# Notice of intention to accept commitments offered by Essential Pharma in relation to the supply of Priadel

Case number 50951

24 November 2020

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# 1. Introduction

1.1. On 5 October 2020, the Competition and Markets Authority ('CMA') opened an investigation (the **'Investigation'**) into the supply of lithium carbonate medicines in the UK pursuant to its powers under the Competition Act 1998 (the '**Act'**).

1.2. On 23 November 2020, Essential Pharma Limited (Malta),[1] Essential Pharma Limited [2] and Essential Pharmaceuticals Limited[3] (together, **'Essential Pharma'**) offered Commitments to the CMA (as defined in Section 5 of this document and set out in Schedule 1), for the purpose of addressing the competition concerns arising from the conduct being investigated.

1.3. Specifically, the Commitments offered by Essential Pharma seek to address the CMA's competition concerns arising from a previous decision by Essential Pharma to withdraw a drug named Priadel in the UK, in circumstances where the potential alternative drugs for patients are more expensive and where the process of switching may result in significant harm to patients (the **'Conduct'**). The CMA is concerned that, while an agreement between the Department of Health and Social Care (**'DHSC'**) and Essential Pharma regarding an increased price of Priadel has been reached since the launch of the CMA's Investigation,[4] this agreement does not in itself remove the possibility of the drug being withdrawn in the future. This threat of withdrawal gives rise to the same competition concerns.

1.4. The CMA hereby gives notice that it proposes to accept the Commitments offered by Essential Pharma to address the competition concerns identified by the CMA in relation to the Conduct. The text of the proposed Commitments is summarised below and is set out in further detail in Schedule 1 to this Notice of Intention to Accept Commitments (the **'Notice'**). The CMA invites representations on the proposed Commitments, which will be considered before a final decision is made on whether to accept the proposed Commitments. Details of how to comment are provided at the end of this document. The closing date for comment is **9 December 2020 by 5pm.**

1.5. Formal acceptance of the proposed Commitments by the CMA would result in the termination of the Investigation, with no decision made as to whether or

[1] Registered office Vision Exchange Building Triq it-Territorjals, Zone 1, Central Business District, Birkirkara, CBD 1070 Malta.
[2] Registered office 7 Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RB, UK company number 07514667.
[3] Registered office 7 Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RB, UK company number 077449900.
[4] The CMA notes that Essential Pharma's position is that it was previously making losses on Priadel.

not the Conduct amounted to an infringement of UK and/or EU competition law.

1.6. Acceptance of the proposed Commitments would not prevent the CMA from continuing the Investigation, making an infringement decision, or giving a direction in circumstances where the CMA had reasonable grounds for:

- believing that there had been a material change of circumstances since the Commitments were accepted;
- suspecting that a person had failed to adhere to one or more of the terms of the Commitments; or
- suspecting that information which led the CMA to accept the Commitments was incomplete, false or misleading in a material particular.

1.7. This Notice provides information on the Investigation, the key characteristics of the supply of lithium carbonate medicines in the UK, and the competition concerns identified by the CMA as arising from the Conduct. It then summarises the Commitments offered by Essential Pharma and sets out why the CMA provisionally considers that the proposed Commitments address the competition concerns and that acceptance of commitments is appropriate in this case.

# 2. The CMA's investigation

## The Investigation

2.1. In June 2020, the DHSC approached the CMA in relation to the conduct of Essential Pharma in the supply of lithium carbonate medicines in the UK – specifically the planned withdrawal of Priadel by Essential Pharma. The CMA subsequently received a number of complaints from Clinical Commissioning Groups (**'CCGs'**), medical practitioners and community pharmacists.

2.2. On 5 October 2020, the CMA informed Essential Pharma that it had opened a formal investigation under the Act, having determined that it had reasonable grounds at that stage to suspect that Essential Pharma had infringed the provisions set out in Chapter II of the Act (the **'Chapter II prohibition'**) in relation to the supply of lithium carbonate medicines in the UK.[5]

2.3. In particular, the CMA took the decision that it had reasonable grounds for suspecting that Essential Pharma:

- holds a dominant position in the market for the supply of lithium carbonate medicines and/or in separate markets for the supply of Priadel and Camcolit branded or generic medicines in the UK; and
- has abused this dominant position as a result of a strategy to withdraw the supply of Priadel medicines in the UK, directly or indirectly imposing unfair prices for the supply of lithium carbonate medication and/or forcing patients to switch to an alternative product, despite the prejudice to patients arising from this and the increased cost to the NHS.

2.4. Prior to opening its formal investigation, the CMA received an application from the DHSC requesting that the CMA give interim measures directions to Essential Pharma under section 35 of the Act, for the purpose of preventing

[5] Section 18 of the Act prohibits any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market if it may affect trade within the United Kingdom. On 10 November 2020, the CMA notified Essential Pharma that it had reasonable grounds to suspect that the Conduct also infringes Article 102 of the Treaty on the Functioning of the European Union (**'Article 102 TFEU'**), which prohibits any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it in so far as it may affect trade between Member States. Under the European Union (Withdrawal Agreement) Act 2020, section 2(1) of the European Communities Act 1972 (under which EU law has effect in the UK's national law) is 'saved' until the end of the 'Transition Period'. This means that directly applicable EU law, including Articles 102 TFEU and Council Regulation (EC) No 1/2003 of 16 December 2002, continues to apply EU law in the UK during the Transition Period.

significant damage to patients and the NHS while the CMA completed the Investigation.[6]

2.5. The CMA gave serious consideration to the application; however, immediately after having been informed that the CMA had launched a formal investigation (and before the CMA had reached a decision on whether to propose interim measures directions), Essential Pharma informed the CMA and the DHSC that it would continue to supply Priadel in the UK, in order to facilitate discussions on pricing. This step by Essential Pharma removed the immediate threat to patients and the NHS, thereby rendering interim measures unnecessary.

2.6. In the course of the Investigation, the CMA took steps to gather evidence from Essential Pharma and third parties. These steps included sending formal notices requiring documents and information under section 26 of the Act to Essential Pharma, its parent company, the DHSC and the Medicines and Healthcare Products Regulatory Agency. Some third parties also submitted information voluntarily to the CMA.[7]

## The commitments offer

2.7. On 6 November 2020, following an agreement with the DHSC regarding increased pricing of Priadel, Essential Pharma submitted an intention to offer commitments to address the CMA's competition concerns under section 31A of the Act. This submission was made by Essential Pharma without prejudice to its position that it has not infringed the Chapter II Prohibition and/or Article 102 TFEU. Accordingly, and in line with paragraph 10.22 of the CMA's guidance on its investigation procedures under the Act (the **'Procedural Guidance'**),[8] the CMA proceeded to discuss with Essential Pharma the scope of commitments which the CMA considered would be necessary to address the concerns it had identified.

2.8. By way of background, section 31A of the Act provides that, for the purposes of addressing the competition concerns it has identified, the CMA may accept, from such person or persons concerned as it considers appropriate, commitments to take such action (or refrain from such action) as it considers

[6] The application from the DHSC was submitted on 2 October 2020. Under section 35 of the Act, the CMA can require a business to comply with temporary directions (interim measures) where: (i) the investigation has been started but not yet concluded; and (ii) the CMA considers it necessary to act urgently either to prevent significant damage to a person or category of persons, or to protect the public interest. In giving interim measures directions, the CMA can act on its own initiative or in response to a request to do so.

[7] In addition to receiving voluntary submissions from the DHSC prior to the investigation launching, the CMA also received submissions from clinicians.

[8] *Revised Guidance on the CMA's investigation procedures in Competition Act 1998 cases (Revised CMA8, November 2020).*

appropriate. The Procedural Guidance describes the circumstances in which it may be appropriate to accept commitments and the process by which parties to an investigation may offer commitments to the CMA.

2.9. In accordance with paragraph 10.21 of the Procedural Guidance, a business under investigation may offer commitments at any time during the course of the investigation until a decision on infringement is made. In this case, no decision on infringement has yet been made.

2.10. The Commitments being offered to the CMA by Essential Pharma are set out in Schedule 1. The offering of commitments does not constitute an admission by Essential Pharma of an infringement of the Chapter II Prohibition and/or of Article 102 TFEU.

2.11. Having considered Essential Pharma's proposed Commitments, the CMA is currently of the provisional view that these address its competition concerns, for the reasons set out in this Notice. Formal acceptance of the proposed Commitments would result in the CMA terminating its investigation and not proceeding to a decision on whether or not the Chapter II Prohibition and/or Article 102 TFEU have been infringed.

## The party and the products under investigation

2.12. Essential Pharma Limited (UK) (**'Essential Pharma UK'**) is a private limited company incorporated in England and Wales. Its reported revenue for the year ending on 31 March 2019 was £23.3 million. In 2014, Essential Pharma UK acquired the UK marketing authorisation rights in respect of Camcolit 250mg tablets (renamed as Lithium Carbonate Essential Pharma 250 mg film-coated tablets in 2015) and Camcolit 400mg Controlled Release Lithium Carbonate tablets.

2.13. Essential Pharma Limited (Malta) (**'Essential Pharma Malta'**) is a company incorporated in Malta. Its reported revenue for the seven-month period following incorporate in May 2018 and ending on 31 December 2018 was EUR1.9 million. In July 2018, Essential Pharma Malta acquired the product Priadel from Sanofi S.A. and its group companies, including the intellectual property rights and UK marketing authorisation for Priadel.

2.14. Priadel and Camcolit are branded drugs and subject to price regulation in the UK. Specifically, Priadel and Camcolit are drugs included in the voluntary pricing scheme set up pursuant to section 261 of the National Health Service Act 2006 (the 2019 Voluntary Scheme or **'2019 VS'**). Under the 2019 VS, a supplier has freedom, within certain parameters, to set the list price of a new

drug.[9] Once the list price is set, the 2019 VS prevents the supplier from increasing the price except in very limited circumstances.[10,11]

[9] It is assumed however that prices at launch will be set at a level that is close to their expected value as assessed by the National Institute for Health and Care Excellence (**'NICE'**). NICE assesses the clinical and cost effectiveness of most new medicines launched in the UK market. *The Pharmaceutical Price Regulation Scheme 2014*, Department of Health and Association of the British Pharmaceutical Industry, December 2013, paragraph 7.14.

[10] Specifically, the DHSC will not approve a list price increase unless a supplier's estimated and forecast profits on its portfolio of drugs falling within the scope of the 2019 VS are below 50% of the relevant Return on Sales target or Return on Capital target (i.e. 6% and 21% respectively). A price increase above these levels may only be agreed by the DHSC in exceptional circumstances (see *The 2019 Voluntary Scheme for Branded Medicines Pricing and Access,* Department of Health and Association of the British Pharmaceutical Industry, paragraphs 5.20 – 5.21 and paragraph 5.24). To increase its price, the 2019 VS member can apply to the DHSC for approval to increase a price. The CMA understands it is very rare for a 2019 VS member to seek individual price increases.

[11] In the case of Priadel, any request for a price increase of Priadel is based on Priadel estimated and forecast profits alone. The CMA understands this is because the entity supplying Priadel does not supply any other branded drug in the UK.

# 3. Background

3.1. This section sets out the CMA's preliminary view of:

- the most plausible definition or definitions of the relevant market(s) for the supply of lithium-based medicines that may be prescribed for the treatment of bipolar disorder in the UK;
- Essential Pharma's position in the relevant market; and
- Essential Pharma's conduct in the relevant market.

3.2. The purpose of this section is to provide context for Section 4, which describes the CMA's assessment of competition concerns.

## The relevant market(s)

3.3. The CMA has given preliminary consideration to the most plausible definition or definitions of the relevant markets for the supply of lithium-based medicines that may be prescribed for the treatment of bipolar disorder.

3.4. The available treatments are based on the lithium molecule, either as a tablet (lithium carbonate) or as a liquid (lithium citrate). The CMA has considered the substitutability of:

- lithium carbonate and citrate medicines; and
- different lithium carbonate medicines.

3.5. The CMA understands that lithium citrate (i.e. the liquid formulation) is generally only prescribed to patients who are unable to swallow lithium carbonate tablets. The CMA also understands that it is particularly difficult to switch patients between lithium carbonate and lithium citrate medicines because different release properties make it difficult to calculate equivalent dosages, which could result in toxic or sub-therapeutic dosages being prescribed.[12]

3.6. There are currently four lithium carbonate medicines (i.e. tablets) supplied in the UK, with varying dosages. The table below sets out (as at October 2020) the different presentations for these medicines, their manufacturer, the estimated number of patients using each medicine, the number of prescriptions for each medicine, the share of supply this represents, the price of each presentation and their formulation.

[12] NHS England and NHS Improvement response to a CMA section 26 notice, dated 22 September 2020.

**Table 1 – Lithium carbonate medicines supplied in the UK**[13]

| Brand name | Manufacturer | Estimated number of patients | Number of prescriptions between June 2019 and May 2020 | Share | Price (per 100 tablets) | Formulation |
|---|---|---|---|---|---|---|
| Priadel 200mg | Essential Pharma Limited (Malta) | 50,000 | 757,323 | 96.6% (86% of patients) | £2.76 | Modified release |
| Priadel 400mg | Essential Pharma Limited (Malta) | | | | £4.02 | Modified release |
| Camcolit 400mg | Essential Pharmaceuticals Limited (UK) | 7,000 | 11,519 | 3% (12% of patients) | £48.18 | Modified release |
| Lithium Carbonate Essential Pharma 250mg film-coated tablets (a generic version of Camcolit) | Essential Pharmaceuticals Limited (UK) | | 11,586 | | £87[14] | Immediate release |
| Liskonum 450mg | Teofarma | <1,000 | 3,170 | 0.4% | £11.64 (per 60 tablets)[15] | Modified release |

3.7. Although the CMA has not reached any conclusions as to relevant market definition, the CMA's preliminary view is that there is limited substitutability between lithium carbonate medicines and each product forms a separate relevant market. However, even if these products were to be considered in the same relevant market, the relevant product market would be no wider than the supply of lithium carbonate medicines in the UK.

3.8. This is because the therapeutic window of lithium-based medicines is very narrow (meaning that the line between beneficial and toxic blood levels is small). Existing clinical guidance[16] states that prescription of lithium-based medicines should be by brand and patients who are managed on a particular brand must be maintained on it.

3.9. The CMA understands that this is because the dosage of each drug is different (except for Priadel 400mg and Camcolit 400mg) and because, once a patient is stabilised on a specific lithium carbonate medicine product, there

[13] Based on information submitted to the CMA by the DHSC, NHS and complainants during the course of the CMA's investigation.

[14] Part VIIIA, September 2020 Drug Tariff.

[15] Part VIIIA, September 2020 Drug Tariff.

[16] The British National Formulary, https://bnf.nice.org.uk/drug/lithium-carbonate.html. NHS and Speciality Pharmacy Service guidance on brand-name prescribing, available at: https://www.sps.nhs.uk/wp-content/uploads/2017/12/UKMi_QA_Brand-name_prescribing_Update_Nov2017.pdf. The second document refers to lithium as an example of a medicine that should be prescribed by brand. It states prescribing by brand should be: "*Where there is a difference in bioavailability between brands of the same medicine, particularly if the medicine has a narrow therapeutic index. In these circumstances, lack of clarity over which preparation is intended when prescribing can lead to the patient receiving a sub-therapeutic or toxic dose*."

are risks in using another product due to different characteristics, such as the speed of release.[17]

3.10. In line with its previous decisions relating to the supply of medicines, the CMA's preliminary view is that the relevant geographic market is the UK.

3.11. The CMA's preliminary view is that each lithium carbonate medicine product forms a separate relevant market, but even if these products were to be considered in the same relevant market, the relevant product market would be no wider than the supply of lithium carbonate medicine.

## Essential Pharma's position on the relevant market

3.12. The CMA considers that the following factors are indications that Essential Pharma is likely to hold a dominant position in relation to the supply of both Priadel and Camcolit:

- Existing clinical guidance advises that lithium-based medicines are prescribed by brand;[18]
- Priadel and Camcolit are long-term medications and patients who are stabilised on these medicines do not typically switch to alternatives (because of the above clinical guidance);
- Essential Pharma has very high market shares (close to 100% even when including all forms of lithium carbonate medicine); and
- Essential Pharma's products (Priadel and Camcolit) appear to be the other's closest substitute, as they are the closest of the lithium carbonate medicines in terms of dosage and release characteristics, compared to Liskonum.[19]

3.13. The significant level of public concern raised when Essential Pharma issued a discontinuation notice in relation to Priadel in April 2020 indicates that there may be a compelling clinical need for the DHSC to ensure that supply of Priadel in the UK is not disrupted. This is further evidence of the strength of Essential

[17] NHS England and NHS Improvement response to a CMA section 26 notice, dated 22 September 2020. The NHS and Speciality Pharmacy Service guidance on brand-name prescribing also states: "Lithium has a narrow therapeutic index and preparations vary widely in bioavailability". See footnote 16 above.
[18] NHS and Speciality Pharmacy Service guidance on brand-name prescribing – see footnote 16 above.
[19] The NHS England and NHS Improvement response to a CMA section 26 notice, dated 22 September 2020 referred to limited data regarding the pharmacokinetic properties of different lithium carbonate medicines.

Pharma's market power, and therefore indicative that may have a dominant position. In particular:

- Significant clinical concerns were raised as regards risks to patients as a result of having to switch to other lithium-based medicines.[20] The key concern around patient health appears to be the uncertainty about how some patients may react to switching, as the exact therapeutic equivalence of Priadel and Camcolit is unknown.

- The CMA understands that, although it is possible to switch a patient to another lithium-based medicine and stabilise them on that product, such a process must be managed very carefully. In submissions to the CMA, the DHSC noted the implications for NHS resources that would arise as a result of the need to support this switching process. For example, the DHSC's Supply Disruption Alert issued on 21 August 2020 stated that all patients being switched to an alternative lithium formulation should have individualised management plans. This would require appointments with GPs to discuss alternatives, pre-switch blood tests to establish a baseline serum lithium level, post-switch blood testing every 5 to 7 days until the patient was stabilised, careful monitoring of the patient's mental and clinical condition and additional monitoring if a patient was taking other medications.

3.14. It is also relevant to note that if Priadel were to be discontinued, initial evidence suggests that most practitioners would prescribe Camcolit 400mg to patients as the closest alternative in terms of dosage and release characteristics. This would also have given rise to an increase in annual costs to the NHS to procure lithium-based medicines, based on the price differential between Priadel and Camcolit.

## Essential Pharma's conduct in the relevant market(s)

3.15. On 6 April 2020, Essential Pharma notified the DHSC that it was intending to discontinue the supply of Priadel from October 2020,[21] arguing that the list price of Priadel was below the costs of supplying the product. The DHSC sought to secure continuation of supply by engaging in price negotiations with

[20] The CMA has received complaints from various NHS bodies, doctors and community pharmacists highlighting the potential risks to patient safety. For example, concerns were raised by key stakeholders in a letter to Matt Hancock on 15 September 2020: "*Lithium is an essential medication recommended by NICE guidance; it is proven to treat bipolar disorder and to prevent suicide. If it is stopped suddenly there is a significant risk of rebound relapse. If levels become toxic, it can cause permanent kidney damage and can be fatal.*" https://www.rpharms.com/Portals/0/Lithium%20Concerns_letter_Matt_Hancock_final_approved_version.pdf?ver=2020-09-15-123448-710

[21] Pursuant to regulation 29 of The Health Services Products (Provision and Disclosure of Information) Regulations, a supplier is required to inform the DHSC of a planned discontinuation six month before any anticipated impact on any patient.

Essential Pharma. These attempts were unsuccessful, although Essential Pharma offered to extend the remaining period of supply of Priadel to April 2021.

# 4. The CMA's competition concerns

4.1. The CMA is concerned that, through its conduct earlier in 2020, Essential Pharma may have sought to exploit a suspected dominant position in relation to Priadel and/or Camcolit by withdrawing the supply of Priadel with a view to imposing unjustifiably high prices for its supplies of lithium carbonate medicines in the UK (either by securing a price increase for Priadel or by causing the switch of large numbers of patients to the significantly more expensive Camcolit, despite the DHSC's concerns regarding risks to patients[22]).

4.2. In particular, Essential Pharma submitted a discontinuation notice for Priadel in the UK on the basis it was making losses for Essential Pharma, notwithstanding: (i) the DHSC's view that there was a compelling clinical need for the DHSC to ensure that supply of Priadel in the UK was not disrupted; (ii) the significant concerns being raised by the DHSC and medical practitioners regarding patient welfare; and (iii) the material financial and administrative implications for the NHS of having to switch large numbers of patients.

4.3. Further, and as noted above, it seems likely that most practitioners would have prescribed Camcolit 400mg to patients as the closest alternative in terms of dosage and release characteristics.[23] Therefore, it is also clear that Essential Pharma would have benefitted from a switch of patients from Priadel to Camcolit, because, in the UK, Camcolit is significantly more expensive than Priadel.

4.4. Notwithstanding that a price for Priadel has now been agreed, this agreement does not in itself remove the possibility of the drug being withdrawn in the future, giving rise to the same concerns; that is, a switching of patients to Camcolit (with the associated risks to patients and increased costs) or putting pressure on the DHSC to agree to an unjustified and unfair price increase.

4.5. If the threat of the withdrawal of Priadel were to be removed, it is likely that in the future the DHSC would be in a better position to resist any unsubstantiated requests to increase the price for Priadel, over and above the price agreed with the DHSC under the terms of the 2019 VS on 5 November 2020.

[22] In 2015, the DHSC agreed under the statutory scheme a significant price increase for Camcolit, from £4.30 to £48.18 for 100 tablets, i.e. an increase of 1020%. This price increase was agreed at a time when only small volumes of Camcolit were supplied in the UK. Around the same time, Essential Pharma increased the list price of the generic version of Camcolit from £3.22 to £87 for 100 tablets, i.e. an increase of 2602%.
[23] Response from NHS England and NHS Improvement to a notice from the CMA under section 26 CA98, referred to at FN 19 above. This point also appears to be supported by the CMA's review of certain internal documents provided Essential Pharma in response to requests for information from the CMA.

# 5. The Commitments offered by Essential Pharma

5.1. In order to address the CMA's competition concerns (as described in Section 4), and without prejudice to its position that it has not infringed the Chapter II Prohibition nor Article 102 TFEU by the Conduct, Essential Pharma has offered formal commitments to the CMA relating to that conduct, as set out in further detail in Schedule 1 to this Notice and summarised below (the **'Commitments'**).

## Essential Pharma's proposed Commitments

5.2. Essential Pharma has proposed the following Commitments to be in force for a period of 5 years, from the date of their acceptance by the CMA.

5.3. Essential Pharma has offered to:

- continue to ensure appropriate and continued supplies of Priadel to the UK on terms agreed from time to time with the DHSC; and
- not serve a discontinuation notice to the DHSC relating to Priadel.

5.4. Essential Pharma has also offered to ensure that the potential divestment of, or grant of a licensing agreement in relation to, the supply of Priadel in the UK does not affect the application of the proposed Commitments. In particular, any such divestment or licensing shall be made on terms that ensure that Priadel continues to be supplied in the UK until the end of the period of 5 years from the acceptance of the proposed Commitments.

5.5. In order for the CMA to effectively monitor Essential Pharma's compliance with the proposed Commitments, Essential Pharma will:

- Provide information and documents as requested by the CMA for the purpose of monitoring the proposed Commitments;
- Promptly notify the CMA of any intention to divest itself of Priadel and/or Camcolit; and
- Maintain and produce any records that the CMA may specify in writing that relate to the operation of the proposed Commitments.

# 6. The CMA's assessment of the proposed Commitments

6.1. For the reasons set out below, the CMA has reached the provisional view that its competition concerns would be addressed by the proposed Commitments, once implemented. Formal acceptance of the proposed Commitments would result in the CMA terminating the Investigation and not proceeding to a decision on whether the Chapter II Prohibition and/or of Article 102 TFEU has been infringed.

6.2. A decision by the CMA accepting commitments will not include any statement as to whether Essential Pharma infringed competition law.

## The CMA's Guidance

6.3. Pursuant to section 31A of the Act, for the purposes of addressing the competition concerns it has identified, the CMA may accept from such person (or persons) concerned as it considers appropriate, commitments to take such action (or refrain from taking such action) as it considers appropriate.

6.4. The Procedural Guidance states that the CMA is likely to consider it appropriate to accept commitments only in cases where: (a) the competition concerns are readily identifiable; (b) the competition concerns are addressed by the commitments offered; and (c) the proposed commitments are capable of being implemented effectively and, if necessary, within a short period of time.[24]

6.5. However, the CMA will not accept commitments where compliance with such commitments and their effectiveness would be difficult to discern or where the CMA considers that not to complete the relevant aspect of its investigation and make a decision would undermine deterrence.[25]

## The CMA's assessment

6.6. As explained in Section 4 above, the Conduct has given rise to competition concerns that Essential Pharma may threaten to withdraw Priadel in the future with a view to imposing unjustifiably high prices, notwithstanding the clinical need for that product and the risks to patients and to the NHS that would arise from that discontinuation of supply.

6.7. The CMA has reached the provisional view that the proposed Commitments, once implemented, would address its competition concerns. The proposed

[24] Revised CMA8, November 2020, paragraph 10.18.
[25] Revised CMA8, November 2020, paragraph 10.20.

Commitments will ensure that, for a period of 5 years, Essential Pharma will continue to supply the UK market with Priadel on terms agreed from time to time with the DHSC and will not serve a discontinuance notice to the DHSC relating to Priadel.

6.8. The CMA considers that, absent any threat by Essential Pharma to withdraw Priadel, it is likely that the DHSC will be in a better position to resist any unsubstantiated requests to increase prices. Moreover, patients will have security of supply for at least 5 years.

6.9. The proposed Commitments contain specific provisions to ensure that their purpose cannot be frustrated as a result of the divestment of Priadel to a third party and to ensure that Essential Pharma will not take any other action to circumvent any of the proposed Commitments.

6.10. Essential Pharma has undertaken to act in accordance with the proposed Commitments from the date of their acceptance by the CMA. The proposed Commitments involve Essential Pharma refraining from taking certain actions, and as such, they do not require any specific positive action to be taken and are capable of being implemented effectively with immediate effect.

6.11. Given the straightforward nature of the proposed Commitments, compliance will not be difficult to discern. The DHSC will also be able to inform the CMA if there are issues relating to compliance with the Commitments.

6.12. The CMA considers that accepting the proposed Commitments will have a positive impact on deterrence. The rapid change to Essential Pharma's conduct and business strategy in reversing its decision to withdraw Priadel and committing to maintain supply for 5 years to address the CMA's concerns will send a strong signal to other businesses, deterring them from engaging in practices which may be anti-competitive.

6.13. The CMA also notes that by accepting the proposed Commitments early on in its Investigation, it is able to resolve its competition concerns quickly, giving welcome certainty to the NHS and patients.

6.14. Accepting the proposed Commitments would not preclude the CMA taking further enforcement action in relation to other suspected breaches of competition law concerning the supply of lithium carbonate medicines in the UK, or related markets, that raise competition concerns and may harm consumers.

6.15. In the light of the above, the CMA considers that this is an appropriate scenario in which to accept commitments from Essential Pharma and

provisionally considers that the proposed Commitments address its competition concerns.

# 7. The CMA's intentions and invitation to comment

## The CMA's intentions

7.1. For the reasons set out above, the CMA provisionally considers that the Commitments offered by Essential Pharma, as set out in Schedule 1 to this Notice, are sufficient to address the competition concerns identified by the CMA. Therefore, the CMA proposes to accept the Commitments offered by Essential Pharma by means of a formal commitments decision.

7.2. As required by paragraph 2(2)(d) of Schedule 6A of the Act, the CMA now invites interested third parties to make representations on the Commitments offered by Essential Pharma and will take such representations into account before making a final decision on whether to accept commitments.

## Invitation to comment

7.3. Any person wishing to comment on the proposed Commitments should submit written representations to the email address given below, by **9 December 2020 by 5pm**. Please quote the case reference 50951 in all correspondence related to this matter.

Emails:

Elizabeth.Sinclair@cma.gov.uk

Sadrul.Islam@cma.gov.uk

# Schedule 1: The Commitments offered by Essential Pharma

## 1. INTRODUCTION

1.1 On 5 October 2020, the CMA commenced an investigation under section 25 of the Act in relation to the supply of lithium-based medication for the treatment of bipolar disease.

1.2 In order to address the CMA's competition concerns, Essential Pharma hereby offers Commitments under section 31A of the Act.

1.3 Consistent with sections 31A and 31B of the Act, the Commitments are offered on the basis that if the CMA accepts the Commitments in accordance with section 31A(2) of the Act, it shall not continue the investigation, make a decision within the meaning of section 31(2) of the Act, or give a direction under section 35 of the Act.

1.4 The offering of the Commitments by Essential Pharma does not constitute an admission of any wrongdoing by it and nothing in these Commitments may be construed as implying that Essential Pharma agrees with any concerns identified by the CMA in its investigation, including in a Commitments Decision. Essential Pharma has not been the subject of any infringement decision or statement of objections in respect of the investigation.

## 2. DEFINITIONS

2.1 For the purposes of these Commitments the following definitions apply:

"**Act**" means the Competition Act 1998;

"**CMA**" means the Competition and Markets Authority;

"**Commitments**" means the commitments given by Essential Pharma hereunder pursuant to section 31A of the Act;

"**Commitments Decision**" means a formal decision by the CMA under section 31A of the Act to accept these Commitments, such that section 31B of the Act applies;

"**DHSC**" means the Department of Health and Social Care;

"**Effective Date**" means the date on which Essential Pharma receives formal notification of a Commitments Decision;

"**Essential Pharma**" means Essential Pharma Limited (Malta), Essential Pharma Limited and Essential Pharmaceuticals Limited;

**"Essential Pharma Corporate Group"** means the group of interconnected bodies (within the meaning of section 129(2) of the Enterprise Act 2002) that

includes Essential Pharma; references to Essential Pharma Corporate Group shall be to the group of interconnected bodies including Essential Pharma as constituted from time to time; and

"**Priadel**" means Priadel 200mg and 400mg tablets.

## 3. THE COMMITMENTS

3.1 For the period specified in 3.5 below, Essential Pharma undertakes as follows:

3.1.1 to ensure appropriate and continued supplies of Priadel to meet the needs of patients in the UK, on terms agreed from time to time with DHSC;

3.1.2 not to serve a discontinuance notice to the DHSC relating to Priadel; and

3.1.3 to refrain from practices which:

(a) have the effect that the number of tablets of Priadel commercialised in the UK is limited or reduced to a level that would not meet the needs of patients in the UK; or

(b) may cause the UK marketing authorisation in respect of Priadel to be withdrawn, revoked, suspended or varied,

subject to the following:

3.1.4 in respect of 3.1.1, 3.1.2, and 3.1.3(a), the marketing authorisation in respect of Priadel not having been revoked, suspended or varied through the imposition of conditions by a relevant licensing authority;

3.1.5 in respect of 3.1.1 and 3.1.3(a), the sufficient availability from contract manufacturers of product which meets the requirements of the UK marketing authorisation for Priadel;

3.1.6 in respect of 3.1.2, the availability from contract manufacturers of product which meets the requirements of the UK marketing authorisation for Priadel; and

3.1.7 nothing in 3.1.3(b) shall prevent Essential Pharma from undertaking any activities to comply with its regulatory obligations as a marketing authorisation holder nor shall it prevent Essential Pharma from undertaking activities in relation to a change of ownership of the marketing authorisation for the purposes of divesting or licensing Priadel in accordance with 3.3.

3.2 Essential Pharma shall not in any way circumvent, by actions or omissions, any of the Commitments, including, but not limited to, by selling, assigning or otherwise transferring any part of its business relating to the supply of Priadel to any other entity within the Essential Pharma Corporate Group as a result of which that entity would do anything that is prohibited by these Commitments.

3.3 During the period that the Commitments remain in force, Essential Pharma will not be prevented by the Commitments from licensing or divesting itself of Priadel in the UK, including the intellectual property rights and UK marketing authorisation for Priadel. Should Essential Pharma elect to grant such a licence or make such a divestment it will ensure that:

3.3.1 the rights to supply Priadel in the UK are transferred to the third party on terms determined by Essential Pharma acting in good faith and in a manner that does not circumvent or attempt to circumvent the Commitments;

3.3.2 any licensor, purchaser, assignee or transferee of Priadel in the UK is contractually bound to abide by the Commitments until the end of the period specified at 3.5 below; and

3.3.3 the rights to supply both Priadel and Camcolit are not both acquired, licensed, assigned or otherwise transferred to the same third party undertaking unless Essential Pharma's obligation to comply with the Commitments is transferred to that undertaking by way of an assignment or other contractual mechanism. Essential Pharma shall ensure that the effect of such transfer is that, unless that third party undertaking has a reasonable excuse for the default, the CMA will be able to seek to take enforcement action in court against any default by that undertaking of the Commitments (including by applying for leave to seek an order from a court requiring the undertaking to make good on such default within the time specified in such order). Prior to entering into such transfer, Essential Pharma will seek confirmation from the CMA that the proposed contractual mechanism achieves the aims of this paragraph (such confirmation not to be unreasonably withheld or delayed).

3.4 For the avoidance of doubt, nothing in 3 prevents the divestment of shares in any entity within the Essential Pharma Corporate Group (including the marketing authorisation holders of Priadel and Camcolit) by the shareholder/s of such entity.

3.5 The Commitments set out at 3.1, 3.2 and 3.3 shall remain in force for a period of five (5) years from the Effective Date.

## 4. VARIATION, RELEASE AND SUPERSESSION

4.1 Without prejudice to the generality of section 31A(4)(b) of the Act, Essential Pharma may request that the CMA review the Commitments with a view to varying, releasing or superseding the Commitments including (without prejudice to the generality of Essential Pharma's right to make such a request) where (a) the availability of Priadel from contract manufacturers is constrained or (b) Essential Pharma's costs have increased, but the DHSC has declined to allow a supply price increase in accordance with the procedures under the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (or any successor scheme) having taken into account such increased costs.

4.2 In the event that Essential Pharma requests to vary, release or supersede these Commitments, the CMA will respond in writing as soon as is reasonably practicable having regard to the nature of the request, the aim of these Commitments and to its statutory duties. The CMA shall accept all such requests where it considers it appropriate to do so.

4.3 The variation, release or supersession of these Commitments shall not affect the validity and enforceability of any rights or obligations that arose prior to such variation, release or supersession.

## 5. REPORTING AND COMPLIANCE

5.1 Essential Pharma:

5.1.1 will provide to the CMA any information and documents which the CMA reasonably requires for the purposes of enabling the CMA to monitor and review the operation of the Commitments or any provisions of the Commitments;

5.1.2 will promptly notify the CMA, by email at RemediesMonitoringTeam@cma.gov.uk, of any intention to divest itself of Priadel or Camcolit (or both) in the UK; and

5.1.3 may be required by the CMA to keep, maintain and produce those records specified in writing by the CMA that relate to the operation of any provision of the Commitments.

5.2 The obligations at 5.1 shall apply for the period that these Commitments are in force.

## 6. EFFECT OF INVALIDITY

6.1 Should any provision of these Commitments be contrary to law or invalid for any reason, Essential Pharma shall continue to observe the remaining provisions.

## 7. GOVERNING LAW

7.1 The Commitments shall be governed by and construed in all respects in accordance with English law.

7.2 Disputes arising concerning the Commitments shall be subject to the exclusive jurisdiction of the courts of England and Wales.

SIGNED on behalf of Essential Pharma