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From: General Secretariat of the Council
To: Council

Subject: **Employment, Social Policy, Health and Consumer Affairs Council**
meeting on 16 June 2017
Pharmaceuticals in the environment
– *Information from the Swedish Delegation*
(Any Other Business item)

Delegations will find attached an information note from the Swedish Delegation on the above mentioned subject.

Pharmaceuticals in the environment

The pollution of water and soil by pharmaceutical residues is an emerging environmental concern. The challenges posed by pharmaceuticals in the environment are gaining increased attention in Europe and globally.

Besides the environmental consequences, pharmaceutical residues in the environment can be harmful to human health. For example, the release of agents with antimicrobial activity into the environment can contribute to the emergence of antimicrobial resistance (AMR), an increasing global threat for different sectors and sustainable development at large. Further action is needed and anticipated in order to support a life cycle perspective in the manufacturing and handling of pharmaceuticals, where good manufacturing practice (GMP) is a cornerstone, and while considering patients' health.

On 28 April 2017 the European Commission published a roadmap regarding a foreseen communication on a strategic approach to pharmaceuticals in the environment, anticipated to be published during the first quarter of 2018.¹ The initiative is based on a formal requirement to develop the strategic approach.² The roadmap is expected to be followed by a 12-week open public consultation in due course. An inclusive approach would benefit a broad sense of ownership of the final product. It is crucial that different stakeholders and sectors are adequately involved, including but not limited to sectors such as environment and health.

In the light of the above, Sweden invites the Commission to inform the Council about the present work and the future process in the area of pharmaceuticals in the environment.

¹ Ares(2017)2210630. Available from:

http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-2210630_en

² Article 8c of Directive 2008/105/EC (OJ L348, 24.12.2008, p. 84-97) as amended by Directive 2013/39/EU (OJ L226, 24.8.2013, p. 1-17).