Global Counsel

Balancing innovation, pricing and supply chain resilience in the EU Pharma Strategy

Blog post by Giulia Corsi, Senior Associate and Elly Darkin, Associate, 26 November 2020

The pharmaceutical strategy published on Wednesday outlines the European Commission's plan for the sector over the next five years. Its central message is clear: the EU needs to increase cooperation between member states and boost its overall competence in health policy. But perhaps more ambiguous is how the strategy will walk the fine line between incentivising innovation and reacting to political pressures, such as demands for lowering drug prices and 'bringing manufacturing home'. While the plan sets some much-needed direction in terms of addressing headline issues like antimicrobial resistance and medicine shortages, several core tensions remain unresolved.

One of the key issues the strategy addresses is the need to strengthen innovation in areas of unmet need while keeping costs low. The general view is that innovation favours common therapy areas where financial incentives are clear and demand is high, but less so in areas of clinical importance with lower demand. When companies do innovate in these areas, particularly on paediatric medicine and orphan drugs, the price tag is often too high. Drugs like Zolgensma for spinal muscular atrophy, for instance, are increasingly of interest to policymakers from a population health perspective, but less so from a price tag one.

The strategy aims to address this problem by focusing on how to provide financial incentives like increased R&D funding on the one hand and speeding up the approval process on the other. This would, in theory, help lower drug development costs as the timeline from development to market approval is shortened, and incentivise innovation in the sector. However, beyond its intent to revise legislation and break silos between organisations responsible for the approval process, the strategy fails to provide concrete details on how these objectives will be achieved. While there is a clear need to balance incentives for developing novel medicines with the drive to supress costs in a context of increasingly stretched public finances, it is yet to be seen whether the commission has fully grappled with the practicalities of this.

Another pillar of the strategy aims to avoid future shortages of medicines and reduce dependence on non-EU manufacturing, which ties into the EU's recent mandate to achieve "strategic autonomy". The implications for industry here are two-fold. For one, companies can expect greater regulatory pressure to monitor their supplies. The commission will require earlier notification of shortages and comprehensive reporting on stock levels and supply routes by 2022. Translating the concept of 'resilience' into a standardised methodology for reporting on supply chains is the key challenge that lies ahead. Getting this right will help businesses to adjust to new reporting obligations.

On the flip side, enhancing supply chain resilience may involve financial incentives for companies to move manufacturing closer to home. An example of this can be found in France's recent announcement to award state financing of up to 50% to re-shore production of critical industries – of which pharmaceuticals and healthcare are front and centre. Although such initiatives do not yet exist on an EU-wide level, France's plans create a clear direction of travel for future European policy. These financial incentives should be viewed with caution as re-shoring may well raise production costs. State aid may offset these costs in the short term, but businesses will need to assess long term prospects before overhauling global supply routes.

Overall, the strategy raises important questions about the ways in which policy can incentivise innovation, lower costs and reduce over-dependence on individual suppliers in globalised supply chains. The next set of questions will be about how the commission balances these competing aims and how well they align with other initiatives like the IP Action Plan and Data Governance Act. The answer will inevitably involve trade-offs between industry and patient needs and will likely be a case of incremental progress rather than a sector unbound through inventive policymaking.