

3 drug firms accused of illegal market sharing

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](#), 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](#).

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

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](#), 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](#), 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.

Open consultation: Highly Protected Marine Areas review: call for evidence

Seeking views on whether and how to introduce Highly Protected Marine Areas (HPMAs) in English inshore and offshore waters and Northern Irish offshore waters.

Secure by Design – UK-Singapore IoT Statement

At the Commonwealth Heads of Government Meeting in April 2018, Singapore along with 52 nations, through the Commonwealth Cyber Declaration agreed to commit to work towards the development and convergence of approaches for internet-connected devices and associated services, in order to promote user security by default.

As part of the Singapore-UK Strategic Partnership, it was agreed that the two countries would work together on areas of common interest including greater cooperation, alignment and coordination to support a global consensus for 'secure by default'. In 2018, Prime Minister Lee Hsien Loong and Prime Minister Theresa May agreed to launch the SG-UK Partnership for the Future and formally launched in January 2019 by the UK's Foreign Secretary Jeremy

Hunt and Singapore's Minister for Foreign Affairs Dr Vivian Balakrishnan.

Singapore and the UK endeavour to take a leading role in driving improvements in the security of smart consumer products. We want to ensure that internet-connected devices have security built in by design and the public and industry are protected against related security threats, such as cyber attacks, theft of personal data and risks to physical safety.

At the same time, we must ensure that IoT industry can continue to grow and innovate and the public can fully benefit from these products and services.

UK and Singapore have committed to share initiatives and approaches, and to exchange valuable information and experience in order to make tangible progress.

Both nations will adopt a multilateral approach by working with our partners, both internationally and regionally, including industry and consumer groups, to promote the implementation of good practice as set out in the relevant industry global standards. Implementing clear good practice principles from Industry across all their consumer IoT devices will result in citizens and the wider economy being made safer and more secure whilst using their products. UK and Singapore recommend that manufacturers implement industry best practices such as:

1. Discontinuing the most blatant security shortcomings, such as the use of universal default passwords.
2. Normalising vulnerability disclosure processes across the IoT industry, so that researchers can report security vulnerabilities and manufacturers can respond accordingly.
3. Encouraging the development and deployment of software security updates so that consumers and the wider technical ecosystem are protected throughout the entire life-time of IoT products. Manufacturers should define a support period for the fixing of vulnerabilities.

We support the development of IoT assurance schemes and other efforts designed to give consumers confidence in the security of their products. The UK and Singapore have a shared interest in enhancing our bilateral cooperation in this area, as we develop our national approaches.

We are committed to strengthening our dynamic partnership for the 21st Century. We cooperate closely around the world. The UK and Singapore will work together with our partners and stakeholders to protect and promote the safety of our citizens and the security of our economies.

Singapore and the United Kingdom will continue to strengthen cooperation and explore options for further collaboration, including through the sharing of best practices.

New restrictions on exports to tackle HRT shortages

The government has confirmed new restrictions on the export of all variations of HRT products, some of which currently face supply shortages due to manufacturing issues.

The restrictions will stop some medicine wholesalers from 'parallel exporting'. This is when companies buy medicines meant for UK patients and sell them on for a higher price in another country, potentially causing supply problems.

Around 360,000 prescriptions of HRT are dispensed a month to relieve symptoms of the menopause. Currently, some HRT drugs are being parallel exported. The new restrictions will end this practice to ensure people can still access the medicines they need.

Nineteen HRT drugs will be subject to export restrictions to ensure that alternatives remain available for the HRT drugs that are in short supply. Similar measures are in place in other European countries, including France and Spain.

New restrictions for a further 5 medicines, including all adrenaline auto-injectors and hepatitis B vaccines, have also come into force to protect supplies of these products for patients.

[A full list of the medicines that cannot be parallel exported from the UK has been published.](#)

The Department of Health and Social Care (DHSC) has been working closely with affected suppliers to monitor the situation and reduce the potential impact on patients. The new measures will further reduce the impact on patients.

DHSC has written to holders of wholesale dealer licences to tell them that the government will exercise its powers to stop parallel exporting of medicines that are needed for UK patients.

Companies that parallel export a medicine that is on the list may face action from the Medicines and Healthcare products Regulatory Agency (MHRA).

The government has also introduced serious shortage protocols for the antidepressant fluoxetine, to further protect UK patients from medicine shortages. This means pharmacists can supply an alternative strength or pharmaceutical form of fluoxetine when patients have a prescription for the 10mg, 30mg and 40mg capsules, which are currently in shortage.

The serious shortage protocol will be in place while manufacturing issues mean the drug is temporarily in short supply, to ease pressure on the supply chain.

Serious shortage protocols are drawn up with senior, specialist doctors and pharmacists and are approved by national experts, including the Chief Pharmaceutical Officer and the National Medical Director at NHS England.

Medicine shortages do occasionally occur in the UK. DHSC has existing, well-established processes to deal with and resolve shortages. The new parallel export restrictions and serious shortage protocol will support this approach.

The medicine supply chain is complex and highly regulated, so problems can arise for a variety of reasons, including manufacturing issues or problems with raw ingredients.

Health and Social Care Secretary Matt Hancock said:

I know how distressing medicine shortages can be for those who rely on drugs like HRT and it's absolutely crucial patients can always access safe and effective treatments through the NHS.

The new measures we're introducing today will help us ensure patients get the medicines they need and the high-quality care they deserve.

Helping the NHS is a priority for this government, and people should be fully reassured that we will always act to ensure that there is an adequate supply of the medicine you need.

Dr Rick Greville, Director of Supply Chain at the Association of the British Pharmaceutical Industry, said:

The decision to take precautionary measures to protect medicines supplies will be very much welcomed by our members.

It means that these stockpiles of medicines which companies have built over previous months are better protected and available for use only by the NHS patients for which they were intended.

Companies can now work with the department to identify any problem areas.

[Press release: Public to have their say on stronger protections for UK](#)

waters

Independent panel calls for views on introduction of Highly Protected Marine Areas