Question for written answer E-003310/2022
to the Commission
Rule 138
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Subject: Need for academic pathway for cell therapy cancer treatment

Cell therapy is a promising development in the treatment of cancer, specifically for cancers of high unmet need, such as acute myeloid leukaemia (AML), glioblastoma and melanoma. Throughout the EU, cancer organisations are investing in academic research on cell therapy, since commercially developed cell therapy is unlikely to solve every unmet need.

However, despite recent efforts by the European Medicines Agency (EMA) to reach out to academics (e.g. to offer them access to the PRIME scheme for priority medicines), the European authorisation procedure is geared towards commercial players. The certification procedure of the Committee for Advanced Therapies is open to small and medium-sized enterprises, but not to academic centres. Gaining market access for these innovative treatments is difficult, which hampers patient access and is not in line with the goals set out in the pharmaceutical strategy. A non-commercial, academically driven pathway is therefore needed to ensure effective, safe and affordable treatments for all patients.

1. Does the Commission agree that all European patients deserve the best possible cell therapy cancer treatment?

2. How will the Commission develop a specific authorisation procedure accessible to academics?

3. Is the Commission considering regulatory pilots in the ‘sandbox’ to develop pathways for the academic development, manufacture and administration of cell therapy?