<u>Press release: CMA alleges anti-</u> <u>competitive agreements for</u> <u>hydrocortisone tablets</u>

The Competition and Markets Authority (CMA) alleges that between January 2013 and June 2016, Concordia (formerly Amdipharm), and Actavis UK (formerly Auden Mckenzie), entered into agreements under which Actavis UK incentivised Concordia not to enter the market with its own competing version of hydrocortisone tablets.

In a statement of objections issued to the parties today, the CMA provisionally finds that both companies broke competition law by reaching these anti-competitive agreements, and it also alleges that Actavis UK abused its dominant position by inducing Concordia to delay its independent entry into the market.

Under the agreements, Actavis UK instead supplied Concordia with a fixed supply of its own 10mg tablets for a very low price for Concordia to resell the product to customers in the UK. Actavis UK remained the sole supplier of the tablets in the UK during most of this period, when the cost of the drug to the NHS rose from £49 to £88 per pack.

In December, a separate CMA investigation <u>accused Actavis UK of charging</u> <u>excessive prices to the NHS for the tablets following a 12,000% price rise</u> <u>over the course of several years</u>.

The CMA has provisionally found that the agreements enabled Actavis UK to prolong the high prices in the market, depriving the NHS of the significant price falls that would be expected to result from true competition.

Concordia was the first potential competitor to Actavis UK to obtain a marketing authorisation for 10mg hydrocortisone tablets, a necessary step to enter the market and compete with Actavis UK.

Actavis UK was the sole supplier of hydrocortisone tablets from 2008 until 2015, after it bought the previously branded version of the drug from another company. That purchase meant the drug became de-branded and no longer subject to NHS price regulation, as other companies were then allowed to produce competing 'generic' versions.

Hydrocortisone tablets are used as the primary replacement therapy for people whose adrenal glands do not produce sufficient amounts of natural steroid hormones (adrenal insufficiency), as for example with Addison's disease.

Andrew Groves, CMA Senior Responsible Officer, said:

Anti-competitive agreements can cost the NHS, and ultimately the taxpayer, by stopping competition bringing down the cost of

lifesaving drugs like hydrocortisone tablets.

We allege these agreements were intended to keep Actavis UK as the sole supplier of a drug relied on by thousands of patients — and in a position which could allow it to dictate and prolong high prices.

As always at this stage in an investigation, these findings are provisional and no conclusion should be drawn at this stage that there has in fact been any breach of competition law. We will carefully consider any representations of the companies under investigation before determining whether the law has been infringed.

The CMA opened this investigation in April last year. For more information see the <u>case page</u>.

In December 2016 the CMA fined the pharmaceutical suppliers Pfizer and Flynn Pharma a total of nearly £90 million for charging excessive prices for the anti-epilepsy drug phenytoin sodium, after that drug was also de-branded. In February 2016 the CMA fined a number of pharmaceutical companies a total of £45 million for anti-competitive 'pay for delay' agreements and conduct in relation to the supply of the anti-depressant drug paroxetine. The CMA has 2 other ongoing investigations into the pharmaceutical sector.

Notes for editors

- The CMA is the UK's primary competition and consumer authority. It is an independent non-ministerial government department with responsibility for carrying out investigations into mergers, markets and the regulated industries and enforcing competition and certain consumer law.
- 2. The Chapter I prohibition in the Competition Act 1998 covers anticompetitive agreements and concerted practices between businesses which have as their object or effect the prevention, restriction or distortion of competition within the UK. The Chapter II prohibition in the Competition Act 1998 prohibits the abuse of a dominant position by one or more companies which may affect trade within the UK or a part of it. Similarly, Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU) prohibit respectively anti-competitive agreements and the abuse of a dominant position which may affect trade between EU member states.
- 3. The CMA may impose a financial penalty on any business found to have infringed each of these prohibitions up to 10% of its annual worldwide group turnover. In calculating financial penalties, the CMA takes into account a number of factors including seriousness of the infringement(s), turnover in the relevant market and any mitigating and/or aggravating factors.
- 4. A statement of objections gives parties notice of a proposed infringement decision under the competition law prohibitions in the Competition Act 1998 and the TFEU. It is a provisional decision only and does not necessarily lead to an infringement decision. Parties have the opportunity to make written and oral representations on the matters set

out in the statement of objections. Any such representations will be considered by the CMA before any final decision is made. The final decision will be taken by a case decision group, which is separate from the case investigation team and was not involved in the decision to issue the statement of objections.

- 5. The statement(s) of objections will not be published. However, any person who wishes to comment on the CMA's provisional findings, and who is in a position materially to assist the CMA in testing its factual, legal or economic arguments, may request a non-confidential version of the statement of objections by contacting the CMA.
- 6. The CMA proposes to find that the undertaking referred to in this press notice as 'Concordia' consists of the following legal entities:
 - From 1 January 2013 until 20 October 2015:
 - Amdipharm Limited
 - Concordia International Rx (UK) Limited (Concordia Rx) (formerly known as Amdipharm Mercury Company Limited)
 - Concordia International (Jersey) Limited (formerly known as Amdipharm Mercury Limited)
 - private equity company Cinven, consisting for the purpose of this case, of Cinven (Luxco 1) S.A., Cinven Capital Management (V) General Partner Limited and Cinven Partners LLP
 - From 21 October 2015 until 24 June 2016:
 - Amdipharm Limited
 - Concordia Rx
 - Concordia International (Jersey) Limited (formerly known as Amdipharm Mercury Limited)
 - Concordia International Corporation
- 7. Out of these entities, the statement of objections is addressed for the full period under investigation to Amdipharm Limited and Concordia Rx because they were directly involved in the alleged infringements and to Concordia International (Jersey) Limited because it was the direct parent company of the group of subsidiaries to which Amdipharm Limited and Concordia Rx belong. The statement of objections is additionally addressed to Cinven as the ultimate parent company of Concordia International (Jersey) Limited from 1 January 2013 until 20 October 2015, and Concordia International Corporation from 21 October 2015 until 24 June 2016.
- 8. The CMA proposes to find that the undertaking referred to in this press notice as 'Actavis UK' consists of the following legal entities:
 - From 1 January 2013 until 28 May 2015:
 - Auden Mckenzie (Pharma Division) Limited; and
 - Auden Mckenzie Holdings Limited;
 - From 29 May 2015 until 24 June 2016:
 - Auden Mckenzie (Pharma Division) Limited;
 - Auden Mckenzie Holdings Limited;
 - Actavis UK Limited; and
 - Allergan plc.
- 9. Out of those entities, the statement of objections is addressed to Actavis UK Limited, because the CMA provisionally considers it was the economic successor of Auden Mckenzie and should therefore be held liable for Auden Mckenzie's direct involvement in the alleged infringements

since 2013. Actavis UK Limited was also directly involved in the alleged infringements since 2015. The statement of objections is additionally addressed to Allergan plc which the CMA provisionally considers is jointly and severally liable as the ultimate parent company of Actavis UK Limited for its suspected conduct in the market from 29 May 2015 to 24 June 2016, and formed part of the Actavis UK undertaking during that period.

- 10. For more information on the CMA see our <u>homepage</u> or follow us on <u>Facebook</u>, Twitter <u>@CMAgovuk</u>, <u>Flickr</u> and <u>LinkedIn</u>. Sign up to our <u>email</u> <u>alerts</u> to receive updates on Competition Act 1998 and civil cartels cases.
- 11. Enquiries should be directed to Rory Taylor (<u>rory.taylor@cma.gsi.gov.uk</u>, 020 3738 6798).