WRITTEN QUESTION E-5698/07
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to the Commission

Subject: Generic medicines

Generic medicines are products which contain the same active ingredients as the corresponding branded medicines but can be purchased by members of the public considerably more cheaply, and consequently it is reasonable to suppose that their market share will increase. Generic medicines cannot be placed on the market unless they are 'bioequivalent' to a medicinal product which has already been authorised and has the same qualitative and quantitative composition in terms of active substances, the same pharmaceutical form and the same therapeutic implications. The indications are that generic medicines are often wrongly assumed to be equivalent for therapeutic purposes, despite the fact that the permitted variation in bioavailability between one medicine and another (around 20% in Italy) can result in important differences between their respective capacity to deliver the active substance. In the context of the market, the raw materials and manufacturing processes used for the production of generic medicines could raise issues of impaired reliability, while modifications of medical prescriptions by dispensing chemists could jeopardise the protection of public health. Finally, there is no specific legislation governing the excipients – the non-active substances – contained in generic medicines, yet such excipients can give rise to problems of intolerance.

In view of the foregoing, would the Commission state what steps it intends to take to ensure the development of a well-ordered and high-quality generic medicine sector and to protect public health more effectively, and what actions it intends to take to introduce more precise and stringent criteria into the rules applying to the mandatory marketing authorisation process for generic medicines?