) that suggests any weightings. She also submitted that there was nothing wrong with having no weightings and that no authority has been cited to the court for the proposition that one must have weightings for every single mark that is awarded. In my view, Ms. Barrington is correct in her submissions. There is a clear parallel here between the approach taken by the PEG in relation to this sub-sub-criterion in relation to these factors and the approach taken by a different PEG in the *Baxter Healthcare* case discussed in para. 169 above. As Peart J. emphasised in that case, unless a contracting authority is expected to set out its requirements in the form of multiple choice questions with a box beside each to be ticked, there must be scope within the tender evaluation process for the evaluation team to reach a score by means of applying its professional judgment to each question. Bodies such as the PEG must be permitted to exercise a degree of discretion in how a section is scored. All of the tenderers here knew that there were 10 marks available for this category and that the PEG would have to allocate those marks in the exercise of their professional judgment. I can see nothing in the approach adopted which suggests that undisclosed weightings were in fact applied. Nonetheless, I will, for completeness, consider the application of the *ATI* test on the assumption that the manner in which marks were deducted for side effects and for the presence of thiomersal and other elements, suggested that weightings were in fact used.

197. The three prongs of the ATI test are set out in para. 154 above. In the first place, it must be shown that the decision to apply weightings does not alter the criteria for the award of the contract set out in the tender documents. In my view, the decision to deduct marks in relation to side effects and in relation to the presence of thiomersal, formaldehyde and aluminium does not in any way alter the criteria for the award of the contract. The attention of tenderers was drawn to the relevance of side effects and the relevance of the presence of thiomersal etc. in the context of this sub-sub-criterion in s. 3.2.2.2 of the Tender Response Document. Everyone was therefore aware that these factors were relevant to this sub-sub-criterion. Everyone was equally aware that there were 10 marks available for this sub-sub-criterion. In my view, it was patently obvious to tenderers that marks could therefore be deducted in relation to side effects or in relation to the presence of thiomersal or any of the other elements that were specifically mentioned in s. 3.2.2.2. Every tenderer knew that the evaluation team would have to form a view as to what marks should be awarded in respect of this sub-sub-criterion and that in awarding a mark the evaluation team (in this case the PEG) would have to take into consideration any side effects and the presence of any of the elements mentioned above. There was accordingly no alteration of the criteria for the award of the contract.

198. Likewise, it seems to me that the decision of the PEG to deduct marks could not have affected the preparation of tenders. Each of the tenderers were aware that side effects and the presence of these elements were relevant factors in any consideration by the evaluation team of this sub-sub-criterion. They were aware that these factors would be taken into account by the evaluation team. They therefore knew from the outset that these factors would have to be addressed by them. Furthermore, there is nothing in the affidavit evidence of Mr. Dempsey to suggest that Sanofi could have dealt with this in a different way had it known that marks might be deducted in relation to these factors. While he does say (as outlined above) that if Sanofi had been aware of the importance of the total cohort, Sanofi could have provided greater information in its tender, he makes no such averment in relation to side effects or the presence of thiomersal and the other elements mentioned above. There is accordingly no basis to suggest that the second limb of the *ATI* test has not been satisfied here.

199. The third limb of the *ATI* test requires that the decision must not have been adopted on the basis of matters likely to give rise to discrimination against one of the tenderers. In light of the affidavit evidence from Ms. Kiersey (as set out in para. 195 above) it is manifest that there was no discrimination against any one of the tenderers. Each one of them was dealt with in the same way. Moreover, Sanofi has placed no evidence before the court to show that there was discrimination against it in relation to this issue.

200. Accordingly, if the deduction of marks in respect of side effects and the presence of thiomersal, formaldehyde and aluminium represented the application of undisclosed weightings, the three specific conditions in *ATI* have been satisfied and in those circumstances there is no basis on which to invalidate the award of the contract on this ground.

Compatibility and interchangeability

201. It will be recalled that in the correspondence from Byrne Wallace, it was indicated that Sanofi achieved full marks for compatibility but 8 marks were deducted "*as a consequence of the lack of interchangeability of [the Sanofi vaccine] with the 6-in-1 vaccine*". The case made by Sanofi in paras. 13.56 to 13.58 of its statement of grounds is that it must follow that at least 8 marks were available for interchangeability. It was originally alleged that this constituted an undisclosed sub-sub-criterion and/or undisclosed weighting thereby infringing the principles of transparency and equal treatment. However, in the course of the hearing, the argument made was that it constituted an undisclosed weighting.

202. In para. 13.58 of the statement of grounds it is alleged that if Sanofi had been aware that 8 of the marks available under this criterion would be earmarked specifically for interchangeability, Sanofi could and would have submitted a different tender response to address the interchangeability issue in greater detail.

203. In para. 56 of his affidavit, Mr. Dempsey says that: -

> *"Had this information been disclosed to Sanofi, I say that it would have structured its Tender Response Document differently and would have obviously placed greater emphasis on and provided more information in relation to the interchangeability of Hexyon with the 6-in-1 vaccine."*

204. However, Mr. Dempsey provides no detail as to what could have been done differently in terms of the Tender Response Document in dealing with interchangeability. It is true that in his third affidavit, Mr. Dempsey seeks to make the case (at paras. 38 – 39) that the respondent is incorrect in its assessment that Hexyon is only interchangeable if an additional fourth dose is given. However, those paragraphs relate to the claim made by Sanofi (but not pursued at the trial) that the decision of the HSE was irrational and disproportionate. Moreover, those paragraphs do not in fact refer to any additional material that could have been provided by Sanofi to the HSE. The material on which Mr. Dempsey relies in those paras. of his affidavit comprises the SMPC for Hexyon, and Appendix 7 to the Sanofi tender, both of which were submitted with the existing tender.

205. In her affidavit sworn on 9 March 2018, Ms. Kiersey draws attention to s. 3.2.2.3 of the Tender Response Document which addressed compatibility and interchangeability and stated that: -

> *"The Supplier should demonstrate evidence of any compatibility with the current licensed vaccines and interchangeability with 6-in-1vaccine currently in use."*

In paras. 114 – 131 of her affidavit, Ms. Kiersey explains the HSE position very fully. In particular: -

> (a) she maintains in the first instance that the reference in the Byrne Wallace correspondence to "*full marks for compatibility*" does not mean that the compatibility element was scored out of two marks and interchangeability out eight;
>
> (b) She says the expression "*full marks for marks for compatibility*" was used in the correspondence to make it clear that no marks had been deducted in respect of the compatibility element of this sub-sub-criterion. She stresses (as the Byrne Wallace letter of 30 January also did) that the responses of the tenderers were marked "*holistically*" and that no separate marking system was apportioned to compatibility on the one hand and interchangeability on the other;
>
> (c) She also contends that Sanofi was fully aware of the importance of interchangeability (something which is subsequently not denied by Mr. Dempsey in his third affidavit). Ms. Kiersey says that this was clear in the IOT and in the description of compatibility and interchangeability set out in s. 3.2.2.3 of the Tender Response Document (quoted in para. 99 above).
>
> (d) Ms. Kiersey maintains that the deduction of eight marks was entirely justified in light of the factors identified in the Byrne Wallace correspondence. In this context, she rejects the complaint made by Mr. Dempsey that the IOT and Tender Response Document did not disclose any concern on the part of the HSE in relation to the extra workload that would arise in relation to planning, education for health professions, vaccine management or vaccine wastage. Instead she says at para. 122: -
>
> > *"It is blatantly obvious, and would have been obvious to any reasonably well-informed and normally diligent tenderer that adding a 4th boost, as Sanofi proposed, would have necessitated:*
> > *(a) a change in the GP contract to include an extra visit/vaccination;*
> >
> > *(b) a change to the PCI schedules and all materials pertaining to same;*
> >
> > *(c) a change to all the information systems for child records and payment;*

and

(d) training and education (as indeed Sanofi acknowledged in s. 3.2.3.1 of its Tender Response Document)"

(e) Ms Kiersey said it would have been obvious to any RWIND tenderer that in responding to this sub-sub-criterion, it was required to "*demonstrate evidence*" of how issues arising from the change might be addressed. Yet, no suggestions were made by Sanofi to address these issues and no plan was presented by Sanofi as to how its product would be integrated into the current schedule.

(f) Ms Kiersey makes the case that it would also have been obvious to any RWIND tenderer that these factors were inherent in and critical to any assessment of the compatibility and interchangeability sub-sub-criterion and that it was necessary for Sanofi to advance a proposal to deal with these issues and minimise their effect.

(g) In these circumstances, Ms Kiersey contends that, in the exercise of its discretion and judgment, the PEG was fully entitled to deduct 8 marks from Sanofi.

(h) Ms. Kiersey also says that these issues could only be identified upon consideration of tenders. Any proposal to introduce a new vaccine, depending on what is proposed, could raise a range of issues. Those issues could only be identified upon receipt and consideration of tenders. Ms. Kiersey contends that they could not therefore be described as undisclosed.

206. At the hearing, Sanofi confined itself to arguing that the way in which the PEG scored the tenders shows that there was an undisclosed weighting which was 80/20 in favour of interchangeability. This is clear from the transcript of Day 2 at p. 54 and also Day 4 at p. 130. Mr. McGrath argued that no RWIND tenderer looking at the Tender Response Document would understand that 80% of the marks were going for the logistical factor of interchangeability rather than the safety factor of compatibility.

207. On behalf of the HSE it was submitted by Ms Barrington that the members of the PEG had 10 marks to consider and they decided to allocate them in the way that they did in the exercise of their discretion. She stressed that they were not mandated to assign two marks to the compatibility factor and eight marks to interchangeability. It is true that they did allocate them in that way, but Ms. Barrington emphasised that there is no evidence that this is what they were required to do by reference to weightings that were pre-ordained. The allocation of the scores for this sub-sub-criterion were left to the discretion of the members of the PEG using all their expertise and experience. Instead of 2/8 they could have allocated the marks 3/7 or 4/6, or 5/5.

208. It seems to me that the observations of Peart J. in the *Baxter Healthcare* case (quoted in para. 169 above) are relevant. The fact is that each of the tenderers were aware that it was possible that the PEG would assign a score of somewhere between 0 and 10 in relation to the sub-sub-criterion. As Peart J. emphasised, there must be scope within a tender evaluation process for the evaluation team to reach a score by means of applying its professional judgment. There is no evidence in this case that there was any preordained weighting applied. Instead, the evidence is to the effect that the PEG applied its professional expertise and discretion. It seems to me that they were entitled to proceed in that way having regard to the approach taken in *Baxter Healthcare*.

209. Nonetheless, lest I am wrong in that view, I will, for completeness, consider whether the conditions in the *ATI* test are satisfied in this case.

210. The three limbs of the *ATI* test are set out in para. 154 above. In the first place, I must consider whether the decision to apply a weighting (on the assumption that such a decision was made by the PEG) alters the criteria for the award of the contract as set out in the tender document. It seems to me to be very clear that it does not alter the criteria in any way. This is implicitly acknowledged by the manner in which Sanofi did not ultimately argue that the approach taken by the PEG here involved the application of some undisclosed criterion. Notwithstanding that this is an issue that was raised in the statement of grounds, it was not pursued at the trial. Sanofi confined itself to arguing that there was an undisclosed weighting. Moreover, it is clear that Sanofi, in common with all of the tenderers, knew from the terms of s.3.2.2.3 of the Tender Response Document, that it had to demonstrate that its vaccine was interchangeable with the vaccine currently in use. This was not some passing reference to interchangeability but was a very clear injunction to tenderers to place sufficient material before the HSE to show very clearly (i.e. to demonstrate) that its vaccine would be interchangeable. Standing in the shoes of a RWIND tenderer, it strikes me that any experienced supplier of vaccines would know that the issues described by Ms Kiersey (as summarised in para. 205 above) would be likely to be of importance to a health authority such as the HSE.

211. Nor does it seem to me that there is any sufficient evidence before the court to suggest that this weighting (again on the assumption that such a weighting was applied by the PEG) could have affected the preparation of the tender. While Mr. Dempsey asserts in very broad brush terms, that if this information had been known to Sanofi, it would have structured its Tender Response Document differently and placed greater emphasis on and provided more information in relation to interchangeability, no evidence has been placed before the court to show that there was additional material that could have been added to the tender to make a difference. In this context, it seems to me that Ms. Barrington is correct in suggesting that the onus of proof lies on the applicant in relation to this limb (and indeed the other limbs) of the *ATI* test. This seems to be clear from the judgment of the Court of Justice in the *EUIPO* case where the Court said at para 34 that the General Court was in error in not examining "*whether it had been pleaded and established that those three conditions had not been met*.". In the present case, it has certainly been pleaded that this limb of the ATI test has not been met. However, it seems to me that Sanofi has failed to place any evidence before the court to support this contention and therefore has failed to establish it.

212. Insofar as the third limb is concerned, what must be shown (and the *EUIPO* case says that it must also be pleaded) is that the decision was adopted on the basis of matters likely to give rise to discrimination against one of the tenderers. No such case is pleaded in the statement of grounds in relation to the contention advanced by Sanofi that the principles of equal treatment and transparency were infringed in relation to this sub-sub-criterion. Nor was any argument made at the hearing to that effect. In the circumstances, there is no basis on which the court could now determine that the decision was adopted on the basis of matters likely to give rise to discrimination against one of the tenderers.

213. For the reasons outlined in paras. 210 to 212 above, I have come to the conclusion that Sanofi has failed to establish that the principle of transparency has been infringed in relation to this sub-sub-criterion.

Manifest error

214. At the hearing of these proceedings, Sanofi confined its case on manifest error to a single sub-sub-criterion - namely

presentation. Sanofi received full marks in respect of this sub-sub-criterion while Glaxo received 45 marks out of 50. As set out in para. 13.38 of its statement of grounds, Sanofi considers its vaccine to be so superior to the Glaxo vaccine in terms of presentation as to render the "*minimal differential in marks*" awarded by the HSE to the two tenders to be manifestly erroneous, unreasonable and irrational. In making this case, Sanofi relies on the fact that its vaccine is a fully liquid vaccine which Sanofi contends reduces the risk of handling errors when compared to non-fully liquid vaccines. In the material provided in support of its tender (which included a PowerPoint presentation) Sanofi suggested that the Glaxo vaccine required an additional ten handling steps before it was capable of being administered. The Sanofi tender also explained that studies confirmed that 40% programmatic errors were observed during the administration of the Glaxo vaccine compared with only 10% in the case of the Sanofi vaccine.

215. There was no dispute between the parties as to the legal test to be applied in relation to this ground. The test in relation to manifest error is well established. As Fennelly J. observed in *SIAC Construction v. Mayo County Council* [2002] 3 IR 148, while the error must be "*manifest*" this is not to be equated with "*any exaggerated description of obviousness*". At p. 176, Fennelly J. said: -

> *"The courts must exercise their function of judicial review so as to make the principles of the public procurement directives effective. In the case of clearly established error, they must exercise their powers. The application of these principles may not, in practice, lead to any real difference in result between the judicial review of purely national decisions and of those which require the application of Community law principles."*

216. As Baker J. observed in Somague, it is implicit in the SIAC judgment that the standard of review is different to that applied in *O'Keeffe v An Bord Pleanala* [1993] 1 IR 39.

217. Essentially, the case made by Sanofi in support of its contention that there was a manifest error in the scores awarded by the PEG in relation to this sub-sub-criterion is that the evidence before the PEG all pointed in one direction – namely that, insofar as presentation is concerned, the Sanofi vaccine was significantly superior to the Glaxo vaccine which should have been reflected in the final scores awarded to Sanofi and Glaxo respectively.

218. This is the case which is made by Mr. Dempsey in paras. 46 and 47 of his affidavit. He says that there should have been a much bigger gap between the marks awarded to Sanofi when compared to those awarded to Glaxo. He also says that the absence of such a gap suggests to him that the HSE either did not take relevant considerations into account or took account of irrelevant considerations in the award of marks.

219. Before considering the evidence given on behalf of the HSE in relation to this issue, it is important to bear in mind what was said by Peart J. in *Fresenius Medical Care (Ireland) Ltd. v. Health Service Executive* [2013] IEHC 414 at p. 17 where he said: -

> *"When conducting a judicial review, this Court does not conduct a merits-based review. The Court is not concerned with whether, if it was making the decision, it would come to a different result. The Court is not concerned with whether it considers the scores given by the awarding authority are unduly high or unduly low in any particular section or under any particular heading. The Court will allow an expert body, such as in this case the . . . (PEG), a margin of appreciation or discretion as to the mark which it considers appropriate, and will defer to that body in this respect. That body has a degree of discretion permitted to it since its members have been tasked as an expert body by HSE to assess the bids received. It has significant experience in such matters and must be allowed to do its job without undue and unnecessary interference by the Courts. The Courts must not lightly interfere in the tender process, including the result. That margin of appreciation . . . and the desirability that a Court should not lightly interfere with the decision of an expert body charged with the evaluation of bids in a particular sector, explains and is consistent with the principle by now well-established in the case-law that the Court will not do so except where a manifest error has occurred in the process - in other words a very clear error, an error obvious to the eye, and one which prompts the Court to ask itself could this possibly be correct, and, upon close examination, answer that question in the negative. . . . ."*

220. In the same case, at p. 19, Peart J. referred to the decision of O'Neill J. in *Clare Civil Engineering Ltd. v. Mayo County Council* [20014] IEHC 135 where O'Neill J. said that the applicant carries the onus of satisfying the court that the decision of which he complains has been made in clear error.

221. These principles were emphasised by Ms. Barrington in the course of her submissions. She also drew attention to what was said by Ms. Kiersey in relation to this issue in her affidavit sworn on 9 March 2018. The issue is dealt with in paras. 39 – 68 of that affidavit. Ms. Kiersey explains that while Sanofi has focused solely on the steps required prior to use, the presentation sub-sub-criterion extends to both needles and preparation for use. She also explains that the requirement for reconstitution (as explained in para. 8 above) is not new for vaccinators and there is familiarity with the process of vaccine preparation for use which is now routine practice for medical practitioners. She also addressed in some detail a study which was footnoted in the PowerPoint presentation which was submitted by Sanofi with its tender. However, the point was made at the hearing by Mr. McGrath that there is no indication that this study was before the PEG at the time of its consideration, and for that reason I do not believe that it would be appropriate for me to have regard to what is said by Ms. Kiersey in paras. 51 – 66 of her affidavit.

222. The final point made by Ms. Kiersey in paras. 67 and 68 of her affidavit is that while Mr. Dempsey contends in para. 46 of his first affidavit that the administration of the Sanofi vaccine occurs in three straightforward steps, this is not consistent with the PowerPoint presentation which states that the administration of the vaccine occurs in seven steps. She also says that insofar as it suggested by Sanofi that there are ten additional steps between the administration of the Glaxo vaccine and the Sanofi vaccine, this includes steps not required under NIAC guidelines.

223. In his third affidavit, Mr. Dempsey responds to Ms. Kiersey in relation to the presentation sub-sub-criterion. He deals with this aspect of Sanofi's case at paras. 19 – 28 of his affidavit. Much of this section of his affidavit is concerned with the study (which I have already excluded from my consideration and therefore does not require comment here). In para. 22 of his affidavit, Mr. Dempsey challenges the suggestion made by Ms. Kiersey that reconstitution is routine practice.

224. The HSE responded to Mr. Dempsey's' affidavit in the affidavit sworn by Dr. Corcoran on 13 July 2018. Again, that affidavit is concerned to a large extent with the studies, which I have excluded from my consideration. However, Dr. Corcoran also says the following (in para. 44 of her affidavit) which seems to me to be relevant: -

> *"In Ireland, the general time allowed for the meetings when the vaccine is administered is 25 – 30 minutes. This is because there are certain procedures required before, during and after the vaccine is administered. These procedures are outlined in s. 5 of the Guidelines for Vaccinations in General Practice, a copy of which is exhibited . . . to Mr. Dempsey's Third Affidavit. In this context, a difference of 70.5 seconds required to prepare the non-fully liquid vaccine*

compared to 36 seconds for Hexyon is clearly not significant. In this regard, I also agree with the statement made by Ms. Kiersey . . . that the extra 34.5 seconds in preparation of [the Glaxo vaccine] prior to administration is "negligible"".

225. As noted above, in the light of the absence of any significant records of the deliberations of the PEG, I am not in a position to form any view that any of the studies that are discussed in the affidavits were available to the PEG. For that reason, it would be inappropriate for me to assume that these studies were available to the PEG. I must therefore exclude any consideration of these studies in my decision on this issue.

226. However, I am very conscious that the PEG was comprised of three individuals with very significant expertise and experience. The relevant experience and expertise of the members of the PEG has been summarised in para. 13 above. There is a significant difference between an expert body such as the PEG on the one hand and a non-expert body on the other. A non-expert body will have to depend very much on the submissions that are made to it and the material supplied to it in order to be in a position to assess the evidence and reach a conclusion. Where the evidence submitted to such a body all points in one direction, it may well be irrational and in manifest error for that body to reach a contrary conclusion to the evidence presented to it. However, the PEG is not in that position. It has the expertise and experience to assess and evaluate the information provided to it, including the PowerPoint presentation and the other evidence presented to it by Sanofi in relation to what it contends are the superior qualities of its fully liquid vaccine. In particular, the members of the PEG, with all of the background knowledge and expertise available to them, would be aware, for example, of the way in which vaccines are actually administered to infants in Ireland - and in particular that the vaccines are administered on a visit by a parent and child to a general practitioner and the normal duration of such a visit. They are therefore fully in a position to assess the utility of the additional speed with which the Sanofi vaccine can be administered and are clearly in a position to form a view as to the value of that utility, having regard to the duration of such a visit. They will also be aware from their own experience and expertise (and in particular from the fact that the Glaxo vaccine has been administered over a long period of time in Ireland) as to whether the reconstituted vaccine gives rise to problems in practice. In my view, it is unreal to suggest that they would have to rely on studies in order to educate themselves in relation to this issue.

227. While Sanofi has criticised the evidence placed before the court by the HSE, it seems to me that in fact the deficit in evidence exists on Sanofi's part in relation to this issue. There is no attempt in any of the evidence presented by Sanofi to demonstrate that an expert body such as the PEG is not in a position to evaluate and assess and reach its own conclusion in relation to the material submitted by Sanofi. The approach taken by Sanofi is to effectively suggest that the HSE was required to take its material at face value; not to question it or reach its own view. I cannot see how Sanofi can take that approach in light of the undoubted expertise of the PEG. In my view, if Sanofi were to succeed on this issue, it would have to provide much more by way of evidence to demonstrate that there is no basis on which an expert evaluation body such as the PEG could properly come to the conclusion which it did. That evidence is not before the court. In these circumstances, I do not believe that there is any basis on which the court could come to the conclusion that the scores awarded by the PEG in relation to this sub-sub-criterion are vitiated by manifest error.

Lack of records

228. For the reasons which I have outlined above, I have been able to reach a conclusion in relation to the issues argued before me. I was able to do so notwithstanding the remarkable paucity of records of the proceedings of the PEG. I should, however, make clear that it is highly undesirable that a body such as the PEG should proceed to reach decisions with so little by way of written record. Notwithstanding the undoubted expertise and experience of its members, I believe that a body such as the PEG should be careful to appropriately document its deliberations and to retain that record in the event of a subsequent challenge. However, the statement of grounds was never sought to be amended to include a claim based on the paucity of records. In those circumstances, I do not believe that it is open to me to make any finding relating to the state of the record.

229. In making the *obiter* observations set out in para. 228 above, I would not wish in any way to suggest that it is inappropriate for a body such as the PEG to meet by way of telephone conference rather than in person. While this was the subject of some animadversion at the hearing, I do not believe that there is any reason in principle why a body of experts cannot meet in this way. Indeed, there may well be a significant saving in costs for it to proceed in that way. I would nonetheless strongly urge that an appropriate record should be made of the deliberations.

Conclusion

230. For all of the reasons set out above, I reject the case made by Sanofi save to the limited extent set out in paras. 145-146 above. I will hear the parties in due course in relation to the precise form of order to be made and in relation to costs.

231. Finally, I extend my thanks to the legal representatives for the very clear and comprehensive way in which the matter was argued.