Question for written answer E-007113/2016
to the Commission
Rule 130
Richard Sulík (ECR)

Subject: Restriction of the free movement of goods in Slovakia - distribution of medicinal products

The Slovak Act on Medicinal Products in force since 2012 includes a requirement for distributors to notify the national authorities of their intention to export any kind of medicinal product for human use giving 30 days prior notice. The Commission takes the view that this adversely affects the free movement of goods, and opened an infringement procedure against Slovakia that has been running for two years. The draft amendment to the Act changes this requirement into an obligation, incumbent only upon distributors of medicinal products covered by public health insurance, to inform the Slovak institution of the export of medicinal products within 7 days of export.

Is the above obligation for distributors appropriate for such a wide list of medicines?

The draft goes beyond the required changes. It will permit manufacturers and those distributors authorised by them (licence holders) to export medicines. Among other things, such a regulation will also create a conflict of interests for manufacturers with a dominant position in that they must protect public health, but at the same time operate for profit. Public health objectives should, however, be pursued by the public authorities.

Is it possible under EU legislation to delegate the protection of public interests to private producers that have commercial and private interests?

Until the entry into force of the amendments, for as long as the informal negotiations between the Commission and Slovakia continue and further infringement proceedings may be launched, many people will lose their jobs, competition in the distribution market will be destroyed and after years of correspondence the Commission will ‘force’ Slovakia to make further changes to its law on medicinal products.

Are the proposed changes compatible with the internal market, in the Commission’s view?