Copenhagen Economics

WHY SEEMINGLY UNRELATED EVENTS ARE NOT AND WHAT IT MEANS FOR PHARMA AND PAYERS IN EUROPE

Authors:
Christian Jervelund, Partner
Julia Sabine Wahl, Managing Economist
Tuomas Haanperä, Managing Economist
Nikolaj Siersbæk, Economist

06 October 2020

In 2019, a prophylactic treatment for patients suffering from the swelling disease Hereditary Angioedima (HAE) was approved by the National Health Services (NHS) in the UK.[1] The treatment is a true game changer for the treatment of patients with HAE as it prevents swelling attacks from occurring in the first place compared to the on-demand treatments available which seek only to dampen the attacks when they occur. Results from clinical trials and real-world evidence show that the prophylactic treatment reduces the average number of swelling attacks from 2 a month to less than one every two months, and that up to 44% of patients were attack free over a 26-week period.[2]

Those patients would essentially be living normal lives. However, the enhanced effectiveness or prophylactic treatment comes with a higher cost than that of on-demand treatments. The NHS decided to approve and reimburse the prophylactic medicine to patients experiencing eight or more swelling attacks a month.

Based on real world evidence from the USA and the Nordic countries, this cut-off point would benefit 6% of the patient population in the UK.[3]

> **Companies must consider strategies that better align their value proposition with payer needs. This entails developing more transparent budget impact and payer risk assessments rooted in a deeper understanding of KPIs of payers**

At the same time, tough negotiations were taking place in Sweden around the approval of a new treatment for a rare inherited retinal disease due to mutations in both copies of the RPE65 gene which inevitably cause blindness

in children and adults. The treatment would be administered once instead of continuously over time and is much more expensive than the current (lack of) treatment. In the end, negotiations broke down, and the new treatment was not approved for reimbursement and thus not made accessible to patients in Sweden.[4]

In 2018 and 2019, the Dutch competition authority initiated investigations into the price levels for several 'expensive' drugs. The authority evoked the competition law provision of excessive pricing, a provision rarely used in cases involving pharma companies. Some of these investigations are still ongoing.

Back in 2016, the European Council charged the European Commission with evaluating the impact of the pharmaceutical incentives and rewards for the EU.[5] The Council's motivation was to assess to which extent the EU legislation is efficient and effective and considers whether it is fit for purpose in the light of developments in the area of pharmaceuticals.[6] The Commission responded by commissioning a study on the question, which sparked further discussion.[7] Recently a similar type of study focusing on medicines for rare diseases (orphan medicinal products) was published together with a European Commission staff working document. The main concern in the two documents is how to incentivise further research and development in the vast number of unexplored rare diseases without risking overcompensating pharmaceutical companies, which would result in higher prices and thus increased strains on Member State healthcare budgets.[8]

GROWING GLOBAL GAP POINTS TOWARDS A SHOWDOWN

The above situations are by no means unique. And while they are completely uncoordinated, we do not believe they are unrelated. In fact, they seem to be consequences of a growing global gap between healthcare systems' ambition to curb rising costs through price-focused procurement models and pharmaceutical companies' ambition to secure high prices anchored to the value that their medicines create for patients and society at large.

Consequently, we expect to see an increase in the number of conflicts with defensive outcomes like in the above situations: Medicines approved and reimbursed for a small share of the patient population or not at all; the use of competition law to bring down prices; policy initiatives constrained in their creativity and promise of truly effective solutions by a concern to avoid overcompensation.

HOW COMPANIES AND PAYERS MUST REACT

In this environment companies and payers alike must develop new strategies to bring about the best outcomes for patients and their own organisations.

Companies must consider strategies that better align their value proposition with payer needs. This entails developing more transparent budget impact and payer risk assessments rooted in a deeper understanding of KPIs of payers. This becomes even more important when treatments are leveraging a combination of innovative medicines, devices, and digital solutions to provide higher quality of life during the entire patient life. By addressing the value for payers, companies will be better positioned to capturing part of this value (also for digital solutions, which has proven to be difficult for many companies).

Payers must consider ways of getting a better understanding of companies' business critical points in approval and reimbursement negotiations. To increase bargaining power, payers should consider exploiting different negotiation models - including tendering models - and join forces with payers from other regions and even countries.

If you as a pharma company can answer yes to one or more of the following questions, you will be at risk of facing one or more of the situations above:

1. Is your medicine targeting a rare disease?
2. Does your medicine represent a truly significant improvement for patient lives?
3. Is your medicine a re-purposed one?
4. Is your treatment administered markedly different to the currently available treatments (e.g. one-off treatment compared to ongoing treatment)?
5. Are you able to demonstrate the indirect impacts of your medicine – i.e. the 'value' to healthcare systems and the wider economy?

If you as a payer can answer yes to one or more of the following questions, you will be at risk of facing one or more of the situations above:

1. Is the price of the new treatment markedly more expensive than the current available treatment?
2. Will approval and reimbursement of the new treatment threaten one or more of your organisation's KPIs?
3. Are you concerned that new indications may be applied for at the same high price point?
4. Is the treatment administered markedly different to the currently available treatments (e.g. one-off treatment compared to ongoing treatment)?

LOOKING BEYOND THE HORIZON

While companies and payers can benefit from adapting their strategies to better manage the growing global gap, they should also prepare for radically different strategies to avoid the breakdown of the system as we know it. Manifested through a chronic underinvestment in R&D, any prolonged and amplified misalignment between companies and payers would have drastic consequences for patients, healthcare systems and companies. There is therefore a strong case for increasing efforts to align payers' and companies' understanding of the objectives of health systems with respect to patients and long-term financial sustainability, and the commercial risk associated with meeting those objectives.

How can companies and payers take steps to change the trajectory away from a breakdown towards a long-term sustainable path? We provide our thoughts and practical advice on this in a follow-up article to be presented later this year.

About Copenhagen Economics

Copenhagen Economics is one of the leading economics firms in Europe. Founded in 2000, the firm currently employs more than 90 staff operating from our offices in Copenhagen, Stockholm, Helsinki and Brussels. The Global Competition Review (GCR) lists Copenhagen Economics among the Top-20 economic consultancies in the world, and has done so since 2006.

www.copenhageneconomics.com

FOOTNOTES

[1] NICE (2019). Lanadelumab for preventing recurrent attacks of hereditary angioedema, see https://www.nice.org.uk/guidance/ta606/resources/lanadelumab-for-preventing-recurrent-attacks-of-hereditary-angioedema-pdf-82608899683525

[2] Banerji, A., Riedl, M. A., Bernstein, J. A., Cicardi, M., Longhurst, H. J., Zuraw, B. L., ... & Davis-Lorton, M. (2018), Effect of lanadelumab compared with placebo on prevention of hereditary angioedema attacks: a randomized clinical trial. *Jama*, *320*(20), 2108-2121, see https://jamanetwork.com/journals/jama/fullarticle/2716564.

[3] Copenhagen Economics based on the HAEA and CE survey (2018) and HAEi and CE survey (2019) of 833 patients in total with HAE type 1 or 2. The share is based on patients who are currently using on-demand treatment only (n = 316) and patients using prophylactic treatment, who recall a period without access to their prophylactic treatment (n = 279). In the former group, 17 patients report 8 or more attacks in the month before the survey. In the latter group, 18 patients report 96 0r more attacks per year (8 attacks per month times 12 months) in the period without access to their prophylactic treatment. Combining these groups yields a share of patients with 8 or more attacks per month of (17+18)/(316+279) = 6%.

[4] TLV (2019). Underlag för beslut i regionerna. Luxturna (voretigen naparvovek), see https://www.tlv.se/download/18.2e325bfb16afd0e62b5285d1/1559141988196/bes190506_underlag_luxturna.pdf and https://janusinfo.se/download/18.30896a3216dbdf9df5b3d397/1571053054129/Voretigen-neparvovek-(Luxturna)-191014.pdf

[5] European Council (2016). Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, see https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/

[6] European Commission (2020), see https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1248-Evaluation-of-the-legislation-on-medicines-for-children-and-rare-diseases-medicines-for-special-populations-

[7] Copenhagen Economics for the European Commission (2018). Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, see https://www.copenhageneconomics.com/dyn/resources/Publication/publicationPDF/5/445/1527517171/copenhagen-economics-2018-study-on-the-economic-impact-of-spcs-pharmaceutical-incentives-and-rewards-in-europe.pdf

[8] European Commission (2019). Technopolis Group, Study to support the evaluation of the EU Orphan Regulation, see https://www.eucope.org/wp-content/uploads/2020/08/final-report_orphan-regulation-study_en.pdf