EUROPEAN COMMISSION

Brussels, 27.5.2013
C(2013) 2913 *final*

Mr Pietro GRASSO
President of the
Senato della Repubblica
Piazza Madama, 1
IT – 00186 ROMA

Dear President,

The Commission would like to thank the Senato della Repubblica for its Opinion on the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No. 273/2004 on drug precursors {COM(2012) 548 final} and apologises for the long delay in replying.

As regards your suggestion concerning Article 1(2) (a) to (c) the wording proposed by the Commission concerns the case of special licenses and special registrations that may be granted by competent authorities "to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or the armed forces". This wording is exactly the current wording of Article 3(2) and Article 3(6) of Regulation (EC) N°273/2004, which remain unchanged.

Interpretation of those terms in order to clarify to whom special licenses could be granted has been further discussed with the Competent Authorities, and a common understanding has been agreed and inserted in a 'Question & Answer' guidance document. In line with the agreements achieved, universities would not be covered by the particular regime of special licenses[1]*. Similarly the Commission's proposal amending the registration framework does not foresee any exemption of universities under special registration.*

The words "for an unlimited duration" concern the regime of special licences only and have not been changed but exactly copied from the current wording of Article 3(5) of Regulation (EC) N°273/2004. It should be noted that the full sentence states that, in principle, special licenses – which are anyway at the discretion of each competent authority – shall be granted for an unlimited duration, but may be suspended or revoked by competent authorities under the conditions of paragraph 4 third sentence, i.e. "whenever there are reasonable grounds for believing that the holder is no longer a fit and proper person to hold a licence, or that the conditions under which the licence was granted are no longer fulfilled". The competent authorities granting special licences thus have the possibility to revoke them at any time and there is no reason to limit the duration to three years as this would lead to an unnecessary increase of administrative burdens.

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[1] Details are available in Part I-2 and Part II- 4 of the Q&A Guidance document:
http://ec.europa.eu/enterprise/sectors/chemicals/files/guidance_interpretation_drugprecursors_june2008_en.pdf

The proposed delegation of power would allow the Commission to change the lists of substances included in Annex I with a view to quickly react to new emerging trends that are being observed in the diversion of drug precursors from the Union market.

This proposal reflects the outcome of recent discussions with the Competent Authorities from the Member States, where, in the light of new trends of diversion towards non-scheduled substances, some Member States have requested that fast reactions at EU level should become possible. Indeed for the moment, Annex I of Regulation (EC) N° 273/2004 can only be amended through a full ordinary legislative procedure and only in case of amendments of the tables of the UN Convention 1988. Since 1988, no substance has been added to the 23 scheduled substances included in Table I or Table II of the UN Convention, and it is very unlikely that this will change in the near future, while drug traffickers constantly target new substances for diversion.

The proposal is intended to allow the Union to rapidly respond to such developments, by either changing the category for any substance of the 23 substances included in Categories 1, 2 or 3, or by including a non-scheduled substance in one of the three categories in order to strengthen the regime applied to such substance with a view to eventually ensure that diversion towards production of illicit drugs does not occur. The proposal does not foresee the possibility to change the division into 3 categories, through delegated acts.

The Commission shares the view that any changes affecting the regimes of specific measures that are determined in the basic act and which are applicable for the different categories of scheduled substances would not be covered by the proposed delegation of power and would remain subject to the ordinary legislative procedure.

However, the Commission would like to point out that the EU chemicals legislation allows for the inclusion of specific substances or mixtures in Annexes to the basic act, in the light of scientific or technical progress or new emerging facts or practices, in accordance with the regulatory procedure for scrutiny or under delegated acts.

The need to amend the Annexes to the Regulation could occur at any point in time and a limitation of the duration of the delegation could hamper a quick reaction to new developments. The Commission therefore maintains the view that the proposal, by including both a revocation clause and the right of objection, constitutes a balanced solution to the need to ensure a sensible approach to such a quickly evolving and technical subject-matter while having due regard to the prerogatives of the legislator.

The Commission hopes that these explanations serve to clarify the points raised by the Senato della Repubblica and looks forward to continuing our political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President