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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Employment, Social Policy, Health and Consumer Affairs Council meeting on 8 December 2017
	Issues related to European patients' access to treatment
	 Information from the Romanian delegation
	(Any Other Business item)

Delegations will find in Annex an information note from <u>the Romanian delegation</u> on the abovementioned subject to be raised under "Any Other Business" at the session of the Council (EPSCO) on 8 December 2017.

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Information note on "Issues related to European patients' access to treatment"

Patients' access to effective, innovative and affordable medicines, as well as a functioning and fair pharmaceutical sector are key elements for ensuring adequate health systems in Europe. One of the challenges that many Member States face in achieving this goal is the situation of parallel exports.

In this sense, Romania would like to draw attention to the consequences of parallel exports on the access of patients to treatment. Equality and non-discrimination are two core principles of the European Union; nevertheless, in this particular case, patients of an exporting country have more difficulties in accessing treatment and medicines than other European citizens.

Free movement of goods within the European Union is guaranteed by the Treaty; we respect and support the fundamental freedoms on which the EU is based.

At the same time, we consider that, in the case of parallel export, it should be taken into account that the Treaty also provides for the possibility for a Member State to establish temporary export restrictions, justified on public health reasons. Such prohibitions or restrictions should not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

Romania considers vital that fair and equal access to treatment for all European citizens is ensured, according to the principle of guaranteeing a high level of human health protection enshrined in the Treaty.

The issue of parallel exports requires a coordinated approach in order to jointly identify the most adequate solutions for tackling the existing problems.

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We consider that a European level study on the impact of parallel exports on patients access to treatment, performed by the European Commission's services, would represent a good basis for further common action in this field. In this context, we also look forward to the results of the ongoing study on the supply of medicines.

The challenges that Member States face with regard to ensuring patients' access to effective, innovative and affordable medicines require prompt responses as well as coordinated policies and commitment from all actors of the sector.

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