Question for written answer E-004041/2018
to the Commission
Rule 130
Brian Hayes (PPE)

Subject: Comprehensive SPC manufacturing waiver needed for European patients and SMEs

The Commission recently published a legislative proposal to introduce an export manufacturing waiver to the Supplementary Protection Certificate (SPC) Regulation. Whilst this proposal is welcome, there are significant concerns from industry that it does not go far enough to alleviate existing barriers to enable EU patients to access medicines as soon as the SPC expires, to unlock savings for EU payers, and to allow the development of the generic and biosimilars industry in Europe.

1. Why has the Commission's SPC waiver proposal sought to exclude EU patients from earlier access to more affordable medicines, by limiting its terms to allowing generic companies to produce in Europe only for export outside of the EU?

2. Can the Commission outline the basis for why its existing SPC waiver proposal will prevent access for European patients to more affordable medicines as a result of day one launch after an SPC expiry?

3. Why will the proposal apply only to future medicines and not existing medicines, which are to come off-patent over the coming years, thereby denying more immediate access to affordable medicines to European patients?