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ECL Access to Medicines Task Force

Response to stakeholder consultation on the pilot project 'Market Launch Intentions of Centrally Authorised Products'

Draft response (cap 4,000 characters)

The ECL Access to Medicines Task Force appreciates this initiative of the European Commission. We believe this is a positive step towards increased information sharing and trust-building between companies, governments and other stakeholders. In our view, Member States would be able to anticipate arrival of new treatments and potentially influence the timelines based on national demand. It will also give regulators insights into how market access strategy is formed for different products.

ECL advocates for enhanced transparency throughout the pharmaceutical sector. In this case, we agree that specific information should be kept confidential between the companies and the regulators involved. Nevertheless, publishing a summary report with aggregated data summarising the results of the pilot and its main achievements and shortcoming is crucial.

While reading the project's description, the ECL Task Force identified the following questions:

1. Since participation in the project is voluntary, how does the Commission plan to ensure good representation of companies involved in the project (big pharma vs SMEs, originators vs generics, global vs national etc.)? Will there be any incentives for companies to participate in the project or the potential of better reputation (as to the willingness to cooperate and share this information) among public authorities would be deemed sufficient?

2. We believe question iv. 'What is the underlying reasoning behind the company's intention to not market or delay the launch of a medicinal product in specific countries?' is very important, however, how is the Commission planning to ensure that the information provided by companies is trustworthy and accurate? Would there be any validity check, for instance in terms of comparing the answers of the company with other kinds of data?

3. What would be the role of this project, if any, in relation to the new Pharmaceutical Strategy for Europe and other undertakings, such as the International Horizon Scanning Initiative?

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Thank you for your contribution
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