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Press release

3 drug firms accused of illegal market sharing

The CMA has provisionally found that 3 drug firms signed an illegal agreement that resulted in significant price hikes for an essential medicine.

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Competition and Markets Authority (<https://www.gov.uk/government/organisations/competition-and-markets-authority>)



In a Statement of Objections to be issued today, the Competition and Markets Authority (CMA) sets out its provisional view that, in 2016, pharmaceutical company Aspen unlawfully agreed to pay 2 other firms, Amilco and Tiofarma, to stay out of the UK market for fludrocortisone acetate tablets. This is a prescription-only medicine that thousands of patients rely on to treat primary or secondary adrenal insufficiency, commonly known as Addison's Disease.

This alleged illegal agreement protected Aspen's UK monopoly in relation to the supply of the drug to the NHS and gave the firm the opportunity to increase prices by up to 1,800%.

The CMA has provisionally found that Tiofarma and Amilco colluded with Aspen by agreeing to stay out of the market so that Aspen could maintain its position as the sole UK supplier of fludrocortisone. In exchange, it is alleged that Tiofarma was made the sole manufacturer of fludrocortisone for direct sale in the UK, and Amilco received a 30% share of the increased prices that Aspen was able to charge.

The Statement of Objections follows Aspen's admission, in August 2019, that it took part in this allegedly anticompetitive arrangement. Should the CMA ultimately conclude that there has been an infringement, Aspen has also agreed to a maximum penalty of £2.1 million. Amilco and Tiofarma have made no admission.

The CMA has also today formally accepted Aspen's offer of commitments (<https://www.gov.uk/government/news/cma-pharma-probe-secures-8m-for-the-nhs>), to resolve a related competition concern relating to Aspen's 2016 purchase of a competitor fludrocortisone product from Tiofarma authorised for supply in the UK. This acquisition brought all existing fludrocortisone marketing authorisations in the UK permanently under Aspen's ownership.

These commitments include Aspen, for the first time as part of such a package, offering to pay the NHS £8 million, as well as ensuring that, in the future, there will be at least two suppliers of fludrocortisone in the UK to help the NHS access more competitive prices.

With today's acceptance of the commitments, following a public consultation, this aspect of the CMA investigation has ended and the NHS will receive the £8 million from Aspen within 20 working days.

Michael Grenfell, Executive Director, Enforcement, at the Competition and Markets Authority, said:

The CMA has today provisionally found that Aspen, Amilco and Tiofarma broke competition law by taking part in an illegal agreement which led to a significant price hike for a lifesaving drug.

The NHS should not be denied the opportunity of benefitting from an increased choice of suppliers, and so potential savings on what it spends on essential drugs.

The CMA is also pleased formally to accept Aspen's £8 million payment to the NHS in response to competition concerns about a related arrangement they made for supplying this medicine, which the NHS will receive in 20 working days. This highlights the importance of competition in making sure the NHS, and so ultimately UK taxpayers, do not pay more than they should for medicines.

Amilco and Tiofarma now have the opportunity to respond to the CMA's provisional findings. No assumption should be made that Amilco and Tiofarma have infringed the law.

More information on this investigation can be found on the Pharmaceutical drugs: suspected anti-competitive agreements and conduct page (<https://www.gov.uk/cma-cases/pharmaceutical-drugs-suspected-anti-competitive-agreements-and-conduct>).

For media enquiries, please contact the CMA press office: 020 3738 6460 or press@cma.gov.uk.

Notes to editors:

1. References in this press release to fludrocortisone acetate tablets and to fludrocortisone are to fludrocortisone acetate 0.1mg tablets.
2. The Competition Act 1998 prohibits, agreements, practices and conduct that may have a damaging effect on competition in the UK. The Chapter I prohibition covers anti-competitive agreements and concerted practices between businesses which have as their object or effect

the prevention, restriction or distortion of competition within the UK. Article 101 of the Treaty on the functioning of the European Union ('TFEU') covers equivalent agreements or practices which may affect trade between EU member states. Any businesses found to have infringed the prohibitions in the Competition Act 1998 or the TFEU can be fined up to 10% of its annual worldwide group turnover.

3. The Statement of Objections to be issued by the CMA today relates to a Supply and Distribution Agreement ('SDA') in relation to sales in the UK of fludrocortisone acetate tablets entered into by Aspen, Amilco and Tiofarma in March 2016 and terminated in October 2016. The Statement of Objections provisionally finds that the SDA breached the Chapter I prohibition and Article 101 TFEU. Under the terms of a settlement with the CMA announced in August 2019 (<https://www.gov.uk/government/news/cma-pharma-probe-secures-8m-for-the-nhs>), Aspen admitted to a breach in this regard and agreed to pay a maximum financial penalty of £2.1 million. Amilco and Tiofarma now have an opportunity to respond to the allegations and make representations to a case decision group separate from the case team that has conducted the investigation up to this point. Amilco and Tiofarma have made no admissions and no assumption should be made that either undertaking has infringed competition law pending the outcome of any process involving the case decision group.
4. A party under investigation may ask to enter into settlement if it is prepared to admit that it has breached competition law and is willing to agree to a streamlined administrative procedure for the remainder of the investigation. In return, the CMA may agree to impose a reduced penalty on the business where settlement would achieve clear efficiencies, resulting in earlier adoption of any infringement decision and other resource savings.
5. Aspen also offered in August 2019 to make a payment of £8 million to the NHS (<https://www.gov.uk/government/news/cma-pharma-probe-secures-8m-for-the-nhs>), to reintroduce and commercialise Cold Storage Fludrocortisone Tablets and to divest Ambient Storage Fludrocortisone Tablets in order to introduce increased competition in the market. Those commitments were offered to address the CMA's competition concerns in relation to Aspen's purchase from Tiofarma in October 2016 of the marketing authorisations that were, prior to that acquisition, the subject of the SDA with Aspen.
6. Amilco is a British company that provides consultancy services to drug companies. Tiofarma is a Dutch pharmaceutical manufacturer that makes products including fludrocortisone acetate.

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During working hours, please contact the main press office number. For any urgent out of hours media questions, contact the out of hours mobile.

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