

Decision to accept commitments offered by Essential Pharma in relation to the supply of Priadel

Case number 50951

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1. Introduction

- 1.1. In this decision (the '**Decision**') made under section 31A of the Competition Act 1998 (the '**Act**'), the Competition and Markets Authority (the '**CMA**') accepts the commitments offered by Essential Pharma Limited (Malta),¹ Essential Pharma Limited² and Essential Pharmaceuticals Limited³ (together, '**Essential Pharma**')⁴ as set out in the Schedule 1 to the Decision (the '**Commitments**').
- 1.2. Essential Pharma offered the Commitments to the CMA in the context of its investigation into suspected anticompetitive conduct in the supply of lithium carbonate medicines in the UK. Specifically, the Commitments 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**'). In particular, the CMA has concerns 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since the launch of the CMA's investigation,⁵ this agreement did not in itself remove the possibility of the drug being withdrawn in the future. The threat of withdrawal by Essential Pharma in the future therefore continues to give rise to the same competition concerns.
- 1.3. As a result of accepting the Commitments, the CMA will discontinue its investigation into whether or not Essential Pharma has infringed the prohibition in section 18 of the Act (the '**Chapter II prohibition**') and/or Article 102 of the Treaty on the Functioning of the European Union (the '**TFEU**').⁶ The CMA has made no final decision as to whether or not the Conduct amounted to an infringement of the Chapter II prohibition and/or Article 102 TFEU.

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⁴ Each of Essential Pharma Limited (Malta), Essential Pharma Limited and Essential Pharmaceuticals Limited are part of the same corporate group. They are under the control of the same parent company and form a single economic unit or undertaking.

⁵ The CMA notes that Essential Pharma's position is that it was previously making losses on Priadel.

⁶ 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. Article 102 TFEU 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.

1.4. Acceptance of the Commitments does not prevent the CMA from continuing its investigation, making an infringement decision, or giving a direction in circumstances where the CMA has 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.⁷

1.5. The remainder of this Decision is structured as follows:

- Chapter 2 sets out details of the CMA's investigation and the undertaking under investigation;
- Chapter 3 sets out background, including the key characteristics of the market and Essential Pharma's position in that market;
- Chapter 4 sets out the CMA's competition concerns arising from the Conduct;
- Chapter 5 summarises the Commitments offered by Essential Pharma;
- Chapter 6 sets out the CMA's assessment of the Commitments and of the representations submitted in response to the CMA's notice of intention to accept commitments published on 24 November 2020;
- Chapter 7 sets out the CMA's decision to accept the Commitments.

⁷ Section 31B(4) of the Act.

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, 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 to suspect that Essential Pharma had infringed the Chapter II prohibition in relation to the supply of lithium carbonate medicines in the UK. During the course of its investigation, the CMA also informed Essential Pharma that it had reasonable grounds to suspect that Essential Pharma had infringed Article 102 TFEU.
- 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
 - had 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 significant damage to patients and the NHS while the CMA completed its investigation.⁸
- 2.5. The CMA gave serious consideration to the application; however, immediately after having been informed that the CMA had launched a formal investigation

⁸ 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) an investigation has been started under section 25 of the Act 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.

(and before the CMA had reached a provisional decision on whether to impose 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 of significant damage 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.⁹

The commitments offer and consultation process

- 2.7. On 6 November 2020, following an agreement with the DHSC regarding increased pricing of Priadel, Essential Pharma submitted a proposal to offer commitments to address the CMA's competition concerns under section 31A of the Act. Following discussions with the CMA, Essential Pharma revised its proposal and formally offered commitments to the CMA on 23 November 2020. These submissions were made by Essential Pharma without prejudice to its position that it has not infringed the Chapter II prohibition and/or Article 102 TFEU.
- 2.8. On 24 November 2020, the CMA issued a notice setting out Essential Pharma's proposed commitments and the reasons why the CMA proposed to accept them. The CMA also invited parties likely to be affected by the proposed commitments to make representations on them.
- 2.9. The consultation period ran from 24 November 2020 to 9 December 2020. The CMA received responses from six interested parties. The consultation responses and the CMA's consideration of them are summarised in Chapter 6. Following the consultation, the CMA discussed minor modifications to the proposed commitments with Essential Pharma, mainly in relation to Essential Pharma's reporting and compliance obligations (clause 5.1 of the Commitments). In light of these discussions, Essential Pharma submitted slightly amended Commitments on 15 December 2020. The CMA did not consult interested parties on these modifications as it does not consider that they amount to a material modification of the Commitments for the purposes of paragraph 5 of Schedule 6A to the Act. A document showing the

⁹ In addition to receiving voluntary submissions from the DHSC prior to the investigation launching, the CMA also received submissions from clinicians.

modifications made to the Commitments is included at Schedule 2 to this Decision.

- 2.10. The CMA has given full consideration to all the relevant material in its possession, including the representations received following the CMA's notice of intention to accept commitments, and considers that, for the reasons set out in Chapter 6 of this Decision, the Commitments address its competition concerns in this case. The CMA has therefore decided to accept the Commitments in the form set out in Schedule 1 to this Decision.

The party and the products under investigation

- 2.11. Essential Pharma Limited (**'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.
- 2.12. Essential Pharma Limited (Malta) (**'Essential Pharma Malta'**) is a company incorporated in Malta. Its reported revenue for the seven-month period following incorporation 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.
- 2.13. 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.¹⁰ Once the list price is set, the 2019 VS prevents the supplier from

¹⁰ 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.

increasing the price except in very limited circumstances.^{11,12}

¹¹ 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.

¹² 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 chapter sets out the preliminary view taken by the CMA on the following:

- 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(s); and
- Essential Pharma's conduct in the relevant market(s).

3.2. The purpose of this chapter is to provide context for Chapter 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 have difficulty swallowing 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.¹³

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.

¹³ NHS England and NHS Improvement response to a CMA section 26 notice, dated 22 September 2020.

Table 1 – Lithium carbonate medicines supplied in the UK¹⁴

Brand name	Manufacturer	Estimated number of patients	Number of prescriptions between June 2019 and May 2020	Share of patients	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 ¹⁵	Immediate release
Liskonum 450mg	Teofarma	<1,000	3,170	0.4%	£11.64 (per 60 tablets) ¹⁶	Modified release

3.7. Although the CMA has not reached any conclusions as to relevant product 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.

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 guidance¹⁷ 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

¹⁴ Based on information submitted to the CMA by the DHSC, NHS and complainants during the course of the CMA’s investigation.

¹⁵ Part VIIIA, September 2020 Drug Tariff.

¹⁶ Part VIIIA, September 2020 Drug Tariff.

¹⁷ The British National Formulary reference for Lithium Carbonate, available at <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.”

a patient is stabilised on a specific lithium carbonate medicine product, there are risks in using another product due to different characteristics, such as the speed of release.¹⁸

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.

Essential Pharma's position on the relevant market

3.11. 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;¹⁹
- 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.²⁰

3.12. 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 Pharma's market power, and therefore indicative that it 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.²¹ The key

¹⁸ 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 17 above.

¹⁹ NHS and Speciality Pharmacy Service guidance on brand-name prescribing – see footnote 17 above.

²⁰ 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.

²¹ 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

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.

3.13. 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)

3.14. On 6 April 2020, Essential Pharma notified the DHSC that it was intending to discontinue the supply of Priadel from October 2020,²² 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 Essential Pharma. These attempts were unsuccessful, although Essential Pharma offered to extend the remaining period of supply of Priadel to April 2021.

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

²² 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 months before any anticipated impact on any patient.

4. The CMA's competition concerns

- 4.1. The CMA's competition concerns arise from the previous decision by Essential Pharma to withdraw Priadel in the UK. Specifically, the CMA is concerned that 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).²³
- 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.²⁴ 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 for Priadel.
- 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

²³ 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%.

²⁴ Response from NHS England and NHS Improvement to a notice from the CMA under section 26 of the Act, dated 22 September 2020. 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.

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.

5. The Commitments

- 5.1. In order to address the CMA's competition concerns as regards the Conduct (as described in Chapter 4), and without prejudice to its position that it has not infringed the Chapter II prohibition or Article 102 TFEU by the Conduct, Essential Pharma has offered formal commitments to the CMA, as set out in further detail in Schedule 1 to this Decision and summarised below.
- 5.2. Essential Pharma has proposed that the Commitments be in force for a period of 5 years, from the date of their acceptance by the CMA.
- 5.3. For that period, 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 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 Commitments.
- 5.5. In order for the CMA to effectively monitor Essential Pharma's compliance with the Commitments, Essential Pharma will:
 - provide information and documents as requested by the CMA for the purpose of monitoring the Commitments;
 - provide a signed annual compliance statement;
 - promptly notify the CMA of any breaches of the 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 Commitments.

6. The CMA's assessment of the Commitments

- 6.1. For the reasons set out below, the CMA has concluded that the Commitments set out in Schedule 1 address the competition concerns that have been identified in relation to the Conduct.
- 6.2. As a result of its acceptance of the Commitments, the CMA will discontinue its investigation with no decision made on whether the Chapter II prohibition and/or Article 102 TFEU has been infringed.
- 6.3. In reaching the decision to accept the Commitments, the CMA has considered the representations made in response to the CMA's notice of intention to accept commitments, as required by Schedule 6A to the Act²⁵ and has taken these into account in making this Decision.

The CMA's Guidance

- 6.4. 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.
- 6.5. The relevant CMA 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.²⁶
- 6.6. 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.²⁷

²⁵ See paragraph 2(1)(b) of Schedule 6A to the Act.

²⁶ Guidance on the CMA's investigation procedures in Competition Act 1998 cases: CMA8, November 2020, paragraph 10.18.

²⁷ Guidance on the CMA's investigation procedures in Competition Act 1998 cases: CMA8, November 2020, paragraph 10.20.

The CMA's assessment

The Competition concerns are readily identifiable

6.7. As explained in Chapter 4 above, the Conduct has given rise to readily identifiable 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.

The Commitments address the competition concerns

6.8. The CMA reached the view that the Commitments, once implemented, address its competition concerns. The Commitments 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 discontinuation notice to the DHSC relating to Priadel

6.9. 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.

The Commitments are capable of being implemented effectively and, if necessary, within a short period of time

6.10. The 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 Commitments.

6.11. Essential Pharma has undertaken to act in accordance with the Commitments from the date of their acceptance by the CMA. The 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.

The effectiveness of the Commitments will not be difficult to discern

6.12. Given the straightforward nature of the 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.

Accepting the Commitments will not undermine deterrence

- 6.13. The CMA considers that accepting the 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 competition concerns will send a strong signal to other businesses, deterring them from engaging in practices which may be anti-competitive.
- 6.14. The CMA also notes that by accepting the Commitments early on in its investigation, it is able to resolve its competition concerns quickly, giving welcome certainty to the NHS and patients.
- 6.15. Accepting the Commitments does 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, which raise competition concerns and may harm consumers.

Assessment of the consultation responses

- 6.16. The CMA received six responses to the consultation. These responses were from:
- the DHSC;
 - the Royal Pharmaceutical Society and College of Mental Health Pharmacy;
 - NHS England and NHS Improvement; and
 - two NHS trusts and another healthcare body in Northern Ireland.

Summary of the responses

- 6.17. **The DHSC** expressed its support for the Commitments, including Essential Pharma's commitment to maintain the supply of Priadel in the UK for at least 5 years on terms agreed with the DHSC. The DHSC believe that the Commitments address the significant concerns that have been raised within the healthcare community about the impact of the withdrawal of Priadel for a vulnerable group of patients and the financial impact for the NHS of having to support patients through this process and also switch patients to more expensive drugs.
- 6.18. **The Royal Pharmaceutical Society and College of Mental Health Pharmacy** provided a joint response and welcomed the removal of the

immediate risks to patients. However, they expressed concern about what might happen once the 5-year period of the Commitments has expired and raised the possibility of a price increase at the end of that period. Additionally, it expressed the view that legislation was needed to prevent companies which are dominant from exploiting their market position by removing important medicines from the market and to protect vulnerable patients from being disadvantaged.

- 6.19. **NHS England and NHS Improvement** welcomed the Commitments. However, it considered that after the expiry of the Commitments in 5 years' time, in order to avoid a "*cliff edge*" scenario, Essential Pharma should also be required to give a minimum of 2 years' notice for the withdrawal of Priadel.
- 6.20. **The Cumbria, Northumberland, Tyne & Wear NHS Foundation Trust** expressed concern about Essential Pharma's conduct with regard to Priadel, which it considered was an attempt to abuse a dominant position. It objected to the CMA ending its investigation (i.e. by accepting the Commitments) at this stage. It was particularly concerned that Essential Pharma and other pharmaceutical companies could engage in similar conduct in the future and sought assurances that once the Commitments expire in 5 years' time, such conduct could not be repeated.
- 6.21. **A healthcare body in Northern Ireland** also contacted the CMA during the consultation period to express concerns that, despite the fact that Essential Pharma had withdrawn its discontinuation notice, Essential Pharma was still able to secure a significant price rise for Priadel resulting in additional costs to the NHS.
- 6.22. **The Sussex Partnership NHS Foundation Trust** welcomed the CMA's actions in this investigation; however, it raised a number of concerns regarding the regulations governing withdrawal of drugs from the UK market, especially generic medicines which are very important for certain patients. This Trust made a number of points about the regulatory process governing the supply of generic medicines to the NHS, including:
- noting that the current notice period of six months that is required by the NHS from manufacturers is insufficient to switch patients safely and effectively and suggested that a period of three years should be considered for medicines with a narrow therapeutic index. Moreover, it suggested that when serving a discontinuation notice, a company should be required to submit an impact analysis and that communications regarding the discontinuation should be regulated to prevent panic and confusion amongst clinicians and vulnerable patients;

- questioning whether there was sufficient clarity regarding Essential Pharma's obligations for the 5-year period of the Commitments, in particular whether manufacture would cease, or whether supplies of Priadel would be exhausted at that point;
- recommending that a pharmaceutical company be required to notify the DHSC if it becomes the sole supplier of a product to the UK market and that safeguards should be adopted to prevent an abuse of a monopoly position and associated price increases by that company (suggesting that a reference to the CMA may be required);
- recommending that the DHSC should review in the future how it might communicate the withdrawal of medicines from the market; and
- recommending a strategic review by the DHSC of the impact of withdrawal or discontinuation of certain medicines on the NHS.

The CMA's consideration of the responses

6.23. The CMA is grateful for the responses to its consultation, which it has carefully considered, and acknowledges the important role played by medical bodies and practitioners in protecting patient welfare.

6.24. The CMA notes, in particular, the concerns that have been raised about what may happen to the supply of Priadel after expiry of the Commitments period and about whether legislative change, or additional safeguards, are needed in relation to the supply of particular medicines to vulnerable groups of patients. The CMA's response to these concerns is as follows:

- The CMA considers that it is unnecessary, in order to address the CMA's competition concerns, for the Commitments to require that Essential Pharma should give an extended period of notice of any planned withdrawal of Priadel at any point in the future (beyond the 5-year period of the Commitments), and that accepting Commitments will not undermine deterrence:
 - i. First, the CMA considers that the Commitments keep Priadel on the market for a specific period of time, therefore providing the NHS with security of supply for at least 5 years. After the 5-year period of the Commitments, it would be open to the CMA to investigate Essential Pharma's conduct if it suspected that a planned withdrawal of Priadel (or a proposed price increase for a particular product in connection with a threatened product withdrawal) infringed competition law; within that context, it would have powers to impose

interim measures to prevent significant damage to a person or category of persons or to protect the public interest.

- ii. The CMA has the power to investigate suspected infringements of the prohibitions contained in the Act and to take action if it finds that an infringement has occurred. No specific legislative change is required in order for the CMA to investigate the proposed withdrawal (or actual withdrawal) of a particular medicine, where the CMA considers that this may infringe the prohibitions contained in the Act.
 - iii. Further, the CMA considers that its prompt intervention (and the outcome) in this case should act beyond that 5-year period as a strong deterrent against Essential Pharma (or other pharmaceutical companies) seeking to pursue strategies that infringe competition law.
- A number of points have been raised in relation to the regulatory process governing the supply of generic medicines to the NHS (such as measures being taken to protect the supply of certain medicines to vulnerable groups of patients, or changes to the length of time that a company should be required to give notice of an intended product withdrawal). These points relate to the regulatory regime established by legislation and the DHSC.²⁸ Changes to that regulatory regime are outside the scope of the CMA's investigation under the Act (or indeed the Commitments). However, the CMA will bring these submissions to the attention of the DHSC for it to consider.

6.25. With regard to representations concerning the price for Priadel agreed between the DHSC and Essential Pharma on 5 November 2020, the CMA notes that its competition concerns do not relate directly to the price that was agreed and this price is outside the scope of the Commitments. Rather, the CMA's concerns relate to a possible future threat by Essential Pharma to withdraw Priadel, which may force the DHSC to agree to unsubstantiated requests to increase prices above the level that has now been agreed between the DHSC and Essential Pharma.

6.26. On this basis, the CMA is satisfied that the responses do not require any amendments to the Commitments to ensure they meet its competition concerns.

²⁸ Including regulations regarding discontinuation or anticipated supply shortages under Part 6 of the Health Service Products (Provision and Disclosure of Information) Regulations 2018.

Conclusion

6.27. Having carefully considered the responses to the consultation, the CMA remains of the view that the Commitments address its competition concerns, and therefore considers that it is appropriate to accept the Commitments.

7. The CMA's decision

7.1. For the reasons set out above, the CMA considers that the Commitments offered by Essential Pharma, as set out in Schedule 1 to this Decision, address the competition concerns it has identified and that it is appropriate to accept the Commitments. Accordingly:

- the CMA has decided to accept the Commitments by means of this Decision; and
- the CMA will discontinue its investigation as of today's date.

Signed:

[✂]

Ann Pope

Senior Responsible Officer and Senior Director, Antitrust

For and on behalf of the Competition and Markets Authority

Date: 18 December 2020

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;

“**Camcolit**” means Camcolit 400mg tablets;

“**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),²⁹ Essential Pharma Limited³⁰ and Essential Pharmaceuticals Limited³¹;

²⁹ Registered office Vision Exchange Building Triq It-Territorjals, Zone 1, Central Business District, Birkirkara, CBD 1070 Malta.

³⁰ Registered office 7 Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RB, UK company number 07514667.

³¹ Registered office 7 Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RB, UK company number 07449900.

“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;

“Priadel” means Priadel 200mg and 400mg tablets; and

“Working Day” means any day other than a Saturday, Sunday or any other day that is a public holiday in England.

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 3.1, 3.2 or 3.3 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 provide to the CMA a signed annual Compliance Statement within three Working Days of each anniversary of the Effective Date,³² until the fifth anniversary. The Statement must be signed by the CEO (or an individual with appropriate delegated authority) on behalf of the group of Essential Pharma companies giving the Commitments and must be in the form annexed to these Commitments (**Annex 1**);
- 5.1.3 will promptly notify the CMA, as soon as practicable (and, at the latest within five Working Days³³) by email at RemediesMonitoringTeam@cma.gov.uk if it becomes aware of any breach of the Commitments, and commits to providing information concerning the nature and duration of the breach;
- 5.1.4 will promptly notify the CMA, as soon as practicable, and prior to any divestment agreement (or similar) being executed, by email at RemediesMonitoringTeam@cma.gov.uk, of any intention to divest itself of Priadel or Camcolit (or both) in the UK; and
- 5.1.5 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.

³² The first Statement shall be provided to the CMA within three Working Days of the first anniversary of the Effective Date. The second, third, fourth and fifth Statements shall be provided to the CMA within three Working Days of the relevant anniversary of the Effective Date.

³³ Starting from the first Working Day after the date on which Essential Pharma became aware of the breach.

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.

Annex 1 to Schedule 1: Template Compliance Statement for Essential Pharma

[Note: Annual Compliance Statements should be provided to the CMA within three Working Days of each anniversary of the Effective Date for the 5 years following the Effective Date and must cover the 12-months period prior to relevant anniversary of the Effective Date]

I, [insert full name], [Chief Executive Officer/title of authorised delegate] of Essential Pharma Limited (Malta), Essential Pharma Limited and Essential Pharmaceuticals Limited confirm that for the 12 months to [amend date as appropriate], each of Essential Pharma Limited (Malta), Essential Pharma Limited and Essential Pharmaceuticals Limited has complied with the following obligations (subject where applicable to the qualifications at 3.1.4 - 3.1.7 inclusive and 3.4 of the Commitments):

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 Department of Health and Social Care ('DHSC');
2. not to serve a discontinuance notice to the DHSC relating to Priadel;
3. to refrain from practices which:
 - i. 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
 - ii. may cause the UK marketing authorisation in respect of Priadel to be withdrawn, revoked, suspended or varied.
4. to 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.
5. to ensure that 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.

Any failures to meet these commitments during this 12-month reporting period were notified to the CMA within 5 Working Days of Essential Pharma becoming aware of them and are also listed below for completeness.

Signed.....

Full name.....

Date.....

Schedule 2: Modifications to the Commitments contained in the CMA’s notice of 24 November (in track change)

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;

[“**Camcolit**” means Camcolit 400mg tablets;](#)

“**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),¹ Essential Pharma Limited² and Essential Pharmaceuticals Limited³;

“**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; and

“**Working Day**” means any day other than a Saturday, Sunday or any other day that is a public holiday in England.

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 3.1.33.1.3(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;

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 07449900.](#)

- 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 [3.1, 3.2 or 3.3](#) 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~~[will provide to the CMA a signed annual Compliance Statement within three Working Days of each anniversary of the Effective Date,⁴ until the fifth anniversary. The Statement must be signed by the CEO \(or an individual with appropriate delegated authority\) on behalf of the group of Essential](#)

⁴ [The first Statement shall be provided to the CMA within three Working Days of the first anniversary of the Effective Date. The second, third, fourth and fifth Statements shall be provided to the CMA within three Working Days of the relevant anniversary of the Effective Date.](#)

Pharma companies giving the Commitments and must be in the form annexed to these Commitments (**Annex 1**);

5.1.3 will promptly notify the CMA, as soon as practicable (and, at the latest within five Working Days⁵) by email at RemediesMonitoringTeam@cma.gov.uk if it becomes aware of any breach of the Commitments, and commits to providing information concerning the nature and duration of the breach;

~~5.1.2~~5.1.4 will promptly notify the CMA, as soon as practicable, and prior to any divestment agreement (or similar) being executed, 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~~5.1.5 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.

⁵ Starting from the first Working Day after the date on which Essential Pharma became aware of the breach.

Annex 1 to Schedule 1: Template Compliance Statement for Essential Pharma

[Note: Annual Compliance Statements should be provided to the CMA within three Working Days of each anniversary of the Effective Date for the 5 years following the Effective Date and must cover the 12-months period prior to relevant anniversary of the Effective Date]

I, [insert full name], [Chief Executive Officer/title of authorised delegate] of Essential Pharma Limited (Malta), Essential Pharma Limited and Essential Pharmaceuticals Limited confirm that for the 12 months to [amend date as appropriate], each of Essential Pharma Limited (Malta), Essential Pharma Limited and Essential Pharmaceuticals Limited has complied with the following obligations (subject where applicable to the qualifications at 3.1.4 - 3.1.7 inclusive and 3.4 of the Commitments):

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 Department of Health and Social Care ('DHSC');
2. not to serve a discontinuance notice to the DHSC relating to Priadel;
3. to refrain from practices which:
 - i. 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
 - ii. may cause the UK marketing authorisation in respect of Priadel to be withdrawn, revoked, suspended or varied.
4. to 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.
5. to ensure that 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.

Any failures to meet these commitments during this 12-month reporting period were notified to the CMA within 5 Working Days of Essential Pharma becoming aware of them and are also listed below for completeness.

Signed.....

Full name.....

| Date.....