Briefing | EP BECA - Joint debate on: a Pharmaceutical Strategy for Europe, The Proposal for a regulation on health technology assessment and the Aspen case

Dods - Committee Summary

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Source: European Parliament Special Committee on Beating Cancer (BECA)

On 1 July, the European Parliament BECA Committee met for a joint debate on ongoing files relating to Europe's Beating Cancer Plan. During the debate, MEPs who took the floor agreed with the rapporteur for the Pharmaceutical Strategy for Europe's insistence that equality must be seen across Europe in terms of access to medicines and their affordability. In this regard, several members noted that levels of access were notably lower in eastern European countries and that joint procurement between Member States could be one way to remedy this. Moreover, parliamentarians supported the progress made on the health technology assessment file, though reservations were heard as obligations would not be binding on Member States. Concerning the Aspen case, MEPs welcomed the Commission's intervention and stated that such exorbitant price increases should no longer be permitted, especially as the six medicines in question were originally produced in the 1950s and thus did not have patents attached. Please see below for a full summary of the joint debate.

BECA Vice-Chair Joanna Kopcińska (ECR, PL) noted that many topics were included under the Pharmaceutical Strategy for Europe, including ensuring that medicines were affordable for all. The first wave of the pandemic highlighted the deficits of the pharmaceutical industry. The Proposal for a regulation on health technology assessment could also be very relevant when it came to brining new treatments to patients. On the Aspen case, this could have a directive, positive impact on providing affordable medicines to patients. Availability and affordability of medicines were key for patients and a better insight into how pharmaceutical operators acted was needed.

Dolors Montserrat (EPP, ES), ENVI rapporteur on the Pharmaceutical Strategy, noted that more than 700 amendments had been received and a complete text would be prepared. The vote in ENVI was scheduled for October 11/12 and the vote in plenary would be in November. New criteria were being called for regarding incentives for researching innovative medicines in particular. She agreed with the Commission on the need to ensure access to innovative cancer drugs to meet patients' needs, especially those of children. The report underlined the need to reduce delays for paediatric drugs and stressed the need for equal access. There were currently 25 percent in terms of survival rate differences across Europe.

Moreover, the report called for shortages of medicines to be addressed and for more generics and biosimilars to be made available. The price should also be fixed and the supply chain more resilient and

based in Europe. Setting up time frames for national marketing should also be put in place and joint procurement for emergency medicines should also be rolled out, for example. A one health approach should also be taken and the entire life cycle of medicines should be taken into account; in this regard, anti-microbial resistance (AMR) needed to be tackled. Early diagnostics and treatments also needed to be built up as early detection of cancer was key and could be life saving and was more economically advantageous. Safe secure and equal access was required and public-private partnerships should also be promoted.

Furthermore, boosting exchanges of information between countries would also be key, including between health professionals. The full application of the clinical trials regulation should also be guaranteed and this applied harmonising clinical trials and having improved collaboration between and within Member States. There should also be higher standards of safety for all participants and more transparency. More patient-centred clinical trials was also called for in the report. The impact of COVID-19 was also included in the text and the report called for the need to shorten delays of medicines due to health emergencies.

Jytte Guteland (S&D, SE) noted that there was now an inter-institutional agreement on the health technology assessment. Council had been blocked for 4 years but a common position was finally reached in March. The purpose of the HTA was to support decision making in healthcare and this could allow for comparing clinical issues and could also consider other issues, such as social issues. Future cooperation would have, at its core, the output of joint clinical assessments, though voluntary cooperation on non-clinical issues would also be possible. Cooperation would focus on medicinal products and devices, in addition to disease diagnostics, for example. This was a research based tool and numerous authorities in Europe were currently using this tool. It would allow for increased joint scientific assessments which would further improve the quality of HTA and thus facilitate market access to the benefit of patients. The agreement was confirmed yesterday by COREPER and included two short timelines for the full implementation of the scope of health technologies it would enter into force up to 2024 and 2029, for example. For instance, for orphan drugs it would apply from 2027. Oncological methods would be first category to be implemented. There would also be a clear voting mechanism for the coordination group and various sub-groups would also bring together representatives from Member States. These members should be independent and, if a vote was needed, the voting mechanism would be done by qualified majority and simple majority, depending on the substance. There would also be improved stakeholder collaboration and safeguards to assure that the joint clinical assessment was taken place. Parliament also fought to defend the binding nature of clinical assessments and Member States would have to annex the European report to this national work. This was a strong agreement that would strengthen EU agreement on the HTA, she finished.

Rainer Becker, Markets and Cases, DG COMP, on the Aspen Case, noted that the anti-trust case concerned six medicines. The medicines were used to treat different forms of blood cancer and dated from the 1950s. Authorities had no chance but to accept Aspen's price increases of several hundred cases. In such extreme cases, the Commission could intervene and the Commission applied a two-step test. As a starting point, Aspen's net prices and resulting profits were analysed. The analysis showed that Aspen's profits had greatly risen since increasing prices. The question was: when were profits no longer reasonable and could be considered obsessive. A sample of other pharma companies was also considered so there could be fair comparison. None of these comparative firms earned profits that came close to what Aspen was earning and Aspen was earning more than 300 percent more than competitors on average.

The Commission also investigated whether Aspen had legitimate reasons for such a price increase, such as whether they had innovated the drugs. The answer was no to all such questions posed and these were old medicines whose patents had expired 50 years ago. The motives were then investigated and it was found that Aspen had realised that European health systems depended crucially on certain medicines. Thus, the sole aim was to exploit this dependency. When confronted, Aspen proposed to remove all risk of excessive pricing and positive feedback was received from Member States. Aspen's commitments were legally binding, he noted. Aspen must reduce its process by 73 percent on average for 10 years. Moreover, the reduction applied retroactively. Second, Aspen, must comply with supply commitments which would

last for an initial 5 year period. Aspen was currently implementing said commitments and this was being monitored closely.

BECA Vice-Chair Joanna Kopcińska (ECR, PL) underlined that patients must be supported as they were fighting an unequal battle.

Peter Liese (EPP, DE) stressed the importance of Ms Montserrat's report. In many cases, cancer patients could not be offered the right treatment and the right type of innovation was needed. HTA would also help in this regard. It would help to develop the drugs that patients really needed and had an added value. He highlighted the importance of Intellectual Property (IP) and more investment and innovation was needed. Mr Liese then noted that incentives for cancer drugs for paediatric cancer cases were not good enough. What could be done to trigger more innovation in this context?

Nicolás González Casares (S&D, ES), on the pharmaceutical strategy,agreed that there was great disparity when it came to access, even within Member States. He asked Ms Montserrat how this could be addressed under the strategy. Addressing Mr Becker, he said this file was working really well. A shameful abuse had been seen and sick people had been exploited. Was the Commission aware of any other similar cases?

Nicolas □tefănu□ă (RE, RO) , addressing Ms Montserrat,noted that, due to the wide variety of paediatric cancers, there was a lack of incentives to invest in medicines in this area. New incentives were needed and he asked what potential new incentive mechanisms could tackle this issue.

Kateřina Konečná (The Left, CZ), on the Aspen case, said the aim of EU Commission policy was to protect the welfare of consumers. The pharmaceutical sector must be better regulated regarding prices. As a result, people were dying at the expense of billionaires. Why were there millions of people who would not be getting vaccinated until COVID until 2023 while certain companies were becoming very rich?

Marian-Jean Marinescu (EPP, RO) remarked that the Aspen case showed the power of the pharmaceutical industry. Other companies also had a similar approach when it came to pricing and the problem was also a lack of transparency when it came to R&D. Addressing Mr Becker, he noted he had table several pilot projects over the last few years on fair pricing for essential medicines and he received the response that the Commission was already working in this area. When would the Commission come up with such a framework? When would there be a framework on a European system for reimbursement? What would be done about the parallel trade for medicines?

Sara Cerdas (S&D, PT) stated that the availability and accessibility of therapeutics in an affordable and timely way must be ensured under the strategy, regardless of the location of citizens. R&D into new tools must also be increased and capacities to develop clinical trials must also be boosted. Robust and large pan-European clinical trials should also be rolled out. On AMR, cancer patients were much more prone to infections due to comprised immune systems. The potential threats of AMR must be mitigated in this regard.

Vlad Gheorghe (RE, RO) underlined the need for the pharmaceutical strategy to work for serious chronic diseases and cancers. He highlighted the EU added value in addressing inequalities when it came to access to medicines, especially in eastern Europe. Such countries were the least likely to obtain the drugs they needed as profit was lower for pharmaceutical companies there. Availability should not depend on one's Member State of residence. When could medicine shortages realistically be expected to disappear? Europol recently indicated the increase in illicit waste management and medical drugs and utensils must be properly disposed of. What was the main avenue to combat pharmaceutical waste's impact on public health?

Michèle Rivasi (Greens/EFA, FR) noted that the pharmaceutical strategy stated that there must be access to medication for all and that it must be affordable. Doctors working with cancer patients have said that such an approach could threaten access to real therapeutics, however. On the other hand, some researchers have said there was not necessarily a correlation between price and efficacy. The Aspen case was extremely telling when it came to disfunctions within the system. A lot had been said about public-private partnerships, but there must be conditions built in, including on transparency. It was

unacceptable that contracts were not made available to MEPs when EU public money was being used. There should also be competitiveness in the market, unlike the Aspen case where they practically have a monopoly. She welcomed the Commission's response in this regard.

Piernicola Pedicini (Greens/EFA, IT) said that the current system was based on giving fair compensation to companies for their high R&D costs. Usually, the cost came down greatly when patent protection had expired. However, the Aspen case showed this was not always the case as the company in question had a monopoly. Addressing Mr Becker, he asked about the possibility of setting a clear precedent, such as giving Aspen a fine. The Commission decision sent a strong signal but this was not enough; how would the strategy tackle the issue of exorbitant prices, especially in cases where no alternative medicine was available.

Margarita de la Pisa Carrión (ECR, ES), on the Pharmaceutical Strategy, stated that this was an opportunity for long-term solutions. However, current debates seemed to only focus on the short-term. How could long-term ambitions be concentrated on, such as when it came to changes to the IP system. New mechanisms were needed when it came to innovative treatments in areas not covered. Access to medication also needed to be focussed on as this could lead to higher death rates. It was also about addressing inequalities in pricing and access. There was also the issue of ethical principles regarding patients. Was there a focus on bioethics under the strategy?

Deirdre Clune (EPP, IE), on the Pharmaceutical Strategy, asked whether the report looked at orphan drugs? Was there a way to incentivise research into such drugs? Rare cancers needed more attention, she underlined. Concerning the Aspen case, asked how the strategy could prevent such a case from occurring in the future.

Romana Jerković (S&D, HR) said she wanted to focus on access and affordability of life-saving cancer treatments. Evidence suggested that the majority of medicines on the market extremely costly which was an issue for many. Timely and affordable access must be ensured for all. She supported promoting transparency in pricing as true costs for companies were unknown.

Bronis Ropė (Greens/EFA, L T) underlined that medication must be made affordable and accessible; otherwise, no real progress would be made. Not enough had been done for many years and the pharmaceutical industry was abusing the system. The banking system had been regulated, for example, and the State could also intervene in this field. Member States could achieve a lot with the right will and he supported common procurement as this could result in equal treatment for all citizens. He asked what price differences were across Member States. Moreover, on public aid for the industry, they should open affiliates in different Member States so medication would not have to travel across the EU. Thus, production should be decentralised.

Andrey Slabakov (ECR, BG) noted that a lot had been heard about achieving faster and better results. At the same time, new medicine and technology needed to be rolled out and applied equally across all Member States. Currently, it took too long to get new treatments on stream. Doctors, wherever they were operating, must be equally well trained and have access to cutting edge technology.

Tomislav Sokol (EPP, HR) echoed the issues of accessibility and affordability between Member States. Currently, one had a 30 or 40 percent higher chance of dying of cancer in certain Member States in eastern Europe compared to western Member States. He supported joint procurement. On the HTA, he welcomed that an agreement had been reached. However, the obligation on Member States was not stringent enough and they may not take it on. On the transparency directive, he asked whether the Commission planned on revising it.

Cyrus Engerer (S&D, MT) noted that only 30-50 percent of medicines in Europe could be taken by children and there had been a lack of investment into treatments for paediatric cancers. Increased incentives for industry to strengthen the development of medicines in this area must be ensured. In addition, accessibility and affordability must be improved. He asked what concrete actions could be expected following the adoption of the strategy.

BECA Vice-Chair Joanna Kopcińska (ECR, PL) asked how access to generics could be made easier under the strategy. When would it be possible to come up with the first joint report on cancer treatment?

Andrzej Rys, Director, Health systems, Medical products and Innovation, DG SANTE, said the first achievement of the pharmaceutical strategy was the adoption of the HTA. The first joint report would be published in 2024 and the first package of medicines assessed would be cancer medicines, including orphan drugs and advanced therapies. ***His intervention was cut short due to technical problems.***

Rainer Becker noted that the Aspen case took several years to put together given the amount of analysis that needed to be carried out. On why fines were not imposed, he said that a commitment decision could also be a landmark decision and thus a precedent had been set. The idea was to give a strong message and underlined that excessive pricing was prohibited by competition rules. Colleagues in Member States now also had increased guidance, including national courts. Commitments were a good choice to bring about optimal remedies as quickly as possible and, in this instance, the price reduction applied immediately. Had an infringement decision been opted for, all markets could not have been included and a supply remedy may also not have been secured, for example.

On whether there were similar cases, he said he could not comment on pending or future investigations. However, the Commission was monitoring the market closely for pricing issues, or on delaying tactics or the abuse of dominant positions, for example. Where breaches were found, the Commission was ready to act.

Concerning affordability and availability, he underlined that this was one of the biggest societal challenges. He noted it was mainly colleagues in DG SANTE would be implementing the strategy. A lot of what the Commission did was to stimulate innovation; however, competition rules could not solve all regulatory and legislative issues.

Dolors Montserrat (EPP, ES) remarked that her report also set out the need to incentivise research into paediatric drugs. A review of the transparency directive was also called for in the report. Moreover, the regularity system must be more flexible and align national authorities' approaches with the EMA. More transparency on prices, especially when public money was invested, should also be made available. She supported making a greater number of generics available for patients.

Prices were a national competence. However, the EU would evaluate prices and assess the effective value of the medication and this should be considered by Member States. She supported 50 percent of price reflecting the price of production and 50 percent reflecting the added value of the medication. Many were complaining that Europe was not in control of the whole supply chain and shortages were being faced during COVID, such as a muscle relaxant. The price on the market was 50 or 60 cents and thus production had been delocalised as this was too cheap to produce in Europe. The strategy would also focus on such cross-cutting issues.

Capacity, resources and Member State practices could be bolstered by the EU and joint procurement during the pandemic showed the benefit that implementing a Union for Health would engender. In addition, she supported having more public-private partnerships in terms of funding research into innovate medicines.

Andrzej Rys, on initiatives for developing orphan paediatric medicines, the Commission was gathering answers following a consultation process with stakeholder and action taken would depend on the final judgement. He underlined the importance of finding the right balance between regulating the industry and the Commission was ready to propose a number of regulatory proposals. Concerning initiatives around affordability and access, cooperation with Member States authorities would continue to see how this area could be improved. On shortages, structured dialogue had been undertaken with stakeholders and regulatory measures may be proposed in this area by the end of 2022.

Concerning access to biosimilars and generics, the involvement of Member States was crucial. The issue of ethics was the remit of Member States, he noted. Regarding investment into how to reduce disparities between east and west Europe, Mr Rys gave the example of the importance of European Affairs networks

for knowledge to flow across borders and for patients to have access to experts in the field. Such actions would continue under the EU for Health programme.

On revising the transparency directive, it was possible this would be reassessed but this was not the plan for the time being. Problems with the supply chain were seen during COVID and he agreed that this issue must be approached from a long-term perspective.

Véronique Trillet-Lenoir (RE, FR), on the pharmaceutical strategy, underlined how important it was to strengthen the EU Health Union post-COVID. There must be more rigour regarding checks and transparency. Various other proposals were underway, such as the directive on paediatric medication. She supported the need for more transparency when it came to prices and the need to incentivise research into producing medicines, particularly for paediatrics. Pharmaceutical companies must be encouraged to 'reshore' and produce again in Europe. A further important solution was joint procurement programmes for cancer medicines. A strategic reserve should also be set up for medicines where a shortage was being faced. There must also be a strategy for emergency situations. On the HTA file, joint assessments would be carried out within 3 years and new types of care and therapies had been included under the file. A joint European statement assessing added value and impact on quality of life of patients would also be undertaken. Stakeholders across the board would be discussed with in this regard. The outcome of the HTA negotiations were positive and parliament had managed to get a foot in the door. This would not be mandatory for Member States, but it would be a time saver and money saver for Member States and, if working well, they would make use of it. Agreeing on the added value of medication was the first step when it came to fairly assessing medicines.