



# To Whom It May Concern

**23 March 2022**

**Supply Situation for Actemra® IV - Outlook for 2022**

**Roche-Ref.: TW1690162**

Dear Madam,

Dear Sir,

The purpose of this communication is to provide an update on the supply situation of Actemra IV. Subsequent to our communication dated 13-Sept-2021, this update takes into consideration Roche's expanded manufacturing capacity, the recent approvals for the use of Actemra in COVID-19 patients (e.g. emergency use authorizations in the United States and approvals in Australia, EU/EEA and some other countries), and the uncertainties associated with the further development of the global pandemic situation.

In our communication of 13-Sep-2021, we have informed about the risk of supply interruptions up to December 2021 in many countries, especially for Actemra solution for intravenous infusion (Actemra IV). We were hoping that sufficient re-supply would be available to allow countries to build up safety stocks after December 2021.

## Current Status of Production Capacity and Outlook into 2022

Over the course of 2021, Roche has more than doubled the production capacity of Actemra IV compared to pre-pandemic levels in order to meet the growing demand across the world. We will continue our efforts to further expand the production capacity for Actemra IV also in 2022, and we expect to almost triple production compared with pre-pandemic levels.

## Demand for Actemra IV

The global demand for Actemra continues to be unprecedentedly high and highly uncertain. The

already realized and the projected expansion of production capacity would be sufficient to avoid further drug shortages only under the assumption that the global demand in 2022 remains at a comparable level as in 2021. Given, however, the recent surge of infections, the uncertain impact of the new omicron-variant, and expected approvals of Actemra for Covid-19 treatment in additional countries, we have to expect a further increase of the demand for Actemra IV. The risk of shortages will continue to be substantial also in 2022.

#### Distribution of Actemra IV

Roche will therefore continue to follow a central allocation model to try and meet patient needs in the most equitable way possible across the globe.

After the recent approvals of Actemra for COVID-19 in Australia and EU/EEA, we expect that more countries will approve Actemra for this indication for the benefit of those suffering with severe COVID-19, which may further increase the global demand. Therefore, and in order to maximize the impact of Actemra IV on patients around the world, Roche will apply allocation principles. These principles consider patients with life-threatening conditions who have limited or no other treatment options as first priority (CRS, sJIA). The supply for Covid-19 will then be maximized based on patient need, and then we will make our best efforts to uphold our commitment to meet chronic patients' needs (RA, pJIA).

We regret that, despite our best efforts, the expansion of our production capacities is still not sufficient to allow countries to build safety stocks, and that we will have to continue following an allocation model for Actemra IV in order to avoid stock outs. Roche will continue to work very closely with the individual markets to better understand where the immediate need is and to quickly respond to such needs, and with national Health Authorities in case of actual shortage situations.

#### Call for reporting

Healthcare professionals should report any adverse events, which are suspected to be associated with the use of Alecensa

It is important to inform any Suspicious Adverse Event Report of products. It will help continuously assess the risk/benefits. Healthcare professionals should report any suspicious adverse event reports online to the Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan via website: [www.pharm.am](http://www.pharm.am), emailing: [vigilance@pharm.am](mailto:vigilance@pharm.am) via tel.: (374 60) 830073, (+374 10) 230896 street hot line: (+374 10) 200505; (+374 96) 220505.

You may also contact to Local person for Pharmacovigilance for Hoffmann- La Roche products in Armenia Acti Group LLC, Gayane Ghazaryan via following contacts: mob.: +374 91 796688, email: [gayaneh.ghazaryan@gmail.com](mailto:gayaneh.ghazaryan@gmail.com); or back up, Nune Karapetyan via following contacts: mob: +374 91 721153 or email: [nune.karapetyan.roche@gmail.com](mailto:nune.karapetyan.roche@gmail.com).

You may also direct your reports to Roche Georgia LLC via following contacts: tel.: +995 322 506284; +995 322 507284 or email: [georgia.safety@roche.com](mailto:georgia.safety@roche.com):



Company Contact Point

In case of additional information, you may contact to Gayane Ghazaryan, a Local person for Pharmacovigilance for Hoffmann-La Roche products in Armenia Acti Group LLC, Gayane Ghazaryan via following contacts: mob.:

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