Question for written answer E-003011/2014
to the Commission
Rule 117
Marina Yannakoudakis (ECR)

Subject: Challenges posed by the centralised procedure for switching medicines to non-prescription status

The centralised authorisation procedure for new medicines has largely been a single market success story. As a result, most new medicines are now authorised in this way. A prescription medicine with a proven safety and efficacy profile may subsequently be considered for a 'switch' to non-prescription status. However, a medicine can only be switched in an 'all or nothing' manner across the Union.

Member States have diverse regulatory and health system approaches to the provision of non-prescription medicines, whereby some regulators will consider a medicine appropriate for non-prescription status in the specific context of their health system, while others may not. This prevents consumers from accessing treatments that are considered appropriate in the context of their health system.

In the strategy for the pharmaceutical sector currently being drafted within DG Enterprise and Industry, will the Commission address the challenges posed by the centralised procedure for switching medicines to non-prescription status?