



## **Antitrust: Commission accepts commitments by Aspen to reduce prices for six off-patent cancer medicines by 73% addressing excessive pricing concerns**

Brussels, 10 February 2021

The European Commission has made commitments offered by Aspen legally binding under EU antitrust rules. Aspen has to reduce its prices in Europe for six critical cancer medicines by 73% on average. In addition, Aspen has to ensure the continued supply of these off-patent medicines for a significant period.

Executive Vice-President Margrethe **Vestager**, in charge of competition policy, said: *“As a result of today's decision, Aspen has to radically reduce its prices across Europe for six medicines that are essential to treat certain serious forms of blood cancer, including myeloma and leukaemia. Some patients, including young children, depend on these medicines for their treatment. Aspen's commitments will save European health systems many dozens of million Euros and will ensure that these crucial medicines remain available. Today's decision gives a strong signal to other dominant pharmaceutical companies not to engage in abusive pricing practices to exploit our health systems.”*

### **The Commission's concerns**

On [15 May 2017](#), the Commission announced a formal investigation into Aspen's pricing practices regarding six critical off-patent cancer medicines mainly used in the treatment of leukaemia and other haematological cancers. After acquiring the cancer medicines from another company, Aspen started in 2012 to progressively increase its prices, often by several hundred percent, in all countries in Europe where it sold the medicines.

The Commission's analysis of Aspen's accounting data showed that, after the price increases, Aspen has consistently earned very high profits from its sale of these medicines in Europe, both in absolute terms and when compared to the profit levels of similar companies in the industry. Aspen's prices exceeded its relevant costs by almost three hundred percent on average, including when accounting for a reasonable rate of return, although differences did exist between products and countries.

The Commission's investigation did not reveal any legitimate reasons for Aspen's very high profit levels. In particular, Aspen's medicines have been off-patent for 50 years, which means that any R&D investment on the medicines has long been recouped.

Aspen could achieve these price increases, because patients and doctors had mostly no alternatives to using these particular cancer medicines. When national authorities tried to resist Aspen's requests for price increases, Aspen went as far as threatening to withdraw the medicines from the national list of reimbursable medicines and in some cases was ready to even withdraw from normal supply in the market.

Aspen's practices covered the entire European Economic Area, although not every medicine is sold in each country.

The Commission therefore found serious concerns that Aspen's behaviour may be in breach of EU competition rules that, under certain conditions, forbid the imposition of excessive prices on customers.

### **Aspen's commitments**

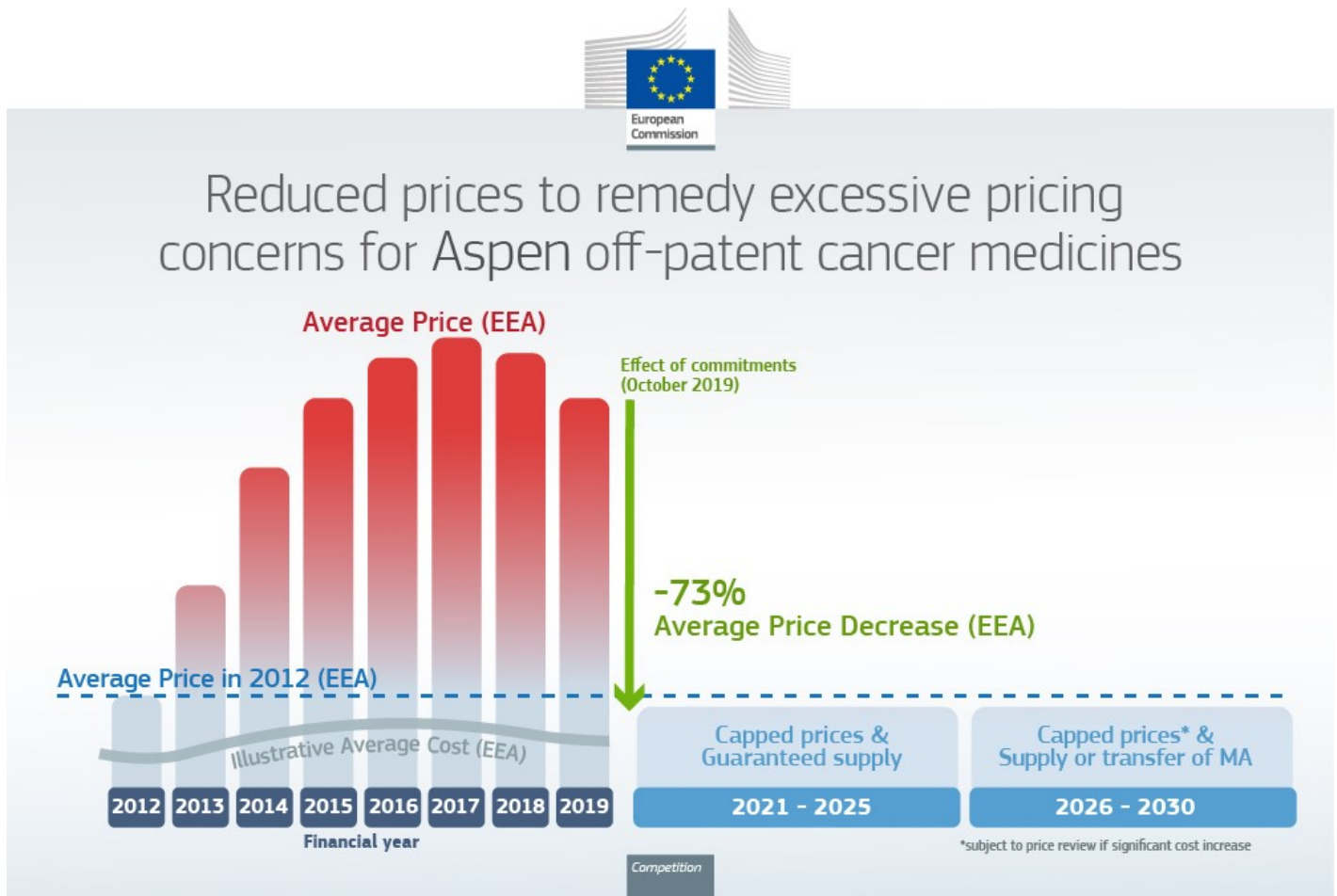
Aspen sought to address the Commission's concerns by proposing a set of commitments. In [July 2020](#), the Commission consulted stakeholders to verify whether the proposed commitments would remove the competition concerns identified by the Commission. In light of the outcome of the market test, Aspen made certain adjustments to its proposed commitments.

The Commission found that Aspen's final commitments offers a fast, comprehensive and lasting solution to the competition concerns it had identified, and therefore has made them legally binding.

Aspen's commitments provide that:

1. Aspen will reduce its prices across Europe for the six cancer medicines by, on average, approximately 73%, which is on average below the prices of 2012, before Aspen's price increases started;
2. The reduced prices will be the maximum that Aspen can charge for the coming 10 years. They will start taking effect already as of 1 October 2019; and
3. Aspen guarantees the supply of the medicines for the next five years, and, for an additional five-year period, will either continue to supply or make its marketing authorisation available to other suppliers.

The commitments will remain in force for ten years. Under supervision of the Commission, a trustee will be in charge of monitoring the implementation and compliance with the commitments.



## Background

Aspen is a global pharmaceutical company headquartered in South Africa, with several subsidiaries in Europe.

On [15 May 2017](#), the Commission initiated proceedings into concerns of an abuse of dominance by Aspen. On [14 July 2020](#), the Commission invited comments from interested third parties on a commitments proposal submitted by Aspen on 9 July 2020.

In the EU, national health authorities are free to adopt pricing rules for medicines and to decide on treatments they wish to reimburse under their social security systems. Each country has different pharmaceutical pricing and reimbursement systems, adapted to its own economic and health needs. Prices of pharmaceuticals are typically negotiated at national level between pharmaceutical companies and national pricing and reimbursement authorities. In cases of critical medicines that have no or few therapeutic alternatives, the negotiating power of authorities is rather small.

[Article 102 TFEU](#) prohibits the abuse of a dominant market position, including the imposition of unfair pricing in the form of excessive prices. The implementation of these provisions is defined in the EU's Antitrust Regulation ([Council Regulation No 1/2003](#)), which is also applied by national competition authorities.

EU competition rules do not apply in all situations of high prices of medicines. However, in certain specific circumstances a pricing conduct can be in breach of competition rules. In such case,

competition enforcement can contribute to more affordable medicines.

Article 9(1) of the [Antitrust Regulation 1/2003](#) enables companies investigated by the Commission to offer commitments in order to meet the Commission's concerns and empowers the Commission to make such commitments binding on the companies. Article 27(4) of Regulation 1/2003 requires that before adopting such decision the Commission shall provide interested third parties with an opportunity to comment on the offered commitments.

If Aspen were to breach the commitments, the Commission could impose a fine of up to 10% of Aspen's total annual turnover, without having to find an infringement of EU antitrust rules.

The full text of today's Article 9 Commission Decision, the commitments and more information on the investigation will be available on the Commission's [competition website](#) in the public [case register](#) under the case number [AT.40394](#).

### **For more information**

[Questions and Answers: Aspen commitments](#)

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### **Questions and Answers - Antitrust: Commission accepts commitments by Aspen to reduce prices for six off-patent cancer medicines by 73% addressing excessive pricing concerns \***

Brussels, 10 February 2021

Today, the European Commission has made commitments offered by Aspen legally binding under EU antitrust rules. Aspen has to reduce its prices in Europe for six critical cancer medicines by 73% on average. In addition, Aspen has to ensure the continued supply of these off-patent medicines for a significant period. These commitments address the Commission's concerns of excessive pricing. The full text of the commitments is available [here](#).

#### **1. Which medicines and countries do the commitments cover?**

The commitments by Aspen cover all medicines and all countries in the European Economic Area for which the Commission identified competition concerns.

##### Medicines

The commitments cover six off-patent prescription medicines that are used in the treatment of certain types of cancer and mainly haematological cancers, such as multiple myeloma, chronic lymphocytic leukaemia or acute lymphocytic leukaemia. Some of these medicines are used only by small patient groups, such as elderly and frail. The medicines are mostly sold under the brand names Alkeran 2 mg Tablets, Alkeran IV / 50mg (Intravenous), Purinethol, Leukeran, Lanvis and Myleran and contain the active ingredients melphalan, mercaptopurine, chlorambucil, tioguanine and busulfan. Aspen acquired these six cancer medicines from another company in 2009. Their patent protection expired 50 years ago.

##### Countries

Aspen's commitments cover the entire European Economic Area (EEA), except Italy, where a decision by the Italian competition authority was taken in 2016 (upheld in the last instance in March 2020) regarding the Italian market and the same medicines (except Myleran). The six medicines are each sold in a different number of countries, so the commitments cover for each of the medicines a different list of countries.

#### **2. How was Aspen able to impose very high prices for the medicines?**

Based on the Commission's preliminary assessment, for most of the six medicines there were no alternative suppliers and, in the few Member States where other pharmaceutical companies entered the market, they did so only recently. Furthermore, the medicines are essential medicines and patients depend on them, sometimes with their life. National pricing and reimbursement authorities were therefore under pressure to ensure the supply of these medicines to patients and effectively had little option but to agree to Aspen's price increase requests. Aspen even went as far as threatening to withdraw the medicines from the national list of reimbursable medicines and in some cases was ready to withdraw the medicines from normal supply in the Member State.

#### **3. What do the commitments achieve?**

The commitments bring to an end Aspen's excessive pricing conduct with respect to its six off-patent cancer medicines, after the Commission had found serious concerns of an abuse of a dominant position. The commitments achieve this by introducing fast, lasting and tangible changes in the markets for each of the six products and in each country where the medicines are sold. They (i) immediately apply price reductions to Aspen's net prices, (ii) impose a 10-year price-ceiling, and (iii) guarantee supply:

##### (i) Reduction in prices

The net prices to wholesalers for each of the six cancer medicines significantly drop in all markets where Aspen's current prices raise concerns under the EU competition rules. On average, Aspen's net

prices drop by approximately 73% across all the medicines and Member States concerned.

The reduced net prices fall on average below the levels of 2012, when Aspen started its strategy of high price increases. After the price reductions, the net prices for the various medicines will still differ between Member States. This is because the reduced net prices have been determined on the basis of Aspen's costs which differ considerably across products and Member States. The reduced net prices for each product and for each Member State are set out in Table 1 of the [commitments](#).

#### (ii) 10-year price ceiling

The prices in the commitments are maximum net prices (price ceilings). This means that prices are not fixed and Aspen is free to charge and agree with Member States on lower prices.

The price ceilings apply from today for a period of ten years. During the second half of that ten-year period, Aspen is entitled to one possible review of the net price ceilings by the Commission, but only if Aspen's costs linked to the medicines increase significantly (by at least 20%). Any resulting change in the net price ceilings would be proportionate to any cost increase, and, as part of the review process, the Commission will ensure that the revised ceiling does not raise any concerns over excessive prices.

#### (iii) Continued supply of medicines

Aspen commits, first, to the continued supply of the six cancer medicines for a guaranteed minimum period of five years (2021-2025).

Then, for a second five-year period (2026-2030), Aspen commits to either continue supplying the medicines, or, if it decides to stop the sale of a given product in a given country, to help continued supply by (a) giving an 18-months notice to the national authorities concerned; (b) at the same time making the medicines' marketing authorisations available for sale to any third party that is interested in taking over supply, eventually at no minimum price; and (c) maintaining the registration of the marketing authorisations until their transfer to another supplier.

#### **4. How will the implementation of the commitments be monitored?**

Aspen's compliance with the commitments will be monitored for their entire duration by an independent monitoring trustee, approved by the Commission. The trustee has reporting obligations to the Commission, for example, on Aspen's progress and timing in implementing the maximum reduced net prices in various Member States. In the event that Aspen does not comply with the commitments, the trustee may also propose measures to Aspen within a specified timeframe to ensure compliance.

#### **5. How will it be ensured that the price reductions are implemented in compliance with rules on pricing and reimbursement of each Member State?**

Price reductions for medicines may be subject to national pricing and reimbursement procedures, e.g. where so-called formal 'list prices' need to change. Where this is the case, Aspen is required to submit immediately applications for list price reductions, in compliance with applicable national procedures. Aspen also has a duty to proactively assist the relevant regulatory authorities to achieve the price reductions.

#### **6. From when and for how long do the reduced prices apply?**

The reduced net wholesale prices apply as from today and will remain capped at that level for the following ten years.

In addition, the reduced prices apply retroactively as of 1 October 2019, the date on which Aspen concretely proposed commitments to the Commission.

To apply the price reductions already from 1 October 2019, Aspen grants a rebate for any amount charged that exceeds the reduced net prices. Aspen pays that rebate to the public and private entities in the Member States that *ultimately* paid or reimbursed Aspen's medicine prices. In Germany and Czechia where limited co-payment existed, also patients receive a small rebate. The rebates apply for the period until the medicines' list prices change or, where list prices do not form part of the national system, until Aspen's reduced net wholesale prices become otherwise effective. The rebates therefore also ensure that no health system or patient pays excessive prices during this transitional period.

#### **7. Why is it important to ensure the supply of the six cancer medicines?**

Aspen's commitments concern the price of six off-patent medicines that are critical for the treatment

of patients, including young children, suffering from certain types of life-threatening cancer, such as leukaemia and multiple myeloma. For patients, it is not only important that the medicines are not sold at excessive prices, but also that the medicines continue to be available in their country. For this reason, the commitments not only envisage a ten-year price ceiling, but also contribute to ensuring supply for ten years.

**8. To what extent has the Commission worked together with Member States on this and other suspected excessive pricing cases in the sector?**

Through the [European Competition Network](#), the Commission works regularly and closely together with national competition authorities, including in the pharmaceutical sector. Regarding Aspen's pricing practices, the Commission has cooperated closely with the Italian competition authority, both in the proceedings against Aspen in Italy (see under Question 1) and those at EU level. National competition authorities may indeed take action against suspected violations of EU competition law on national markets where they have early on sufficient evidence at their disposal. Where it then turns out that the same conduct exists also in other Member States or across the EU, the Commission may decide to launch an investigation as well.

In the Aspen case, the Commission was also in close contact with national health authorities to, amongst others, seek information on Aspen's conduct in the various Member States, and on how the commitments could be implemented at national level.

More generally, national regulators and national health authorities play an important role in designing and implementing effective regulatory frameworks regarding medicine prices and reimbursement. In very specific circumstances, EU competition rules may also apply, namely when a firm in a dominant position imposes such high prices that they amount to excessive prices within the meaning of the EU competition rules. Continuous efforts by all private and public stakeholders are needed to meet the societal challenge of ensuring access to affordable and innovative medicines.

**9. How does the Aspen case fit into the Commission's Pharmaceutical Strategy?**

The [Commission's 'Pharmaceutical Strategy for Europe'](#) is a patient-centred strategy that aims to ensure the access to quality and safety of medicines, while boosting the sector's competitiveness. In particular, the Pharmaceutical Strategy includes a variety of initiatives to address issues such as affordability of medicines and security of supply. Enforcement of EU competition law is an important element for achieving these initiatives.

By achieving a significant reduction in Aspen's prices and security of supply for a significant period for Aspen's cancer medicines, this commitments decision contributes to the aim of affordability of medicines and security of supply under the Commission's Pharmaceutical Strategy for Europe.

**10. How does the case fit also into the Beating Cancer Plan?**

An important goal of Europe's [Beating Cancer Plan](#) [see point 5.3] is to overcome the challenge of shortages of cancer medicines and therefore improve access to cancer medicines. This decision contributes to this objective because it will immediately lead to essential cancer medicines being available at reduced prices and ensure security of supply for a significant period.

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