Question for written answer E-008202/2016
to the Commission
Rule 130
Birgit Collin-Langen (PPE)

Subject: Biotechnologically-produced drugs

On 10 October, DG ECFIN published a Joint Report on Health Care and Long-Term Care Systems & Fiscal Sustainability.

The following appears on page 140 of the report: 'Pharmacies should be allowed to operate generic substitution, and biosimilars substitution under the supervision of a health care provider'.

Substitution by pharmacies is, however, much more controversial in the case of biotechnologically-produced drugs than it is with generic drugs. Many professional entities reject substitution and/or see a need for more evidence in the form of long-term studies, for example.

Under the current authorisation arrangements, the EMA assesses the safety and efficacy of drugs. It does not decide on the suitability of biotechnologically-produced drugs for substitution.

I would like to ask the Commission the following questions:

1. What is the scientific basis for this recommendation by DG ECFIN?

2. Given that the substitution of biotechnologically-produced drugs and their suitability for substitution is not assessed by the EMA and is in fact not authorised in many Member States, can the Commission provide examples of the substitution of such drugs which might support the recommendation?