Question for oral answer O-000049/2022
to the Commission
Rule 136
Kosma Złotowski (ECR), **Anna Zalewska** (ECR), **Beata Kempa** (ECR), **Jarosław Kalinowski** (PPE), **Miriam Lexmann** (PPE), **Andrzej Halicki** (PPE), **Bernhard Zimniok** (ID), **Alexis Georgoulis** (The Left), **Ryszard Czarnecki** (ECR), **Karol Karski** (ECR), **Jörg Meuthen** (NI), **Maria Grapini** (S&D), **Valdemar Tomaševski** (ECR), **Radan Kanev** (PPE), **Krzysztof Hetman** (PPE), **Zbigniew Kuźmiuk** (ECR), **Elżbieta Kruk** (ECR), **Joanna Kopcińska** (ECR), **Gianna Gancia** (ID), **Ondřej Knotek** (Renew), **Elżbieta Rafalska** (ECR), **Andżelika Anna Możdżanowska** (ECR), **Michèle Rivasi** (Verts/ALE), **Jarosław Duda** (PPE), **Anna Fotyga** (ECR), **Hermann Tertsch** (ECR), **Joachim Stanisław Brudziński** (ECR), **Andrus Ansip** (Renew), **Bogdan Rzońca** (ECR), **Beata Szydło** (ECR), **Tudor Ciuhodaru** (S&D), **Manolis Kefalogiannis** (PPE), **Nicola Procaccini** (ECR), **Beata Mazurek** (ECR), **Margarita de la Pisa Carrión** (ECR), **Adam Bielan** (ECR)

Subject: Rebuilding European production capacity for active pharmaceutical ingredients

Currently, the active pharmaceutical ingredients (API) used in medicines produced within the EU come primarily from China and India (about 80 % of API). Similarly, around 40 % of all medicines sold in Europe come from the above-mentioned countries. This situation is caused by the high cost of API production in Europe, determined, among other things, by the need to meet stringent environmental standards.

At the same time, we have not seen adequate EU-level initiatives to encourage manufacturers to invest in API production within the EU. Some countries have already recognised the seriousness of the problem and have introduced local mechanisms to encourage manufacturers to invest in domestic pharmaceutical production. However, for these measures to succeed, EU-wide action needs to be launched.

1. Does the Commission recognise the scale of the problem of the shortage of medicines and the resulting threat to public health in the EU, arising from the dependence of the European pharmaceutical sector on API suppliers from third countries?

2. What actions has the Commission taken so far to strengthen European API production capacity, and have these actions delivered the intended results, including the relocation of API production to Europe?

3. Does the Commission plan to adopt a separate strategy for the restoration of API production capacity in the EU, taking into account the need for regulatory changes and financial support for pharmaceutical companies wishing to produce active pharmaceutical ingredients in Europe?

Submitted: 16.11.2022

Lapses: 17.2.2023