COMPETITION APPEAL TRIBUNAL

NOTICE OF AN APPEAL UNDER SECTION 46 OF THE COMPETITION ACT 1998
Case No: 1524/1/12/21

Pursuant to rule 14 of the Competition Appeal Tribunal Rules 2015 (S.I. No. 1648 of 2015) (the "Rules") the Registrar gives notice of the receipt of an appeal on 12 October 2022 under s. 46 of the Competition Act 1998 (the "1998 Act"), by Pfizer Inc. and Pfizer Limited (together, "Pfizer") in respect of the decision by the Competition and Markets Authority ("CMA") in Case 50908 (*Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*), dated 21 July 2022 (the "Decision"). Pfizer is represented by Clifford Chance of 10 Upper Bank Street, London E14 5JJ (reference: Luke Tolaini).

The Decision concerns phenytoin sodium capsules, an anti-epilepsy drug ("AED") manufactured by Pfizer (originally branded "Epanutin"). In 2012 Pfizer sold its phenytoin sodium capsule marketing authorisations ("MAs") to Flynn Pharma Limited ("Flynn"). This is the CMA's second decision finding that Pfizer's pricing of phenytoin sodium infringed s. 18 of the Competition Act 1998 (the "Chapter II prohibition"). Its previous abuse decision in Case CE/9742/13, dated 7 December 2016 ("the 2016 Decision"), was set aside by the Tribunal in its judgment of 7 June 2018[1] ("the CAT Judgment"). The Court of Appeal upheld that decision in its judgment of 10 March 2020.[2] The matter was then remitted to the CMA as to the question of abuse.

The Decision holds that Pfizer infringed the Chapter II prohibition because it charged an excessive and unlawful supply price to Flynn. The Decision separately finds that Flynn's own prices to its customers were also excessive and unlawful. Each of Pfizer and Flynn was found to have committed four separate abuses, in relation to the four different phenytoin sodium capsule strengths/prices. Pfizer was fined £63.3 million.

In summary, Pfizer relies on the following four grounds of appeal:

(a) ***Ground 1***. The CMA has wrongly ignored real-world indicators of the economic value of phenytoin sodium. Those indicators show that Pfizer's supply price to Flynn from 24 September 2012 to 7 December 2016 (the "Relevant Period") was not unfair. Specifically, the CMA erred in rejecting the following real-word comparators: (i) the Drug Tariff ("DT") price for bioequivalent phenytoin sodium tablets, (ii) the average selling prices ("ASPs") of the bioequivalent phenytoin sodium tablets and (iii) the prices paid by the NHS for other AEDs. Pfizer set its supply price to Flynn by reference to the DT price of phenytoin sodium tablets, a price that was fixed following a bespoke intervention by the DH. That price provided a reliable benchmark for the fair price of phenytoin sodium. The ASPs of the tablet during the Relevant Period also place Pfizer's supply price within the "fair" range. The prices paid by the NHS for other AEDs support the conclusion that Pfizer's supply price was consistent with the economic value that the NHS attributed to seizure control, at this time. The CMA has disregarded this compelling evidence and wrongly found that the only appropriate benchmark for assessing whether Pfizer's prices were fair is its own hypothetical desktop cost-plus methodology.

(b) ***Ground 2***. The CMA has erred in ascribing no therapeutic and economic value to phenytoin sodium beyond that reflected in its narrow cost-plus analysis. The CMA offers a variety of justifications for this approach. None of them is satisfactory. The CMA places particular emphasis on the adverse side-effects of phenytoin sodium but fails to place them in their proper context, by reference to the adverse effects of other AEDs. As a result of this flawed approach, the CMA has failed to take into account the demand-side benefits that phenytoin sodium produces for patients. Pfizer's expert, Dr Skedgel, provides an example of the kind of QALY analysis, similar to that by

[1] Flynn Pharma Ltd and others v CMA [2018] CAT 11.
[2] CMA v Flynn Pharma Ltd and others [2020] EWCA Civ 339.

which NICE appraises which health technologies should be recommended for NHS use, that the CMA could and should have conducted. He concludes that phenytoin sodium offers good value for money to the NHS, by comparison with other third line AEDs on the market at the same time.

(c) ***Ground 3***. The CMA has relied, to the exclusion of all other methodologies, on an unduly narrow cost-plus methodology for assessing economic value. That approach is not fit for purpose, particularly in the context of a generic pharmaceutical market. In doing so, the CMA continues to ignore (i) all valid real-life comparators; (ii) the Tribunal's criticisms of its cost-plus model in the CAT Judgment and (iii) the regulatory and market context in which Pfizer operated when the generic version of the capsule was relaunched by Flynn in 2012. As a result, it wrongly undervalues demand-side factors.

(d) ***Ground 4***. The CMA's investigation into the price of phenytoin sodium has been conducted in an unfair and unbalanced manner. Specifically: (i) the CMA's approach to gathering and disclosing evidence has been inadequate; (ii) the length of the proceedings as a whole has been unreasonable (contrary to Article 6 of the European Convention on Human Rights), causing Pfizer serious prejudice; and (iii) the CMA's overall approach to the remittal investigation has been characterised by confirmation bias. The Decision should be set aside for this reason.

(e) ***Ground 5***. The Decision errs in imposing a fine of £63.3 million on Pfizer. In particular, the CMA has erred in finding that the intention and/or negligence threshold was met, thus permitting it to impose a fine at all. Alternatively, if a fine could lawfully be imposed, the CMA erred in imposing an exorbitant 30% maximum starting point and an unjustified 275% specific deterrence uplift (in particular). Any fine should be greatly reduced. The CMA has repeated the errors that prompted the Tribunal to criticise the disproportionate and unsupportable approach set out in its 2016 Decision.

As regards relief, Pfizer seeks:

(a) the annulment of the Decision in whole or in part;

(b) an annulment of the fine imposed on Pfizer or, in the alternative, a reduction thereof; and

(c) payment of Pfizer's costs incurred in connection with this appeal.

Any person who considers that they have sufficient interest in the outcome of the proceedings may make a request for permission to intervene in the proceedings, in accordance with rule 16 of the Rules.

Please also note that a direction of the President is currently in place as to the electronic filing of documents: see paragraph 2 of the Practice Direction relating to Covid-19 published on 20 March 2020. Therefore, a request for permission to intervene should be sent to the Registrar electronically, by email to registry@catribunal.org.uk, so that it is received within **three weeks** of the publication of this notice.

Further details concerning the procedures of the Competition Appeal Tribunal can be found on its website at www.catribunal.org.uk. Alternatively, the Tribunal Registry can be contacted by telephone (020 7979 7979) or email (registry@catribunal.org.uk). Please quote the case number mentioned above in all communications.

Charles Dhanowa OBE, KC (Hon)
Registrar

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