

client alert

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RESTRICTIONS ON PUBLIC PROCUREMENT OF FOREIGN MANUFACTURED MEDICINES

On 30 November 2015, the Government of the Russian Federation issued Resolution No 1289 (the "**Resolution**") establishing limitations on procurements for state and municipal needs of foreign medicines included on the list of the most important and essential drugs (the "**EDL List**").

The Resolution was officially published on 2 December 2015 and came into force after a seven-day period from its first official publication, i.e. on 10 December 2015.

The Resolution is in line with the strategy of the Russian Government to push for the local production of medicines in Russia. Indeed, the purpose of the Resolution is to develop the national economy, support Russian medicine manufacturers and increase the number of foreign pharmaceuticals companies producing medicines in Russia.

The Resolution provides that, for the purpose of public procurement of medicines included on the EDL List, state and municipal purchasers must reject bids related to the supply of foreign medicines where there are at least two bids proposing medicines (i.e. medicines with the same International Non-Proprietary Name (INN) or, in the absence of INN, with the same chemical or group name) manufactured in the Eurasian Economic Union (currently the Russian Federation, Belarus, Kazakhstan, Armenia and Kirgizstan) (the "**EEU**") by different manufacturers (not being affiliated companies).

The "country of origin" of the medicine is to be determined in accordance with the Treaty on the Rules for Determining the Country of Origin of Goods Within the Commonwealth of Independent States, dated 20 November 2009.

The Resolution provides for a transition period until 31 December 2016 for foreign medicines (i.e. medicines not originating from the EEU) that undergo (i) primary and secondary packaging in the Eurasian Economic Union, or (ii) only secondary packaging but in compliance with high quality control rules. These medicines will be excluded from public tendering procedures starting from 1 January 2017, if at least two local competitors propose generics manufactured in the EEU.

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