Access to medicines and strengthening open strategic autonomy – the role of the Pharma package

The ongoing negotiations on a revision of Commission's pharmaceuticals package will play a significant role in defining and determining the regulatory framework for patients' access to novel treatments and innovative medicines and the European pharmaceutical industry's ability to compete globally.

The pharmaceutical package is timely and necessary, and the Commission's proposal includes many promising elements. However, we are concerned that some of the proposed incentives for industry and requirements related to security of supply will not provide an enabling framework for innovation nor make the EU an attractive market for the newest and most effective treatments.

Furthermore, the pharma package cannot be insulated from horizontal political priorities in the EU and must contribute to strengthening the EU's global competitiveness, decreasing strategic dependencies and mitigating critical supply shortages. The pharmaceuticals package should play an important role in strengthening the EU's open strategic autonomy by reinforcing the European pharmaceutical industry's capacity to develop and provide new medicines and life-changing technologies for all Europeans.

We are especially concerned about reducing incentives for developing innovative medicines in Europe and creating unnecessary bureaucracy for pharmaceutical companies, especially when it comes to regulating incentives and security of supply. An example of this is the proposal to reduce the data protection period for innovative medicines and replace it with a complicated spectrum of incentives that make the investment case and market potential for innovative medicines more unpredictable and uncertain. Another example is the extensive reporting obligations on pharmaceuticals that will be costly for both suppliers and Member States without providing a proportional improvement in security of supply. In fact, these additional burdens may in themselves be barriers for producers to supply innovative medicines and generics to the European market and result in fewer treatments being available to patients in the member states.

Transparency and predictability are essential for the pharmaceutical industry's ability to develop and market new, innovative medicines in Europe. Medicines that could help patients across the EU improve their quality of life. The proposed set of bureaucratic hoops that industry will have to jump through will increase uncertainty and place a substantial administrative burden on Member States. The proposed approach is counterproductive to the EU's strategic objectives of reducing bureaucracy in order to strengthen competitiveness and open strategic autonomy.

There is a need for an alternative approach that address the issues of access to medicines whilst providing industry with strategic incentives that contribute to improving health care and achieving our political goals. When it comes to data protection, we see the need to preserve the current regulatory data protection period and build a simpler and more predictable incentive structure. When it comes to security of supply we see the need for less bureaucracy and more concrete initiatives such as a voluntary assistance mechanism that can facilitate the efficient exchange of critical medicines between member states' stocks when shortages occur. This assistance mechanism should include a methodology for fair compensation for assistance provided by Member States.

We trust the Presidency will consider our concerns and our ambitions on how incentives in the pharmaceuticals package can contribute to achieving our twin political goals of strengthening Europe's economic security as well as improving all Europeans' access to innovative medicines.