ReAct feedback to Pharmaceutical Strategy Roadmap

ReAct welcomes a new EC led Pharmaceutical Strategy. We wish to note some shortcomings of the pharmaceutical system and concerns with how the EC seeks to overcome these challenges. See specific recommendations in attachment.

Public-health driven priority setting
To ensure pharmaceutical industry outputs are aligned with public health needs, the EC must set priorities based on unmet needs, and not what generates economic returns for pharmaceutical companies. Although COVID-19 could not have been predicted, there have been several coronavirus outbreaks over the last two decades. And yet commercially driven priority setting means that unmet health needs were ignored. Despite decades of warnings, there has not been adequate investment to anticipate and address rising drug-resistant infections. Unless the EC and governments set such challenges as a priority and put forward appropriate funding, the EU will lurch from crisis to crisis. One intervention to set priorities is through target product profiles (TPPs) generated via consensus amongst health experts. TPPs encourage the development of products that are effective, appropriate, and affordable.

Transparency
To ensure an effective end-to-end system, the EC should improve transparency of: (1) the terms and conditions negotiated between funders and recipients of research and innovation (R&I) funding; (2) the public and private sector contributions for such partnerships, (3) the actual cost of R&I for each new product, (4) the patenting and licensing terms and conditions of government-funded innovations, (5) preclinical and clinical trial data, and (6) prices paid across the public and private sectors.

Avoiding trade-offs between innovation and access
Relying on patent monopolies and high prices as the sole means to pay for new medicines and vaccines discourages the development of new medicines and vaccines that address unmet public health needs. High medicine prices also deprive people of access to medicines. While COVID-19 has illustrated that the EC can pay for most or all of the R&I to address an unmet need, and assume most of the risk, the EC has not restricted patenting or mandated open-licensing of publicly funded inventions. It is time for the EC to not rely upon the patent system to encourage companies to develop new drugs, especially antibiotics. The EU should seek to introduce new mechanisms and approaches to R&I that separate the returns of R&I from volume-based sales revenue.

Antibiotic resistance (ABR)
ReAct welcomes the focus on ABR in the new strategy. However, there is no way to quickly tackle ABR only through developing a new antibiotic, as resistance can emerge quickly unless appropriately used. Only through consistent, sound, transparent, and predictable investments over the coming decades across the health system can the EU reduce the negative consequences of ABR. COVID-19 has also pointed to some of the challenges that need to be addressed comprehensively through an ABR strategy, including shortages of both active pharmaceutical
ingredients and end-products and the misuse of antibiotics. Such shortcomings should be addressed in a new strategy.

Protecting the public interest from the private sector:
ReAct recognises that the pharmaceutical industry must play a role in supporting the development of new medicines and vaccines to tackle ABR. However, EC-led initiatives, such as the Innovative Medicines Initiative, have allowed conflicts of interest to affect the projects, which can undermine goals of transparency, affordability, and public-health led priority setting. We are also concerned that a new partnership of the European Investment Bank with the pharmaceutical industry will undermine priority setting, transparency, and sustainable access to new products that emerge from this partnership.

ReAct looks forward to working with the EC to both develop the strategy and ensure its success.

Attachment: Feedback to Pharmaceutical Strategy Roadmap
ReAct – Action on Antibiotic Resistance welcomes a new EC led Pharmaceutical Strategy and EC’s commitment in addressing antimicrobial resistance. In this attachment to our general response to the roadmap, we wish to provide specific recommendations to address antibiotic resistance (ABR) and to encourage the development of and sustainable access to new antibiotics. Related to this, ReAct recently published a policy brief on the public health principles needed to ensure sustainable access to novel antibiotics:

1. There should be target product profiles for development of truly novel antibiotics to ensure policies and funding are aligned with WHO Priority Pathogen List.

2. The EU should work with other governments and WHO to build a global entity tasked to develop and ensure sustainable access to new tests, drugs, and vaccines. The EC should build upon the lessons learned and the successes and challenges with the approach employed by the Accelerator for COVID-19 technologies (ACT-A). Such an entity should be guided by the principles of public interest, inclusiveness, transparency and safeguards against conflicts of interests. Such an entity should not be confused with initiatives focusing only on coordination of R&D of antibiotics such as the Global AMR R&D Hub, on which we have issued the following position, in which we reiterate the need for adhering to above principles, need for a broader end-to-end approach and broader buy-in from LMIC: https://www.reactgroup.org/news-and-views/news-and-opinions/year-2018/six-key-points-from-react-on-the-provisional-work-plan-for-the-global-amr-rd-hub/.

3. The EC should continue to support and build upon current investments in virtual drug development platforms, such as ENABLE, which has helped to successfully identify and advance the development of new compounds. While ENABLE has been successful, it will be important to take into account lessons learned from other projects under the IMI and in shaping the European Partnership on Innovative Health of Horizon Europe, especially on the appropriate role of multinational pharmaceutical companies to safeguard that the public interest is at the core of the future European Partnership on Innovative Health, as

4. The EU should find ways to reduce the cost of R&D, including through publicly funded clinical trials and by collaborating through clinical trial networks that help to improve patient identification and reduce costs.

5. The EU should introduce incentives for the development of new antibiotics that seek to separate the cost of R&D from sales revenue (prices and volumes), as a means to ensure both affordability and rational use. The UN High Level Declaration, signed by all Heads of State in 2016, stated that governments commit to: ‘delinking the cost of investment in research and development on antimicrobial resistance from the price and volume of sales so as to facilitate equitable and affordable access to new medicines’. https://digitallibrary.un.org/record/842813?ln=en

We believe that this describes a commitment to what has come to be called ‘full delinkage’ even though that term is not used. In contrast, many funders and companies are only committed to ‘partial delinkage’, which does not ensure affordable access to new medicines and as such, does not fulfill what is stated in the Declaration. Such de-linked incentives could include milestone prizes, public funding for end to end development of a new antibiotic and public buyouts of new compounds.

6. The EU should ensure that any new investments in ABR through the Innovative Medicines Initiative, or through programs led by the European Investment Bank, do not allow companies and industry associations to set priorities and policies. We are concerned that the on-going partnerships between the EU and the pharmaceutical industry have and will undermine the ability of the EU to set priorities guided by the public interest and will result in the adoption of incentives and approaches to research and development that favor the pharmaceutical industry, and undermine sustainable access. Even if the EC or EIB chooses to work in partnership with industry, it must set out policies that protect decision-making from the influence and preferences of the pharmaceutical industry, while also ensuring transparency of how decisions are made and put in place clear safeguards to limit industry influence.

7. The EU should consider pooled procurement of antibiotics across the EU which could improve affordability and demand forecasting, provide visibility to suppliers, ensure timely distribution, manage anticipated or sudden disruptions of supply or demand and identify and assist new suppliers when needed to meet increased demand or to replace a supplier that is exiting the market.

8. The EU should consider green procurement rules for antibiotics that improve transparency and accountability and discourage improper practices throughout the supply chain. The EU should also: (a) establish an EU-wide regulatory framework with environmental quality standards and concentration limits, (b) amend the EU Good Manufacturing Practices (GMP) to regulate the environmental release of pharmaceutical residues from manufacturing facilities throughout the supply chain, and (c) ensure a risk-benefit analysis of medicinal products takes into account their environmental risk
assessment in the market authorisation process.

9. The EU should consider regional and public production of antibiotics and other key medical tools to avoid shortages, ensure affordability, and guard against unanticipated disruptions to the supply chain.

10. The EU should consider supporting the establishment of a global patent pool to collectively manage intellectual property for promising or existing technologies to address AMR, including for medicines, as a means to reduce price and manage relevant IP developed in the public and private sector to ensure public health sector leadership in the development of new antibiotics. This could either be accomplished through the Medicines Patent Pool or by expanding upon the efforts of WHO and governments to launch a COVID19 Technology Access Pool (C-TAP).