European Commission

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union.

European Commission

Explanatory Meeting

Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

8 February 2019, Brussels

General context

Doha Declaration on TRIPs Agreement and Public Health – November 2001

WTO General Council Decision - August 2003

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Need for a Community Intervention: to tackle inter alia HIV/AIDS, malaria and tuberculosis in the drive to reduce poverty.

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Regulation (EC) No 816/2006 represents an instrument aiming to allow the compulsory licensing procedure of the WTO decision to fit within the context of EU MS' national patent law

Main provisions (1)

- *Establishes a procedure for the grant of compulsory licences in relation to patents and supplementary protection certificates (SPC) concerning the manufacture and sale of pharmaceutical products,*

- *… when such products are intended for <u>export</u> to eligible importing countries in need of such products in order to <u>address public health problems</u> (Art.1)*

Main provisions (2)

- *No specific restrictions on the pharmaceutical products covered*
- *Requires notification (Art. 3) to the European Commission regarding the national "competent authority"*

Main provisions (3)

- *Eligible importing countries (Art. 4): LDC and certain WTO members and non-members*
- *Conditions (art. 10):; special labelling; need also of compulsory license for import in the importing country if the product is patented in that market; remuneration; non-exclusive and non-asignable*
- *Prohibits re-importation (Art. 13 to 15); See Regulation (EC) No 953/2003 on anti-diversion of medicines*

Main provisions (4)

- *Any person may submit an applications for a compulsory licence to the "competent authority" (Art. 6); in general, show previous unseccessful negotiations with right-holder (Art. 9.1)*
- *Notification to the patent-holder (Art. 7)*
- *MS will notify the Council for TRIPS through the Commission (Art. 12)*
- *Safety and efficacy of medicines for export (Art. 18)*

2016 Refit

- *One of the trade rules facilitating access is EU legislation encouraging companies to sell medicines at lower, tiered prices in poor countries. In 2016 the Commission evaluated this legislation as part of its REFIT regulatory fitness and performance programme.*

2016 Refit (2)

- *The evaluation concludes that the Regulation still has a role to play in the efforts to target major diseases together with all the other Commission measures in the context of the aim to continue promoting an ambitious global health agenda and better access to medicines in poor countries.*

Thank you for your attention

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