

The Consumer Voice in Europe

COMMITMENTS OFFERED BY ASPEN IN CASE AT.40394

BEUC comments



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BEUC's comments on the commitments offered by Aspen Case AT.40394 – Aspen

BEUC, The European Consumer Organisation, 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.

Preliminary remarks

As shown in several studies³, many pharmaceuticals have reached very high prices over the years. An OECD report noted that concerns about prices and affordability have been driven by a series of events that have shaken the confidence of both payers and patients, and imposed additional pressure on policy makers trying to find a balance between promoting and rewarding innovation, ensuring access to medicines, and sustaining the viability of the health system⁴. It is however striking that price increases have been found in off-patent drugs where investments have already been recouped.

Cases of excessive prices brought by competition agencies are rare due to the complex assessment of what constitutes an excessive price. However, existing cases in Europe reveal that under certain circumstances intervention is much needed⁵ when a firm takes advantage of its dominant position to impose a price on its customers that economically is not 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 commitments⁶.

The research carried out by our members OCU (Spain)⁷, Test-Achats (Belgium)⁸ and Altroconsumo (Italy)⁹ shows that Aspen managed to increase the prices of the medicines by putting pressure on the national pricing and reimbursement authorities e.g. threatening to withdraw the medicines from the market. This greedy behaviour led to authorities agreeing on price increases that exceeded in average the relevant costs by almost 300%,

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 See amongst others: Vogler, S., Schneider, P. & Zimmermann, N., "Evolution of Average European Medicine Prices: Implications for the Methodology of External Price Referencing", *PharmacoEconomics Open* 3, 303–309 (2019) <https://doi.org/10.1007/s41669-019-0120-9>; Health Action International (HAI), "Access to High-priced Medicines in Hospital Settings in Europe. A Study in Four European Countries", available at <https://haiweb.org/wp-content/uploads/2016/04/Access-to-High-priced-Medicines-in-the-Hospital-Sector.pdf>; No Es Sano, "Cancer Drugs: High Prices and Inequality", available at http://noessano.org/es/wp-content/uploads/2018/06/Cancerdrugs_report_2018.pdf;

⁴ OECD, "Pharmaceutical Innovation and Access to Medicines", available at [https://www.oecd-ilibrary.org/docserver/9789264307391-](https://www.oecd-ilibrary.org/docserver/9789264307391-en.pdf?expires=1599734329&id=id&accname=guest&checksum=D942EEBE76EA2F58134E5942FB00B962)

[en.pdf?expires=1599734329&id=id&accname=guest&checksum=D942EEBE76EA2F58134E5942FB00B962](https://www.oecd-ilibrary.org/docserver/9789264307391-en.pdf?expires=1599734329&id=id&accname=guest&checksum=D942EEBE76EA2F58134E5942FB00B962)

⁵ See: European Commission report, "Competition Enforcement in the Pharmaceutical Sector (2009-2017)", available at <https://ec.europa.eu/competition/publications/reports/kd0718081enn.pdf>

⁶ See: BEUC letter to Commissioner Vestager of 20 October 2016, available at http://www.beuc.eu/publications/beuc-x-2016-101_aspen_pharmas_anticompetitive_practices.pdf

⁷ <https://www.ocu.org/salud/medicamentos/noticias/caso-aspen-2018>

⁸ <https://www.test-achats.be/action/espace-presse/communiqués-de-presse/2016/aspen>

⁹ <https://www.altroconsumo.it/organizzazione/international/press-releases/2016/anticancer-drugs-antitrust-authority-fines-aspen-pharma-for-5mio-euros>

which as indicated by the Commission, were almost four times the level of Aspen's costs¹⁰. Further to this, there were no legitimate reasons for such profit levels, especially when the patents on the medicines expired five decades ago¹¹.

Comments on Aspen's commitments

Below we provide comments on the proposed commitments:

- a) *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.*

BEUC welcomes the price reduction.

- b) *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.*

BEUC considers that the commitment to apply the reduced prices for 10 years is appropriate although we would expect it to be the case also beyond that timeframe. Further to this, we welcome the retroactive effect to 1 October 2019. It however would be more appropriate if the company committed to reimburse the payments for the amounts paid in excess also before that date. Thus, it would make only sense that the company reimburses all payers as of May 2012 or the date when the abuse started in the respective Member State. After all, the company would be avoiding a substantial fine if the Commission adopts a decision on the basis of Article 9 of Regulation (EC) No 1/2003.

Regarding reimbursements to consumers that made co-payments to access the medicines, Aspen should establish a system to trace the payers that is compliance with data protection rules in co-operation with the relevant national authority and healthcare providers at national level. In the event the payers cannot be identified in a relevant country, Aspen should make such sums available to NGOs working in the field of affordable medicines or to create a fund to be distributed by the competent national authority amongst organisations fighting against excessive pricing of medicines.

¹⁰ 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.

¹¹ *Ibidem*, paragraph 8.

- c) *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.*

BEUC welcomes the timeframe proposed by Aspen and the commitment to make the marketing authorisation available to any interested third party should Aspen discontinue the supply after 5 years. We would like to recommend that in such a case, the European Commission, supported by an independent monitoring trustee, oversees such operation to ensure that the new supplier or suppliers is/are a legitimate acquirer.

Conclusion

BEUC recommends the European Commission to accept the commitments offered by Aspen and to issue a decision on the basis of Article 9 of Regulation (EC) No 1/2003.



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