PROCEDURAL OFFICER DECISION

2015/2

APPLICATION BY PFIZER IN RELATION TO THE CMA INVESTIGATION UNDER THE COMPETITION ACT 1998 INTO THE SUPPLY OF PHENYTOIN SODIUM CAPSULES

Summary of Application

1 Pfizer[1] has requested a review of the CMA's decision not to grant it an extension of time for submitting written representations on the Statement of Objections (the Statement) addressed to Pfizer in the CMA's Competition Act investigation into the supply of phenytoin sodium capsules (the Investigation). Pfizer requested that it be given an extension of three weeks from the current deadline of 20 November 2015 by which to provide its written representations on the Statement (the Application). The Statement was issued by the CMA on 6 August 2015 alleging that Pfizer and one other party, Flynn[2], have infringed the Chapter II prohibition contained in the Competition Act and/or Article 102 of the Treaty on the Functioning of the European Union.

The SRO's Decision

2. The Senior Responsible Officer (SRO) for the CMA Investigation sent a letter by email to Pfizer's legal advisers, Clifford Chance, on 4 November 2015 refusing Pfizer's request for a three week extension of time to the deadline of 20 November 2015 for submitting its written representations on the Statement (the SRO's Decision).

3. The key issues which Pfizer raised in seeking the extension of time and in making the Application and which were addressed in reasons given in the SRO's Decision are set out below.

The Procedural Officer's Process

4. The Application was received on 11 November 2015 by a letter sent by email to me as the CMA Procedural Officer. I held meetings on 13 November, first with the CMA case team and then with Pfizer's legal advisers, Clifford Chance. I have considered the representations and information provided in those meetings, together

[1] The Application was submitted on behalf of Pfizer. The CMA's Statement of Objections was addressed to Pfizer Limited and Pfizer Inc., collectively referred to as Pfizer in the Statement of Objections and in this decision.
[2] The CMA's Statement of Objections was addressed to Flynn Pharma Limited and Flynn Pharma (Holdings) Limited, collectively referred to as Flynn in the Statement of Objections and in this decision.

with the information set out in the Application. I have also taken account of the reasons set out in the SRO's Decision.

Scope for the Procedural Officer to consider the Application

5. The Application relates to the deadline for Pfizer to submit written representations on the Statement issued in the CMA's Investigation. I consider it falls within the scope of the procedural complaints that can be considered by the Procedural Officer on the request of a party to an investigation[3]. This was not disputed by the case team.

Issues raised by the Application

6. The issues raised by Pfizer in the Application that it considered to have an impact on the time needed to prepare its written representations were presented under five broad headings:

i) The issues raised by the Statement
ii) Delays caused by amendments made by the CMA
iii) The substantial business input required
iv) Pfizer's previous extension request
v) Exercise of Pfizer's rights of defence.

The points made which are relevant to my consideration under each of these five headings are set out in more detail below (paragraphs 8-17). I have then set out my observations on these points (paragraphs 18-33). Some of these points overlap and I have considered them both individually and in the round. The issues raised by Pfizer were presented in the Application in a slightly different way from in the request for an extension of time which was made to the SRO and therefore in the consideration of that request in the SRO's Decision. I do not consider that any differences in that presentation of the issues are material and these have not affected the way in which I have assessed the information which was provided to me, including the information presented in the meetings which I held with the case team and with Pfizer's legal advisers.

Chronology

7. The procedural chronology following the issue of the Statement is important to consideration of the Application. Key points in the procedural chronology following the issue of the Statement are set out below. I have identified these from the Application together with correspondence provided to me by Pfizer and the case team, and from the meetings I have held with them.

[3] The CMA's Guidance on the CMA's investigation procedures in Competition Act 1998 cases (CMA8) expressly lists as within the scope of the Procedural Officer remit: "procedural complaints that relate to … deadlines for parties to respond to information requests, submit non-confidential versions of documents or to submit written representations on the Statement of Objections or Supplementary Statement of Objections", paragraph 15.4.

2015

6 August: The Statement was issued to Pfizer alleging Pfizer has abused its dominant position by charging Flynn unfairly high selling prices in breach of the Chapter II prohibition and/or Article 102 of the Treaty on the Functioning of the European Union. The CMA set a deadline of 30 October for Pfizer to make written representations. This equated to a period of just over 12 weeks.

18 August:

- Pfizer requested an extension of time to submit its written representations of one month until 30 November.
- Pfizer informed the CMA of a number of errors and inconsistencies in revenue and cost figures in the Statement and accordingly requested access to the CMA excel worksheets underlying the numerical calculations.

24 August: The CMA provided Pfizer with a spreadsheet with calculations underlying the cost analysis.

14 September: The CMA granted Pfizer a three week extension of time to the deadline to submit its written representations. This set a revised deadline of 20 November.

17 September: The CMA provided Pfizer with the corrected Statement.

2 October: The CMA provided Pfizer with a revised spreadsheet setting out calculations underlying the cost analysis.

18 October: Flynn requested disclosure of documents relating to Pfizer.

20 October to 3 November (approx.): Period when Pfizer was consulted by the CMA and considered Flynn's request for disclosure of Pfizer cost data within a confidentiality ring.

3 November: Pfizer requested a three week extension until 11 December to respond to the Statement.

4 November:

- The CMA provided Pfizer with further documents relating to Flynn.
- The SRO informed Pfizer of her decision rejecting Pfizer's request of 3 November for an extension and maintaining the deadline of 20 November.

The issues raised by Pfizer

i) The issues raised by the Statement

8. The Application argued that the Statement "raises important issues of law and precedent, factual substance and policy" and underlined the importance for Pfizer to be given a "fair and reasonable amount of time to provide full written

representations". It also argued that a three week extension would cause no prejudice to the Investigation when set in the context of its length. In the meeting with Pfizer's legal advisers, emphasis was placed on the importance of the issues raised by the Statement and the consequences for Pfizer's business including the potential wider precedent for Pfizer and more generally given that the CMA was in Pfizer's view taking a novel approach on this case. The ability for Pfizer to be able to do "a proper job" in its written representations in those circumstances was identified as key.

9. The SRO's Decision noted that by the deadline of 20 November, Pfizer would have had 15 weeks in which to submit its written representations. This was notably longer than the period normally provided for a party to respond to a Statement of Objections in accordance with the timeframe set out in the CMA's guidance[4]. The SRO's Decision noted that according to the guidance this period will usually be "no more than 12 weeks" from the issue of the Statement of Objections. In my meeting with the case team, they questioned the weight which had been attached by Pfizer to the significance of the Statement in considering the appropriate length of time within which to respond; the case team considered it was a comparatively straightforward case.

ii) Delays caused by amendments made by the CMA

10. The Application stated that during the period since the Statement was issued, Pfizer had had to devote significant time to other matters related to the Investigation that could not have been anticipated at the start of this period. These covered three areas: an access to file request by Flynn, mistakes in particular in the calculation of alleged price excesses and costs set out in the Statement, and late disclosure of relevant documents. In my meeting with Pfizer's legal advisers they explained that the mistakes in the original Statement and the fact that a corrected Statement had been issued created a "messy start" with a "moving target" which had caused a significant diversion of resource. This meant that Pfizer and its advisers had had to spend time in understanding the position. They stated that the numerical errors in the Statement were significant given they were material to understanding the excessive pricing alleged by the CMA.

11. The SRO's Decision rejected the argument that consideration of Flynn's disclosure request would have required significant resources on the part of Pfizer or that it necessitated a further extension to the deadline. It also noted that the possibility of the need to consider disclosure requests was taken into account by the CMA when the original timetable was set for responding to the Statement. In my meeting with them, the case team explained that confidentiality issues in the access to file process arose in part because of the issue of a single Statement covering the alleged infringements by both Pfizer and Flynn, a matter that had been discussed with the parties before the Statement was issued. The case team argued that Pfizer was therefore aware that issues of this nature might arise. The case team also argued that since Pfizer had itself identified mistakes in the cost calculations in the

[4] CMA8, see footnote 3 above, paragraph 12.3.

original Statement, it was clear that they were fully engaged on preparing Pfizer's response during this period.

iii) The substantial business input required

12. The Application noted that the Statement "is a very lengthy, detailed and technical document" and that in order to prepare a fully considered response, Pfizer has had "to draw on the time and expertise of its commercial, regulatory, financial, legal and executive teams (located throughout the world) as well as that of its external advisers". In my meeting with Pfizer's legal advisers, emphasis was placed on the need to involve a range of different people across the Pfizer business because of the nature and wider implications of the issues raised in the Statement, and that time was required to co-ordinate this task, to find time in people's different schedules and ensure that the best response to the Statement could be prepared.

13. The SRO's Decision noted that Pfizer is a large and well-resourced company and that it had engaged experienced legal and economic advisers. It also noted that a 15 week period to submit written representations should have provided Pfizer with more than sufficient time to co-ordinate availability. In the meeting, the case team pointed out to me that there had been meetings and dialogue with Pfizer and its advisers during the course of the investigation before the Statement was issued.

iv) Pfizer's previous extension request

14. The Application noted that Pfizer had previously been granted a three week extension to the timetable but pointed out that since the Statement was issued during the August holiday period when many of Pfizer's staff and advisers were away, this additional three weeks simply offset the loss of that time and had little practical effect. Pfizer therefore questioned that it had had 15 weeks in which to prepare written representations. It argued it had had no more than 11 weeks.

15. In the meeting, the case team noted that following the grant of this extension, Pfizer gave no indication that it still needed more time until an application for a further extension was made in an email to the SRO on 3 November.

v) Exercise of Pfizer's rights of defence

16. The Application noted that the effect of the factors put forward (and as set out above) meant that "Pfizer cannot fully exercise its rights of defence in the time currently provided". It stated that it is for Pfizer to assess what it considers to be relevant in exercising its rights of defence. The Application also stated that "an extension provided to one party should also be provided to the other".

17. The SRO's Decision rejected the point that was made in Pfizer's request for an extension that the inextricable link between the two alleged offences meant that fairness and equality of arms would dictate that Pfizer's request for an extension should be granted if Flynn were granted an extension. The SRO's Decision noted: "The two alleged infringements are linked but are not dependent upon each other; they constitute separate allegations of anti-competitive unilateral behaviour on two distinct markets". The SRO's Decision explained that any requests would be considered by reference to the reasons provided and concluded: "In circumstances

where the context to, and reasons for, two requests were to differ, the CMA does not accept that fairness and equality of arms would dictate that any extension that was provided to one addressee should also be provided to another."

Observations on issues raised by the Application

18. In light of the nature of the Application which relates to the time period for responding to a Statement of Objections I have considered in particular the rights of defence. I consider that this covers issues in relation to the right of the party under investigation by the CMA to be heard encompassing:

i) notice of the alleged infringement and the evidence relied on in support of this before any adverse decision is taken with the opportunity to respond (the Statement of Objections)
ii) a reasonable opportunity to inspect the documents in the CMA's file that relate to the matters referred to in the Statement of Objections (access to the file)
iii) opportunity for the business to make known its views on the truth and relevance of the facts and circumstances of the alleged infringement and the documents relied on (the representations)[5].

It is clear that in order to exercise its right to respond to a Statement of Objections effectively, a party under investigation needs to be given the information necessary to understand the case together with a reasonable time to prepare its response to that case[6].

19. I have carefully considered the issues raised by Pfizer in the Application and the SRO's Decision as further developed in the meetings I had with Pfizer's legal advisers and with the CMA case team. I make the following observations in relation to the points that have been raised by Pfizer.

20. The key issue in this Application is whether the revised deadline of 20 November for submitting written representations is (or remains) an appropriate one for Pfizer to submit its written representations on the Statement. In particular I have considered whether any developments occurring since the original deadline was set, and/or since it was later extended, may have given cause to change the assessment of the appropriate period made at those times.

21. The CMA has published guidance which, as noted above, explains that the timetable for a party under investigation to submit written representations on a Statement of Objections will be specified in that document and states:

[5] These issues are covered in Rule 6 of the CMA Rules which deals with notices, access to file and representations: The Competition Act 1998 (Competition and Markets Authority's Rules) Order 2014, SI 2014 No. 458.

[6] The CMA's published Transparency and disclosure: Statement of the CMA's policy and approach (CMA6) states that the CMA "must in some cases, take certain steps to share its provisional thinking or proposed decisions" and provides as an example "in CA98 investigations, if it proposes to make a decision, the CMA must issue a Statement of Objections (SO) to any party suspected of a breach of the CA98", para 3.12.

> "Usually the deadline for an Addressee to submit written representations will be at least 40 working days, and no more than 12 weeks, from the issue of the Statement of Objections."[7]

This published guidance is important to my consideration of the Application in a number of ways, including its relevance to the date from which time should run and the appropriate length of time in light of the nature of this particular case. It is also important to recognise that the guidance states that this will "usually" be the timeframe. I also note the more general statement in this published guidance:

> "The CMA will apply this guidance flexibly. This means that the CMA will have regard to the guidance when dealing with suspected competition law infringements but that, when the facts of an individual case reasonably justify it, the CMA may adopt a different approach."[8]

22. The guidance therefore anticipates that there may be circumstances where the timeframe is not appropriate. By definition, such circumstances will however be unusual. They will be likely to relate to the particular position of an individual party and must be considered within that context. Relevant to my assessment of whether the circumstances are unusual will be their implications for and effect on the rights of defence of the party concerned.

23. I recognise the importance for the efficiency and effectiveness of the Competition Act regime that timeframes are clear, understood and adhered to. This is of benefit to parties as well as to the CMA. It underpins the right to have a decision taken and for proceedings to be resolved within a reasonable time.

24. As noted above, depending on whether or not the August period is included, Pfizer has had either just over 15 or 11 and a half weeks within which to respond to the Statement. In the overall context, this is either close to or well beyond the maximum period of time that published guidance makes clear is usually provided within which to submit written representations. I note moreover that the original timeframe with a deadline of 30 October when the Statement was issued was a period of just over 12 weeks, the maximum set out in the guidance. I note the arguments which have been made by Pfizer in relation to the timing of the issue of the original Statement in August and the various matters Pfizer has raised in relation to developments since the original timeframe was set: its view of the complexity of the issues raised, and the time necessary to handle issues related to disclosure and the mistakes in the original Statement. These issues are considered further below. As part of this consideration, I note that in September Pfizer was granted an extension of three weeks to the original timeframe in which to submit its written representations. In light of the matters raised by Pfizer and discussed in the following paragraphs, I have therefore considered if this overall period of 15 weeks was a reasonable one by which Pfizer should submit its written representations.

25. I acknowledge the points that have been made by Pfizer about the significance of the issues raised in the Statement and the importance to it of

[7] CMA8, see footnote 3 above.
[8] CMA8, see footnote 3 above, paragraph 1.8.

therefore involving those from across the Pfizer business in preparing a response. I note nonetheless that Pfizer has instructed experienced and expert external advisers who have been engaged during the investigation process. It is for parties to ensure that they are in a position to enable them to deal with the full range of matters that may arise as part of their conduct of business, handling appropriate regulatory processes, including the consequences of investigations in relation to their compliance with the Competition Act.

26. Pfizer has also highlighted the need to devote resource to addressing matters in relation to disclosure and other issues associated with the issue of the Statement, in addition to and at the same time as preparing its written representations. I note that, as explained in the SRO's Decision, the timeframe for responding to the Statement had been set by the CMA to allow for disclosure issues to be addressed. Furthermore, the information I have been given does not suggest to me that the time devoted by Pfizer to Flynn's disclosure request was such as to make a significant impact on the timetable. Similarly, while I understand that certain documents have been disclosed to Pfizer late in the process and only just over two weeks before the deadline set for providing written representations, it has not been put to me that these documents were particularly material to Pfizer's response to the Statement, nor that this late disclosure itself caused problems. I understand, as noted above, that the procedural consequences in issuing a single Statement were discussed with the parties before the Statement was issued.

27. I note the concerns raised by Pfizer about the need to devote time in addressing the mistakes which were identified in relation to the CMA's calculation of costs. Although dealing with these mistakes took time and therefore I recognise that it had an impact on the overall time available to Pfizer for preparing its written representations, it is relevant to my consideration of the Application that Pfizer's advisers identified these errors. I consider that this indicates that they were in a position to make an assessment of the calculations. It also indicates that they had been making use of the time in August from when the Statement was issued.

28. I consider that the extension of time which was provided to Pfizer in September was sufficient to offset any limitations which may have arisen in dealing with this matter during the August period and any delays which may have been caused by the mistakes in the Statement. I therefore consider that the developments which have occurred since the original Statement was issued that Pfizer has highlighted as having a significant impact on timing have been addressed.

29. I note the points that have been made by Pfizer to support its argument that it has had at most 11 weeks to prepare its written representations. As noted above, I consider that the original extension which was granted in September was sufficient to address any concerns in relation to the August period and any delays caused by mistakes. In light of this and my comments above in relation to any time that may have been taken in dealing with disclosure issues, I do not consider that the position of Pfizer is such as to take it even further beyond the usual timeframe for submitting its written representations set out in the guidance.

30. The issue of a Statement of Objections in an investigation satisfies the CMA's obligation under the CMA Rules to provide a notice which sets out:

> "the facts on which the CMA relies, the objections raised by the CMA, the action the CMA proposes and its reasons for the proposed action."[9]

It is a key point in any Competition Act investigation. It is only when a Statement of Objections is issued that the case which is being alleged by the CMA against any party is presented clearly and fully to each party concerned. It is therefore an essential procedural safeguard that ensures that a party's right to be heard is respected. As noted above, part of the rights of defence is for a party not only to be provided with such a document but also that the document is fit to enable the party to make its representations.

31. In this context, I note that although, as set out above, time was required for Pfizer's advisers to deal with the mistakes made in the original Statement, no concerns were raised as part of the Application that as a consequence of those mistakes, or more generally, Pfizer was unable to understand the case that was being made in the Statement and therefore not in a position to make written representations in response to that case.

32. I appreciate the points made during my meeting with Pfizer's legal advisers that in light of the nature of the allegations set out in the Statement, they would like to be in a position to be able to prepare a good response. This is however different from the question whether, in the circumstances, they have been allowed a reasonable time in order to ensure that Pfizer's views on the Statement can be put forward for the CMA's consideration. I consider that Pfizer has been allowed a reasonable time to do this in the circumstances and I have not been provided with clear and compelling reasons why Pfizer cannot provide written representations within the current deadline.

33. I have considered the points that have been raised by Pfizer in the Application in the context of Pfizer's own particular circumstances. I note Pfizer's argument in relation to fairness and equality of arms. As stated in the SRO's Decision on this point, I do not see any reasons why Pfizer should automatically be treated in the same way as Flynn in relation to any application for an extension of Flynn's time to submit written representations that may be allowed. I agree with the statement in the SRO's Decision that in circumstances where the context to, and reasons for, two requests differ, fairness and equality of arms does not dictate that any extension that might be provided to one party making such a request should also necessarily be provided to another.

Conclusion

34. In light of my observations set out above, and after considering the issues set out in the Application and the information I have been provided in the meetings I have held with Pfizer's legal advisers and with the CMA case team, I have not been persuaded that refusal of Pfizer's request for a three week extension to the existing

[9] Rule 6(1)(c), CMA Rules, see footnote 5 above.

time limit of 20 November 2015 for submission of its written representations would undermine Pfizer's ability to exercise its rights of defence. In particular I am satisfied that the existing deadline provided a reasonable time to enable Pfizer to respond to the Statement.

Decision

35. After careful consideration, in light of the reasons set out above, on 17 November I decided to dismiss the Application and communicated my decision to Pfizer and the CMA case team.

FRANCES BARR

PROCEDURAL OFFICER

27 NOVEMBER 2015