A STRONG EUROPEAN PHARMACEUTICAL INDUSTRY BEYOND 2020
The BPI e.V., with over 260 members, represents the whole spectrum of the pharmaceutical industry, ranging from multinational corporations to small- and medium sized companies, Mid-Caps as well as Start-ups. These companies ensure timely and safe drug supply for all patients across the European Union and globally. But to remain competitive and to be able to accomplish this mission, the next European legislative cycle should lay the foundation with a targeted industrial policy. In particular, this policy should highlight the importance of SMEs and Mid-caps.
A Strong European Pharmaceutical Industry Beyond 2020

1. Stronger commitment for SMEs and Mid-Caps

Small and medium sized companies (SMEs) as well as Mid-Caps are the driver of the European economy and should as such be strongly supported. The European Union is already strongly supportive for SMEs. However, the existing SME definition is no longer fit for purpose and requires a revision. New business models, digitalisation and globalisation demand a flexible definition which should include sector specifics. Additionally, a strategy for Europe’s Mid-Cap companies should be developed. This would allow to acknowledge the specific needs of several industries, such as the pharmaceutical industry. We therefore strongly advocate to follow up on the resolution passed by the European Parliament in July 2018 to elaborate on a separate strategy for Mid-Cap companies.

2. More focus on incremental innovation

The BPI e.V. acknowledges the fact that disruptive innovations are essential for the benefit of patients all over Europe, especially in the field of Orphan Medicinal Products and Paediatrics. Further, incremental research and drug repurposing, which is the process of identifying new uses for existing medicines, constitute a dynamic field of drug development and hence, offer substantial benefits to a vast patient population. The next European Commission has a unique opportunity to support incremental innovation and not only disruptive innovations. The future research framework programme Horizon Europe should include funds for incremental research as well. Furthermore, the extension of data protection periods for repurposed medicinal products within the regulatory framework could further incentivise incremental research across Europe.

3. Ensure a balanced incentives system

On the quest of the Member States the European Commission has launched the so called “Incentives Review”. It shall scrutinize the legal and economic incentives for pharmaceutical companies in research & development for innovative products, especially in rare diseases and medicinal products for children. These incentives have brought great medical progress and many added benefits to patients all over Europe. It is estimated that 5000 to 8000 distinct rare diseases exist in the European Union1. For orphan medicinal products alone, there are now 1227 products active2 thanks to the incentives laid out in the OMP regulation. In case, the European Commission feels the pressure to propose changes to these incentives, the pharmaceutical industry urges to act with utmost caution as these incentives are the basis for medical progress in Europe as well as a substantial competitive advantage globally.

4. Development of a European Administrative Law

Over the decades, the European Union gained more and more power and competencies. Hence, the confrontation of citizens as well as companies with the Union’s institutions, bodies and agencies increased immensely. However a codified administrative law does not exist up to this date but existing rules and principles on good administration are scattered across a variety of sources. In the case of the pharmaceutical industry, this is most evident in administrative actions taken by the European Medicines Agency (EMA). However, there are no existing procedural rules to dispute any administrative deed issued by the EMA directly with the EMA itself. There is no body comparable to the one that was introduced with the REACH regulation which offers applicants the possibility to object a negative decision issued by the EMA comparable to the one that was created in the ECHA as this would contribute to the certainty of law and reduce the burden of the European Courts.

5. A strong European cooperation on health, while respecting the principle of subsidiarity

To ensure strong health care policies which will contribute to the well-being of European citizens, a strong and effective cooperation is of utmost importance. Especially in areas where a national approach is not effective enough as for example in the area of antimicrobial resistance or communicable diseases. Nevertheless, in areas where there is no clearly identified need for European action, the principle of subsidiarity has to be respected. The organisation of health care systems is and should remain a competence of the Member States as different health care systems throughout the European Union call for different measures. The goal to secure excellent care and accessible medicines for all European citizens can also be achieved with consistent health care policies rather than legislative actions.

1 European Commission (2015): Inventory of Union and Member States incentives to support research into and the development and availability of, orphan medicinal products. State of Play 2015, p.1
2 Ibid, p.3