

vfa response on EU Commission's Roadmap

The Covid-19 pandemic revealed how essential a vital innovation ecosystem is to overcome global health threats, to maintain people's health and to foster European economies. The EU Pharmaceutical Strategy has the potential to strengthen the solid basis we have in Europe and to enhance a policy environment where Europe will catch up to close the gap to other regions regarding medical innovation while recognizing the importance of the pharmaceutical industry.

The German Association of Research-Based Pharmaceutical Companies (vfa) represents the interest of 44 of the world's leading research-based pharmaceutical companies. Its membership employs approx. 80,000 people, 18,000 of them in R&D. In Germany alone, these companies invest more than EUR 7 billion annually in drug research which corresponds to EUR 30 million per working day.

Having a resilient health care system even in pandemic crisis requires a clear commitment to the pharmaceutical industry as a vital building block and a strong collaboration of all relevant stakeholders within the health care system. Hence, the German research-based pharmaceutical industry and the German healthcare system have ensured that all innovative, patented pharmaceuticals have been available in the required quantities through supply chains which withstood stress during the pandemic.

The roadmap currently misses the opportunity to address the necessary drivers of innovation thus, helping to pave the way for Germany and all other European member states to become jointly a world leader in this area. Therefore, the EU Pharmaceutical Strategy must take up the missing elements in order to put Europe on a future-oriented footing. For more pharmaceutical research and development and production in collaboration with reliable international partners, certain factors have a key role:

- A European research infrastructure, the digitization in the health care systems, the availability and the use of health data are needed to generate medical knowledge to develop advanced treatments and vaccines. The structural support for public and public-private research cooperation and close integration with the EU research programme "Horizon Europe" will elevate Europe's potential to speed up patient access. But foremost a European Health Data Space will be an important step for a European exchange of health data.

- A sustainable industrial policy gives companies an incentives framework which is indispensable for progress. Questioning the necessity of intellectual property protection and incentive instruments alike is gambling away confidence in investing in Europe. As a consequence, Europe and especially Germany are increasingly losing ground compared to other countries, specifically the United States and some Asian countries. A strong and reliable IP and incentives framework is key to be an attractive and dynamic location for medical research to meet further unmet medical need i.a. for pediatric patients and patients with rare diseases.
- In contrast to the highly valued patient access to pharmaceuticals in Germany from day 1 of approval, vfa acknowledges that unequal access and lack of availability of medicines in European Member States is seen as an urgent matter that requires solutions. One element to overcome access and availability problems across Europe is the finalisation of the regulation on a sustainable European Health Technology Assessment process, which presents a unique opportunity to ensure harmonisation regarding clinical evidence needs by regulators, HTA and industry. The EU Pharmaceutical Strategy should incorporate this potential and should drive the process between the European legislative institutions.

vfa and its membership stand ready to work with the European Commission, the European Parliament and the national stakeholders, e.g. the Federal Ministry for Health, to come to the best solution for a better healthcare in Europe and consequently in Germany.

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