



Council of the
European Union

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PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	10 September 2015
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2015) 426 final
Subject:	Proposal for a COUNCIL DECISION establishing the position to be taken on behalf of the European Union within the Council for TRIPS and the General Council of the World Trade Organisation as regards the request from least developed country members for an extension of the transitional period under Article 66(1) of the Agreement on Trade Related Aspects of Intellectual Property Rights concerning certain obligations related to pharmaceutical products, and for a waiver from the obligations under Article 70(8) and (9) of that Agreement

Delegations will find attached document COM(2015) 426 final.

Encl.: COM(2015) 426 final



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Proposal for a

COUNCIL DECISION

establishing the position to be taken on behalf of the European Union within the Council for TRIPS and the General Council of the World Trade Organisation as regards the request from least developed country members for an extension of the transitional period under Article 66(1) of the Agreement on Trade Related Aspects of Intellectual Property Rights concerning certain obligations related to pharmaceutical products, and for a waiver from the obligations under Article 70(8) and (9) of that Agreement

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

The objective of this proposal is to allow the European Union to join a consensus in the World Trade Organisation (WTO) on the adoption of two decisions.

First, a decision granting an extension for least developed countries (LDCs) of the Transition Period under Article 66.1 of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) for certain obligations with respect to pharmaceutical products for as long as they remain least developed countries.

Second a decision granting a waiver from obligations with respect to pharmaceutical products under Article 70.8 and Article 70.9 of that Agreement for least developed countries for as long as they remain least developed countries.

The extension and the waiver are due to expire on 1 January 2016. Bangladesh on 23 February 2015 on behalf of the least-developed country Members requested an indefinite extension of the Transition Period under Article 66.1 from TRIPS and an indefinite waiver from obligations under Article 70.8 and Article 70.9 with respect to pharmaceutical products for as long as they remain least developed countries.

The proposal provides that the Council authorises the Commission to take a position on behalf of the European Union within the WTO to join a consensus as regards the said decisions.

- **Consistency with existing policy provisions in the policy area**

The initiative is fully consistent with existing policy provisions. Similar decisions have been adopted previously.

The European Union supported the Doha Declaration on TRIPS and Public Health of 14 November 2001 in which it was agreed that the least-developed country Members would not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement, and the Council for TRIPS was instructed to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement (WTO document WT/MIN(01)/DEC/2).

The European Union supported the Council for TRIPS Decision of 27 June 2002 under Article 66.1 TRIPS which extended the Transition Period during which least-developed countries do not have to provide patent protection for pharmaceuticals products until 1 January 2016 (WTO document IP/C/25).

The European Union supported the related Decision by the WTO General Council on 8 July 2002, giving least-developed countries a waiver from granting exclusive marketing rights under Article 70.9 of the TRIPS Agreement until 1 January 2016 (WTO document WT/L/478).

The European Union also supported extending the general transition period, agreed by WTO members on 11 June 2013, for least-developed countries to apply TRIPS provisions until 1 July 2021 (WTO document IP/C/64).

- **Consistency with other Union policies**

The initiative is fully consistent with European Union policies. It is coherent with the EU's global health policy as defined in the Commission Communication on Global Health and its objective to keep essential medicines accessible and affordable in line with the Doha Declaration (COM (2010) 128 Brussels).¹ It is coherent with other actions to promote access to medicines for all as noted in the EU 2013 Report on Policy Coherence for Development (SWD (2013) 456 final).

2. **LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY**

- **Legal basis**

Article 218(9) of the Treaty on the Functioning of the European Union (TFEU) provides that when a Decision having legal effects needs to be taken in a body set up by an international agreement, the Council, on a proposal from the Commission or the High Representative of the Union for Foreign Affairs and Security Policy, shall adopt a Decision establishing the position to be adopted on the Union's behalf.

The extension of the Transition Period and the waiver fall under this provision as the Decisions are taken in bodies set up by an international agreement (the WTO Council for TRIPS and the General Council) affecting the rights and obligations of the Union.

The envisaged extension of the Transition Period and the waiver relate to matters falling within the scope of the common commercial policy (Article 207 TFEU) and in particular, to obligations under the TRIPS Agreement.

- **Proportionality**

The policy choice is proportional as the proposed two Decisions at WTO level do not go beyond what is necessary to achieve the objective of joining the consensus at the World Trade Organisation on the request of least-developed country Members and the policy choice to support the request is in line with the policy the Union subscribed to in the Doha Declaration on TRIPS and Public Health of 14 November 2001.

- **Choice of the instrument**

As the two Decisions are to be taken at WTO level a Council Decision is the appropriate instrument.

¹ http://ec.europa.eu/health/eu_world/global_health/index_en.htm

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

Not applicable.

- **Stakeholder consultations**

Not applicable.

- **Collection and use of expertise**

Not applicable.

- **Impact assessment**

No Impact Assessment was carried out as the two Decisions to be taken at WTO level are implementing existing policy subscribed to by the European Union in the Doha Declaration on TRIPS and Public Health of 14 November 2001.

- **Fundamental rights**

The two Decisions at WTO level will provide least-developed country Members the flexibility to choose how best to exercise their right to protect public health and, in particular, to promote access to medicines for all.

4. BUDGETARY IMPLICATIONS

There are no budgetary implications aside from the human and administrative resources required to support the adoption of the two Decisions at WTO level.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

No separate monitoring is required aside from general monitoring of compliance of WTO Members with WTO obligations.

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(4), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (the 'TRIPS Agreement') and Public Health stated that the extension provided for in Article 66(1) of the TRIPS Agreement was without prejudice to the right of least-developed country members to seek further extensions of the transitional periods.
- (2) Pursuant to Article 66(1) of the TRIPS Agreement, the Council for TRIPS is, upon duly motivated request by a least-developed country member, to accord extensions of that transitional period.
- (3) In accordance with paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health and with Article 66(1) of the TRIPS Agreement, the Council for TRIPS, by Decision of 27 June 2002, extended the transitional period during which least-developed countries do not have to provide patent protection for pharmaceuticals products until 1 January 2016².
- (4) On 8 July 2002, the General Council of the World Trade Organisation (WTO) adopted a closely related decision, giving least-developed countries a waiver from granting exclusive marketing rights under Article 70(9) of the TRIPS Agreement until 1 January 2016³.
- (5) On 23 February 2015, Bangladesh, on behalf of the least-developed country members group, requested an indefinite extension of the transitional period under Article 66(1)

² WTO document IP/C/25.

³ WTO document WT/L/478.

and an indefinite waiver from the obligations under Article 70(8) and (9) of the TRIPS Agreement⁴ for as long as they remain least-developed countries.

- (6) As there has been a separate waiver for pharmaceutical-related intellectual property rights since 2002, it is appropriate for the Union to agree with the extension so as not to hinder least-developed country members access to pharmaceuticals products.
- (7) Several WTO members appear ready to grant that indefinite extension and permanent waiver, and therefore the Union should join the consensus in line with its continuous support for the Doha Declaration on TRIPS and Public Health. However, if a further temporary extension and waiver is the solution finally reached by the WTO members, the Union should also agree.
- (8) It is therefore appropriate to establish the position to be taken on behalf of the Union within the Council for TRIPS and the General Council of the WTO with regard to the request from least-developed country members for an extension of the transitional period under Article 66(1) of the TRIPS Agreement concerning certain obligations related to pharmaceutical products, and for a waiver from the obligations under Article 70(8) and (9) of the TRIPS Agreement,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on behalf of the Union within the Council for Trade-Related Aspects of Intellectual Property Rights and the General Council of the World Trade Organisation shall be as follows:

- (a) to agree with the request for the granting to least-developed country members of an extension of the transitional period under Article 66(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the 'TRIPS Agreement') concerning certain obligations related to pharmaceutical products;
- (b) to agree with the request for the granting to least-developed country members of a waiver from the obligations under Article 70(8) and (9) of the TRIPS Agreement;
- (c) to accept the proposal for the extension referred to in point (a) or the waiver referred to in point (b) or both to continue to be applicable for as long as each least-developed country member of the World Trade Organisation remains a least-developed country;
- (d) alternatively to point (c), to accept a proposal for a temporary extension or a temporary waiver or both where the proposal is also acceptable to the other members of the World Trade Organisation.

⁴ WTO document IP/C/W/605.

Article 2

This Decision shall enter into force on the day of its adoption.

Done at Brussels,

*For the Council
The President*