Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Roche Registration GmbH submitted in 2021 an application for RoActemra[1] 80mg/4mL vial (20 mg/mL) concentrate for solution for infusion, to be assessed with the aim of including RoActemra in the list of prequalified medicinal products for the treatment of coronavirus disease 2019 (COVID-19) in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.

RoActemra was assessed according to the "WHO Procedure for Prequalification of BTPs or their corresponding SBPs"[2] and relevant applicable guidelines by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

The prequalification of this product by the WHO Prequalification of Medicines Programme is based on the approval by a stringent regulatory authority (SRA), namely the "European Medicines Agency" (EMA; http://www.ema.europa.eu/ema/) in line with the applicable guidelines[2].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Team: Medicines (PQTm). However, according to the above-mentioned guideline WHO verified that the product, and in particular composition/formulation, strength, manufacturing, specifications, packaging, product information, will, at the time of submission and after prequalification, in all respects be the same as the product registered with the reference SRA ("verification"). Furthermore, WHO requested additional data for the safe use of the product in regions relevant for prequalified products and this information is included in the WHOPAR (part 6b). In order to safeguard product quality throughout its entire intended shelf-life, WHO assessed the evidences to verify the adherence to the principles outlined in the most recent version of the WHO guidelines on the international packaging and shipping of vaccines, also partially applicable to other biotherapeutic products[3], to demonstrate suitability of the packaging to regions outside of climatic zone II. The WHO assessment included the packaging procedures for international shipments and the validation protocols and reports of the shipping boxes used for supply of the prequalified product.

Based on the data submitted the team of assessors advised that RoActemra be included in the list of prequalified medicinal products. RoActemra was listed on 10 February 2022[2].

Licensing status:
RoActemra has been licensed / registered in the European Union.

2. Steps taken in the evaluation of the product

Nov-2021	The applicant submitted the dossier
Dec 2021	The assessment team reviewed the submitted data and accepted the dossier for assessment

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.
[2] https://extranet.who.int/pqweb/sites/default/files/documents/01_Prequalification_procedure_General_0.pdf
[3] https://www.who.int/immunization_standards/vaccine_quality/vaccines_packaging_guidelines2019/en/

Dec 2021	The assessment team reviewed the submitted document and further data was requested on pharmacovigilance. Verification and quality and were found to be in compliance with WHO requirements
Jan 2022	The applicant's response letter was received.
Jan 2022	Pharmacovigilance was found to be in compliance with WHO requirements
Feb 2022	RoActemra was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Name and address of the manufacturer of the biological active substance

Genentech, Inc.

1000 New Horizons Way

Vacaville, CA 95688

United States

Genentech Inc.

1 Antibody Way

Oceanside, CA 92056

United States

Samsung Biologics Co Ltd

300, Songdo bio-daero, Yeonsu-gu

Incheon, 21987

Republic of Korea

Name and address of the manufacturer of the drug product

Chugai Pharma Manufacturing Co., Ltd.

16-3 Kiyohara Kogyodanchi

Utsunomiya-city, Tochigi, 321-3231

Japan

Name and address of the manufacturer(s) responsible for batch release

Roche Pharma AG

Emil-Barell-Strasse 1

D-79639 Grenzach-Wyhlen

Germany

Commitments for Prequalification

The Applicant committed to submit to WHO following each marketing authorization, a brief discussion on how the Applicant has addressed, after product prequalification, any potential differences in healthcare settings, compared to SRAs, that have required a revision of the adequacy of the safety concerns, pharmacovigilance activities, risk minimisation measures and/or traceability of the product.

Inspection status

The sites are inspected by a stringent regulatory authority.