(3) The review of Regulation (EC) No 1383/2003 showed that certain improvements to the legal framework were necessary to strengthen the enforcement of intellectual property rights, as well as to ensure appropriate legal clarity, thereby taking into account developments in the economic, commercial and legal areas. That review also showed that border measures should not be applicable to other intellectual property rights, particularly patents and supplementary protection certificates for medicinal products where proper determination of infringement is dependent on highly technical judicial proceedings. Likewise, it was determined that border measures should not be applied to goods-in-transit.
(10) In order to ensure the swift enforcement of intellectual property rights, it should be provided that, where the customs authorities suspect, on the basis of adequate evidence, that goods under their supervision infringe intellectual property rights, those customs authorities may suspend the release or detain the goods whether at their own initiative or upon application, in order to enable the persons entitled to submit an application for action of the customs authorities to initiate proceedings for determining whether an intellectual property right has been infringed.

(10) In order to ensure effective and lawful enforcement of intellectual property rights, it should be provided that, where the customs authorities suspect, on the basis of adequate indications resulting from the applicable legal procedures, that goods under their supervision infringe relevant intellectual property rights, those customs authorities may suspend the release or detain the goods whether at their own initiative or upon application, in order to enable the persons entitled to submit an application for action of the customs authorities to initiate proceedings for determining whether such intellectual property rights have been infringed.

Or. en
(17) Under the ‘Declaration on the TRIPS Agreement and Public Health’ adopted by the Doha WTO Ministerial Conference on 14 November 2001, the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. In particular with regard to medicines the passage of which across this territory of the European Union, with or without transshipment, warehousing, breaking bulk, or changes in the mode or means of transport, is only a portion of a complete journey beginning and terminating beyond the territory of the Union, customs authorities should, when assessing a risk of infringement of intellectual property rights, take account of any substantial likelihood of diversion of these goods onto the market of the Union. It is therefore of particular importance that customs authorities ensure that any measures taken up by them are in line with the Union’s international commitments and its development cooperation policy under Article 208 TFEU, and do not detain or suspend the release of generic medicines the passage of which across the territory of the Union, with or without transshipment, warehousing, breaking bulk, or changes in the mode or means of transport, is only a portion of a complete journey beginning and terminating beyond the territory of the Union, where there are no clear and convincing evidence that they are intended for sale in the Union.
**Justification**

The recital is amended to be in line with the last judgements of the ECJ on goods in transit. The interruption of medicines supply chains, even temporarily, has grave consequences for patients, especially in developing countries and in the case of patients with chronic illnesses who must take medicines at regular intervals.
Amendment 110
Anna Hedh, Evelyne Gebhardt
on behalf of the S&D Group

Report
Jürgen Creutzmann
Customs enforcement of intellectual property rights

Proposal for a regulation
Recital 17 a (new)

Text proposed by the Commission

(17 a) Medicines that bear a false trademark or trade description misrepresent their origin and quality level and thus should be treated as falsified medicines under Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. Adequate measures should be taken to prevent such products from reaching patients and consumers, without hindering legal generic medicine from transiting the customs territory of the Union. By ...* the Commission should present a report analysing the effectiveness of current customs measures aimed at combating trade in falsified medicines, and the possible negative impact on the access of generic medicine in relation to this.

1 OJ L 174, 1.7.2011, p. 74.

*OJ: please insert the date: 24 months after the date of entry into force of this Regulation.

Amendment

Or. en
Justification

Legitimate generic medicines should under no circumstances be treated as falsified medicines.
27.6.2012

Amendment 111
Anna Hedh, Evelyne Gebhardt
on behalf of the S&D Group

Report
Jürgen Creutzmann
Customs enforcement of intellectual property rights

Proposal for a regulation
Article 1 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. This Regulation shall not apply to goods-in-transit, meaning products passing across the territory of the Union, with or without transshipment, warehousing, breaking bulk, or changes in the mode or means of transport, for which transit through the Union is only a portion of a complete journey beginning and terminating beyond the territory of the Union.

Or. en
27.6.2012

Amendment 112
Anna Hedh, Evelyne Gebhardt
on behalf of the S&D Group

Report
Jürgen Creutzmann
Customs enforcement of intellectual property rights

Proposal for a regulation
Article 2 – paragraph 1 – point 1 – point e

Text proposed by the Commission
Amendment

(e) a patent as provided for by the legislation of a Member State;
deleted

Or. en
Amendment 113
Anna Hedh, Evelyne Gebhardt
on behalf of the S&D Group

Report
Jürgen Creutzmann
Customs enforcement of intellectual property rights

Proposal for a regulation
Article 2 – paragraph 1 – point 1 – point f

Text proposed by the Commission
(f) a supplementary protection certificate
for medicinal products as provided for in
Regulation (EC) No 469/2009 of the
European Parliament and of the
Council;

Amendment
deleted

Or. en

Justification

Supplementary protection certificates for medicines should be excluded from the scope of the regulation. Any potential commercial benefits that IP holders could derive from the detention of competitor's medicines at the border cannot offset the damage to public health should legitimate generic medicines be targeted.