

Cancer Leagues' comments on the commitments offered by Aspen Pharma

Case AT.40394 – Aspen

The Association of European Cancer Leagues (ECL) welcomes the opportunity to submit comments on the commitments offered by Aspen¹ in the case of reference in accordance with Article 27(4) of Regulation (EC) No 1/2003² in view of the adoption of a decision under Article 9(1) of the same Regulation.

I. Setting the Scene

Prices of cancer medicines have increased considerably over past years. Such increases have also been identified in off-patent pharmaceuticals where initial investments have already been recouped.

Cases of excessive prices pursued by competition agencies are rare due to the complex assessment of what constitute an excessive price. However, existing cases in Europe revealed that under certain circumstances intervention is much needed, in particular when a firm takes advantage of its dominant position (due to the lack of competition) to impose a price on its customers that is not economically justifiable. This has been the case of the antitrust investigation against Aspen regarding the pricing and the negotiations technique used to obtain extraordinarily high prices for the prescription medicines object of the commitments.

Aspen managed to increase the prices of the medicines by putting pressure on the national pricing and reimbursement authorities and even threatening to withdraw the medicines from the market. This behaviour led to authorities agreeing on price increases that exceeded in average the relevant costs by almost 300%, which as indicated by the Commission, were almost four times the level of Aspen's costs.³ Further to this, there were no legitimate reasons for such profit levels, especially when the patents on the medicines expired five decades ago.⁴

The commitments cover six off-patent prescription medicines that are used in the treatment of certain types of (haematological) cancers, such as multiple myeloma, chronic lymphocytic leukaemia or acute lymphocytic leukaemia. Some of these medicines are used only by small patient groups. 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, mercapto-purine, chlorambucil, tioguanine and busulfan. Aspen acquired these six cancer medicines from another company (GSK) in 2009. Their patent protection had expired 50 years ago.⁵

¹ Communication from the Commission published pursuant to Article 27(4) of Council Regulation (EC) No 1/2003 in Case AT.40394 – Aspen 2020/C 233/06.

² Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty.

³ Communication from the Commission published pursuant to Article 27(4) of Council Regulation (EC) No 1/2003 in Case AT.40394 – Aspen 2020/C 233/06, paragraph 7.

⁴ *Ibidem*, paragraph 8.

⁵ See more details here: https://ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=1_40394

II. ECL' support for Aspen's commitments

1. ECL fully supports the following commitment:

'Aspen will reduce its net prices for each of the Products in all of the EEA Member States where price levels may raise concerns. The reduced net prices are set out per Member State and per Product in the proposed commitments. The price reduction will be on average around 73% for the Products across the EEA. After the reduction by Aspen, there will still remain a significant variation in the prices between Member States, because Aspen's per-unit costs differ between the Member States. The committed net prices are maximum net prices, i.e. price-ceilings, and Aspen is free to apply lower prices.'

2. ECL agrees that the commitment to apply the reduced prices for 10 years, however we believe that measures to prevent radical price increase past this period would be appropriate. ECL also welcomes the retroactive effect set to 1 October 2019. However, more clarity on the feasibility and procedure of retroactive payments should be put in place, to ensure the company follows up on this commitment with least possible added administrative burden for national authorities to enforce agreed rebates. In addition, if applicable, a plan on how to reimburse patients in the case of out-of-pocket payments based on the excessive price during this period should be added.

'The reduced net prices will apply for a period of ten years counting from the day of notification of the Commission's decision accepting the commitments. In the second half of the period, i.e. after year five, there can once be a review of price levels in case of a significant increase in Aspen's direct costs. In addition, on top of the ten-year period mentioned, Aspen commits to apply the reduced net prices already retroactively from 1 October 2019 onwards, when Aspen first approached the Commission with a concrete commitments proposal. Aspen will reimburse the amounts paid in excess of the reduced net prices during the period from 1 October 2019 until Aspen has effectively implemented the price reductions to entities that ultimately pay or reimburse medicine prices in the Member States. These payments are without prejudice to any claims under applicable civil or commercial laws.'

3. ECL welcomes the timeframe proposed by Aspen and the commitment to make the marketing authorisation available to any interested third party should Aspen discontinues the supply after 5 years. In such a case, agreed price levels should also apply for the purchaser to prevent return to abuse of dominant power by another company after 5 years. In addition, European Commission should vigilantly oversee the acquisition, to ensure the legitimacy of the new supplier and guarantee continued supply of the products to patients.

'Aspen commits to continue supplying the Products for a guaranteed first period of five years. For a second five-year period, Aspen commits to continue supplying the Products unless Aspen, if it intends to discontinue supplying, (i) informs, at least one year in advance, the Member State authorities concerned of that intention, and (ii) makes the Products' marketing authorisations available to any interested third party and maintains the marketing authorisations until it has found a purchaser.'

III. Conclusion

Taking into account the above-stated comments, the Association of European Cancer Leagues (ECL) recommends the European Commission to accept the commitments offered by Aspen and issues a decision on the basis of Article 9 of Regulation (EC) No 1/2003.