RUSSIA RATIFIES THE PROTOCOL ON COMPULSORY LICENSING OF MEDICINES PRODUCTION

On 19 July 2017, the Federation Council approved a draft law 'On the Adoption of a Protocol on Amending the Agreement on Trade-Related Aspects of Intellectual Property Rights'.

The Protocol[1] was adopted by the decision of the WTO General Council (WT/L/641) dated 6 December 2005, and is open for adoption by WTO member states until 31 December 2017. As of January 2017, 114 (out of 164) WTO member states acceded to the Protocol.

Pursuant to the Protocol, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is supplemented with Article 31bis and an Annex (the ″Annex″) that defines the extended application of the mechanism allowing WTO member states to issue compulsory licenses for the production of generic medicines for export and, where required, to use immunity if their actions are challenged by other WTO member states.

The mechanism is as follows. The least developed WTO member states or member states that have insufficient production capacities in the pharmaceutical sector or do not have such capacities at all (the 'Importing Members') file an application with the Council for TRIPS, which:

1) shall indicate name and expected quantity of the required medicine;
2) shall confirm that the relevant Importing Member has determined that it has insufficient or no production capacity in the pharmaceutical sector for certain medicine in one of the ways specified in the Annex to TRIPS;
3) shall confirm that if a medicine is licensed in the territory of that state, it has granted or intends to grant a compulsory license in accordance with the provisions of TRIPS and Annex thereto enacted by the Protocol.

An exporting WTO member state, which applies this mechanism for the production and export of medicines to the relevant Importing Member (the 'Exporting Member'), issues a compulsory license that must contain the following conditions:

1) the quantity of medicines necessary to meet the needs of the Importing Member that may be produced under the license and the entirety of this production shall be exported to the member state, which has notified the Council for TRIPS on its needs to;
2) medicines produced under the license must be clearly identified as being produced in accordance with the mechanism by means of special labelling. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price;
3) prior to the delivery of the respective medicines, the licensee shall publish on a website the information on the quantity of medicines to be supplied to each destination point and on the distinguishing features of those medicines.

An Exporting Member shall notify the Council for TRIPS of the issue of the license and terms and conditions thereof. The notices shall include, inter alia, the name and address of the licensee,

[1] Official text: https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm

medicines for which the license was granted, their quantity, state (states) to which the medicines are to be supplied, and the license validity period.

This mechanism can be applied by any WTO member state that meets the requirements for the Importing Member, whose production capacities in the pharmaceutical sector meet the criteria established in the supplement to the Annex to TRIPS.

Therefore, ratification of the Protocol will provide an opportunity for Russian manufacturers to organise the production of generic medicines using patents to the original medicine for the purposes of providing assistance to other states.

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Best Regards,

GRATA International Law Firm (Moscow)

Corporate and Commercial Law Department

What we do:

- advising on the statutory requirements and restriction regarding the import and circulation in Russia and other EAEU member-states of medicines and medical products;
- advising and legal support in participating in public procurement;
- advising on legal compliance of advertising and marketing materials and activities, marking, packing, and labels;
- representing interests of companies of pharmaceutical and medical devices sectors in the course of public discussions of the drafts of regulatory legal acts including acts of Eurasian Economic Commission.

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