Cristian Silviu Buşoi MEP, Chair of the ITRE Committee

Dear Commissioner Kyriakides, Commissioner Gabriel, Commissioner Breton,

We are writing you this letter with the aim to convey our hopes for the future of the EU´s health policies in light of the review of Union´s legislation in the pharmaceutical sector.

We welcome the European Commission´s initiatives to review the pharmaceutical legislation, and we very much hope that it can build on the EU's success of unlocking new medicines, innovative therapies, address unequal access and shortages.

We want to ensure that R&D is again carried out in the EU, that the revised legislation creates more jobs, strengthens the EU's export position and global competitiveness, and that we stimulate the pharmaceutical industry to develop the medicines that we need. We would also like to underscore our concern around the trend of Europe losing ground to other parts of the world when it comes to R&D and clinical trials.

We have successes to build on: over the last decades, we have seen the pharmaceutical industry respond to the incentives put in place at EU level, and this precedent should be the basis of how we ensure the industry continues to direct research and innovation in the areas we, as societies, need most. Particularly the EU legislation on medicines for rare diseases and paediatric medicines has been a success story which we should be proud of as Europeans and look to build on.

As we have seen during the COVID-19 Pandemic, when there are vital issues facing our populations, we need vital EU industries to be able to respond effectively. We should focus on how to make sure the Union continues to play a leading role in vital industries, so as to truly achieve strategic autonomy. This includes setting an EU research agenda and the prioritisation of R&D in areas of societal interest to the EU, be it anti-microbial resistance (AMR), neurodegenerative disease or rare and paediatric conditions to name a few.

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There is more to do when it comes to reducing inequalities and delays in access. These are crucial areas we need to address, particularly at Member State level. We also must ensure that ruthless speculators, such as we have seen with the Martin Shkreli/Valeant cases, do not take advantage of a system without providing any additional value to patients or society. Resolving these issues however should not and does not have to come at the expense of incentives needed to unlock tomorrow's cures. Only with a framework at EU level that encourages more focused medicine development, can our national health systems continue to provide medicines to patients. We note with concern the focus of some actors to clamp down on the role of the pharmaceutical industry, regardless of the impact it has on the development of medicines, and our autonomy as a Union of Member States to determine our future research agenda, while in global competition with, for example, the US and China.

As such, we call for three key priorities to be kept in mind in the revision of all health legislation:

First, take back control of the research agenda by ensuring the environment for R&D in the Union is highly competitive, including through world class regulatory procedures that attract more research and clinical trials to take place in the EU – this includes better access to more (anonymised or pseudonymised) health data for both private and public researchers to unlock the power of data and avoid that ideas in scientists' minds get lost due to a lack of access to data. In fact, to respond to developments in science and technology and to keep pace with fierce global competition, Europe's regulatory framework must evolve and EMA processes should become more agile. This includes for instance the use of new types of clinical trials or better dialogue throughout medicine development between EMA and sponsors.

Second, ensure that Europe has vital industries within its borders to reinforce our strategic autonomy in health research, especially as a bulwark against future crises: this means that any legislative change should drive industry and public research bodies to develop more, not fewer, medicines. This means we ought to build on the legacy of the Orphan and Paediatric legislation by strengthening incentives for treatments for these diseases, incl. through new incentive models aligned with our societal values, instead of limiting the existing incentives. This includes maintaining eligibility criteria and current thresholds for the orphan incentives. Equally, this means continuing to maintain current intellectual property incentives: these have been vital to attract private investment into R&D to research unmet need. Where this does not yield results, we ought to find ways that attract more investment and removes roadblocks, without losing what currently works well.

Third, fight against inequalities and delays in access to medicines: this must take on board a holistic analysis of root causes of launch inequalities, taking into account the complex interplay of 27 autonomous healthcare systems. This also means refraining from disproportionate obligations or elements over which economic

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operators have limited controls. For instance, linking incentives to the launch status of medicines – as has been floated by the Commission – does not take into account that pricing and reimbursement processes and speed are governed by national rules over which companies have no control. At best, it would be ineffective to reduce inequalities, and at worst it disincentivises launches in Europe altogether, further hurting EU production and competitiveness. As such, we need solutions that accelerate the filing for pricing and reimbursement by companies, but also quicker and more effective national procedures.

We hope that these considerations can form the basis of pharmaceutical legislation in the next years, that we learn the lessons of COVID-19 around the need for a robust research engine in Europe, that supports EU global competitiveness and exports, and that the final legislation unlocks the next EU success story in addressing the needs of vulnerable patients.

Sincerely,

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