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Brussels, 19 May 2022

**Subject: Voluntary commitments from pharma industry should not prevent  
legislation to tackle inequities in access to medicines in the European Union**

Dear Commissioner Kyriakides,

I write to you on behalf of the European Consumer Organisation (BEUC), to reiterate our support for the Commission's efforts to identify legislative measures that help tackle disparities in access to medicines across the European Union.

Pharmaceutical companies today are not legally required to market centrally-authorized medicines across Member States within a given timeframe. This leads to an inequity in accessing innovative treatments across the EU.

The pharmaceutical industry in Europe is currently proposing to address the situation with voluntary action.

While voluntary action could help address some inequities in access to innovative medicines, it will not solve matters of public health which are too important to be left to self-regulatory initiatives by the industry. The gains for public health are also likely to be more limited than legislative action. Thus, any voluntary commitments from the industry in response to the Commission's plans with the revision of the pharmaceutical legislation should not stop the EU from adopting ambitious measures that contribute to equitable access to medicines.

We are fully aware that patient access to medicines depends on companies' market entry plans, but also on drug prices and reimbursement-related considerations and decisions. However, patients will not be able to access new, innovative medicines in a timely way if companies delay the filing of pricing and reimbursement (P&R) applications in some Member States, or never in fact do it.

Therefore, the revised EU legislation should either require marketing authorisation holders to file these applications in all EU countries within a short timeframe, or at least require originator companies that do not want to place a product in a specific market to enable generic companies to enter earlier, under fair and reasonable licensing conditions.

You can find in annex our preliminary reaction to the pharma industry's commitments to address inequalities in access to medicines in Europe.

Yours sincerely,

Monique Goyens  
Director General

## **Annex – BEUC reaction to EFPIA’s commitments<sup>1</sup> to address patient access inequalities in Europe**

### **1) A commitment from the industry to file pricing and reimbursement applications in all EU countries no later than 2 years after EU market authorisation, and creation of an ‘European Access Portal’**

Although we welcome a commitment in the current situation, ‘self-regulation’ by the industry often does not cover the whole market and gives no guarantees that initiatives are ambitious enough. Furthermore, in case of non-compliance, the measures are not enforceable by public authorities and failure to comply can consequently not be sanctioned.

Based on voluntary action alone, companies could still unjustifiably delay the filing of their P&R applications and decide based on their own commercial interests that they do not want to file in a particular market, potentially leaving a treatment gap. Thus, we see a need to find legislative approaches that would contribute to improving medicine availability across the EU.

In addition, the portal through which the industry plans to collect information from companies on the P&R status of their medicines, and any report they publish out of it (with aggregate data most likely), should be complemented with a public register managed by the European Commission that reports on the status of medicines availability across the EU. We call for the upcoming pharmaceutical legislation to incorporate such a public register at least for centrally-authorised products.

### **2) Equity-based tiered pricing and novel payment models**

Medicines are essential goods, indispensable to fulfill the human right to health, and should not become luxury goods. The proposal from the industry to create a framework for tiered pricing and other ‘novel pricing and payment models’ does however not guarantee that new medicines will have a fair price. For example, whilst in principle it is positive that industry suggests charging lower prices to a group of Member States with relatively less ‘wealth and ability to pay’,<sup>2</sup> its model could lead to prices that would continue to be too high for countries in both groups.

A key problem is that the industry’s approach to pricing is built upon elements of secrecy and a distorted view to the concept of medicines’ ‘value’. Under such an approach, the price of a medicine is disproportionately linked to its ‘value’, understood broadly as ‘‘therapeutic value to the patient and economic value, including indirect benefits and societal value’’,<sup>3</sup> which will favour the company’s interests. Put simply, the industry proposes that medicine prices fully reflect the benefits they have for society. We join healthcare professionals in opposing the logic that the price of a medicine should equal the costs it saves society.<sup>4</sup>

Instead, we consider that price-setting mechanisms must build on principles of affordability, transparency of costing factors, and public return on public investment. Fair prices are also those that allow drug developers to recover their actual research and development costs without leading to excessive profit margins. In addition, although including added therapeutic value in medicine prices can be a way to reward innovation, this should be done within reasonable limits so that most effective treatments are affordable.

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<sup>1</sup> EFPIA, [‘Addressing patient access inequalities in Europe’](#), 2022.

<sup>2</sup> EFPIA, [‘A shared approach to supporting Equity Based Tiered Pricing’](#), 2022. According to EFPIA’s proposal, Member States in the lower tier would pay less than those in the upper tier for a product’s net price, in the first indication at launch. Companies applying voluntarily this concept of tiered pricing could decide to create additional tiers.

<sup>3</sup> EFPIA, [‘Novel pricing and payment models: new solutions to improve patient access’](#), 2020, page 13.

<sup>4</sup> CPME, [‘The concept of value should not be misused to justify high medicine prices’](#), 2022.

Finally, to ensure information symmetry between national authorities and companies in drug pricing negotiations, authorities should be able to know the price paid by other states for a medicine. The industry's pricing model however opposes information-sharing among payers on medicines' net prices.

Whilst these questions are not strictly linked to the revision of the general pharmaceutical legislation, they are important for the bigger picture regarding how the originator industry's approach to medicine pricing might raise a number of concerns.