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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE REFIT EVALUATION

of the

Council Regulation (EC) 953/2003 to avoid trade diversion into the European Union of certain key medicines

{SWD(2016) 124 final}

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE REFIT EVALUATION

of the

Council Regulation (EC) 953/2003 to avoid trade diversion into the European Union of certain key medicines

Council Regulation (EC) No 953/2003 established a procedure to ensure that HIV/AIDS, tuberculosis (TB) and malaria medicines sold to developing countries at discounted prices would not enter the EU to be released for free circulation, re-exported or placed under suspensive procedures or in a free zone or warehouse. The aim was to encourage pharmaceutical producers to make the products available in developing countries at heavily reduced prices and in significantly increased volumes by ensuring that they remain on those markets. Companies can register products that they are supplying at a heavily discounted price in beneficiary countries. Those products cannot then be imported into the EU for any of the above purposes.

The Regulation was part of a comprehensive framework that the EU adopted to step up its action on HIV/AIDS, malaria and TB in the context of poverty reduction. It aimed to address a specific issue as part of a wider 2001 European Commission action plan on HIV/AIDS, malaria and TB. It also demonstrated the EU's commitment to tiered pricing as a mechanism to improve the affordability of, and hence access to, medicines. The plan included other ongoing action not covered by this evaluation, e.g. research and development (R&D) programmes on health, development programmes for the supply of essential medicines in developing countries, the EU's 'global health strategy' and EU action under the World Health Assembly's 'global strategy and plan of action on public health, innovation and intellectual property'.[1]

The Regulation was included in the Commission's regulatory fitness and performance (REFIT) programme for 2013, as the mechanism had been used only to a limited extent. Only one company, GlaxoSmithKline (GSK), had registered medicines under the Regulation and the volume of sales had declined enormously. The Commission reported periodically to the Council on the application of the Regulation, but did not conduct a full review. It was therefore considered appropriate to conduct an evaluation to understand the reasons for such limited use. The evaluation covers the Regulation's functioning and impact from its adoption until 2015.

An external contractor, Charles River Associates (CRA), was commissioned to gather data to evaluate the Regulation. The Regulation was evaluated on four criteria: effectiveness, efficiency, coherence and relevance. This allows us to assess it against key REFIT objectives, i.e. whether it is fit for purpose, whether it has delivered on its objectives at minimum cost and whether there is potential for simplification.

[1] *Global strategy and plan of action on public health, innovation and intellectual property*, 61st World Health Assembly, 24 May 2008; http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf

The Commission's evaluation guidelines[2] mention five standard evaluation criteria: the four above, plus 'EU added value'. This is not covered in this study, as the Regulation relates to matters falling within the scope of the common commercial policy (Article 207 of the Treaty on the Functioning of the European Union (TFEU)); as this is an exclusive competence recognised under Article 3 TFEU, only action by the EU is possible.

On **effectiveness**, CRA found no evidence that registered products were imported into the Community, but noted that this cannot be attributed solely to the Regulation, as GSK took additional measures to prevent diversion.

There appear to be various reasons why other companies chose not to use the Regulation. They no longer judged the risk of re-importation as significant, since they had already taken mitigating measures (e.g. differentiated packaging) themselves. Some companies did not like the fact that the Regulation involved price-capping.

Overall, CRA found that prices fell, but this could not be attributed to the Regulation. However, it did find that the Regulation increased supply of GSK's HIV/AIDS products to the target countries between 2004 and 2008. Although GSK itself sold significantly lower volumes of HIV medicines under the Regulation from 2009, overall more of its medicines were supplied as it granted licences to generic manufacturers. In 2011, medicines sold under the Regulation and by licensees represented one year's supply for over a million people. GSK's medicines thus represented an important contribution to HIV treatment.

On **efficiency**, CRA found that the Commission only incurred administrative costs in running the scheme. These pertain to the working time for introducing the Regulation, for the work of the expert committee and for drawing up annual reports, and are not substantial. Overall, CRA estimated the costs at around 40 person/weeks. There were no costs for customs.

GSK incurred costs in registering products with the Commission and adding a logo on its packs. CRA estimates these at around €200 000 for the whole period. There were also one-off costs of getting regulatory authorities to amend/extend marketing authorisations for the medicines due to a change of packaging. As the fee for such amendments in several countries is estimated at more than €100 000, CRA estimates the overall costs associated with the logo at several hundred thousand euros.

Other companies choosing to use the Regulation would face similar administrative and authorisation costs.

In addition to the logo, GSK used other more costly methods. It changed the colour and formulation of two products, which required regulatory approval in Europe and other countries where the products were sold. In turn, this required additional evidence to demonstrate comparable efficacy and safety. GSK put the regulatory approval costs at several million euros.

Companies that do not use the scheme are under no legal obligation to take measures and so face no additional administrative burden.

The benefits of the Regulation include an offsetting of costs, as it reduced GSK's need to use other, more costly anti-diversion processes for some products in some areas. CRA concluded

2 http://ec.europa.eu/smart-regulation/evaluation/index_en.htm.

that the benefits can be assumed to have offset the administrative costs. Also, the Regulation improved transparency on the prices at which HIV, TB and malaria medicines were sold to developing countries. Lastly, it sent a signal of support for the use of tiered pricing to improve access to medicines.

Therefore, the costs of the EU intervention appear proportionate to the benefits.

CRA found that the Regulation is **coherent** with other EU policies and action, in particular medicines and trademarks legislation, and trade policy measures on customs and international customs cooperation, and highly compatible with the EU's international obligations and cooperation in the field of health and development, e.g. the WHO global strategy and plan of action (see above), to which the EU is committed and which aims *inter alia* to encourage differential pricing.

CRA found that, given the low risk of HIV/AIDS, TB and malaria products being diverted, the Regulation is of limited **relevance** today as a means of preventing imports of tiered-price products into the EU. However, it found that tiered pricing can still contribute in general to better access to medicines.

It can be considered questionable whether a Regulation to reduce the risk of trade diversion is still needed, as this is largely addressed by action taken by the pharmaceutical companies themselves, better control of supply chains under aid programmes and legislation on the control of medicine supply. For example, access to modern treatment has improved greatly with the creation of the Global Fund to fight AIDS, Tuberculosis and Malaria, which spends USD 3.5 billion a year in developing countries. Collectively, the EU contributes about 50 % of Global Fund resources, the Commission about 5 % (€370 million for 2014-2016 from the Development Cooperation Instrument and the European Development Fund).

However, most stakeholders consider that the Regulation still has value as a signal of support for the concept of tiered pricing. CRA's analysis concludes that the most likely consequence of repealing the Regulation is that the EU would be seen as retracting its support for tiered pricing.

Overall, CRA concludes that the Regulation has limited value, but the costs are equally limited (and justifiable) and repealing the Regulation carries a risk. Although the net benefits of the scheme are small, there is justification for maintaining it.

In view of these conclusions, the Regulation was assessed against the **REFIT objectives**.

It is considered that the objective of improving access to medicines in the poorest developing countries remains relevant, that tiered pricing still has value and that the Regulation is a signal of EU support for it.

As the costs of using the Regulation are small in comparison with the other costs associated with putting medicines on the market and companies that do not use the scheme face no administrative burden, it is concluded that the associated costs and burdens are minimised and that there is no further potential for simplification.

An EU regulation is required to achieve the objective of ensuring that customs authorities prevent the re-importation into the EU of HIV/AIDS, TB and malaria medicines sold to the poorest developing countries at discounted prices. Action at EU level was needed, as the existing rules did not empower customs to seize re-imports of parallel-traded medicines. The

Regulation empowered the customs authorities to detain, or suspend the release of, products registered under the Regulation. Therefore, there is added value in intervention at EU level.

Furthermore, intervention as such has added value in the context of the EU's commitment to the WHO global strategy and plan of action; one aspect of encouraging differential pricing is to take action against product diversion.

In that context, the Regulation has added value as a signal of support for tiered pricing. Private initiatives cannot send the same signal of public support. Stakeholders are receptive to such signals and the most likely consequence of withdrawing the Regulation is that the EU would be seen as retracting its support for the concept of tiered pricing.

We therefore conclude that, in view of the small administrative burden, the benefits that have been realised, the added value of a signal of support for tiered pricing, and its place in the overall context of action targeting major diseases, the Regulation still has a role in the future in the context of the Commission's aim, as stated in the *Trade for all* Communication[3], to promote an ambitious global health agenda and better access to medicines in poor countries.

As an example of the other action being taken, on 6 November 2015 the World Trade Organisation (WTO) Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) decided to exempt least developed countries (LDCs) from obligations to provide patent protection for pharmaceutical products, so as to support access to medicines until at least 2033. The EU gave its full support to this measure.

Other EU action includes the global health strategy (part of the commitment to the WHO global strategy and plan of action), Commission-funded development programmes for the supply of essential medicines in developing countries and health aspects of research programmes with developing countries.

[3] COM/2015/0497 of 14 October 2015