



Ministry of Health and Medical Education
Islamic Republic of Iran

09-Dec-2025

Subject:

The Belgium Health Authority (FAGG) posted on their website information on the contra-indication for patients receiving immunosuppressive treatment and updated pregnancy data - Measles-mumps-rubella vaccine

Dear Sir/Madam:

The Belgium Health Authority (FAGG) posted on their website the "VIG-news" (edition November 2025) containing information on the contra-indication for patients receiving immunosuppressive treatment and updated pregnancy data

Measles-mumps-rubella vaccine and measles-mumps-rubella-varicella vaccine: new contraindication and updated pregnancy data

After analyzing the available data, the PRAC concluded that the SmPC of Priorix must be updated to include a contraindication in cases of concurrent immunosuppressive treatment (including high doses of corticosteroids). Priorix is not contraindicated for individuals receiving local or parenteral corticosteroids in low doses (for example, for asthma prophylaxis or as replacement therapy). This contraindication was already applicable to M.M.R. VaxPro and ProQuad.

Section 4.6 of the SmPC of Priorix and ProQuad, containing pregnancy data, has also been updated. It now states, as with M.M.R. VaxPro, that in a study of more than 3,500 women who were unknowingly in the early stages of pregnancy when vaccinated with a rubella-containing vaccine, no cases of congenital rubella syndrome were reported. Post-marketing research showed that congenital rubella syndrome occurred due to a rubella vaccine strain in a pregnant woman who inadvertently received a measles, mumps, and rubella vaccine. Fetal harm has not been documented when pregnant women received measles, mumps, or varicella vaccines.

Company position:

Belgian Health Authority website posting, containing contraindication information for patients receiving immunosuppressive therapy and during pregnancy, is consistent with the Company Core Data Sheet (CCDS) and the EU Prescribing Information (Summary of Product Characteristics, SmPC) for the measles vaccine, live attenuated virus combined with mumps and rubella vaccine, which states that M-M-R II (also known as M-M-RvaxPro in EU and UK) and ProQuad are contraindicated for patients receiving immunosuppressive therapy and for pregnant



women.

Kindly note that the labeling reference market for MMR II Vaccine for Iran is USA.

In addition, please note that ProQuad Vaccine is not registered in Iran.

Best Regards

Emad Samir Naguib
Electronically signed by:
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Notification regarding MMR Vaccine_ NSS_368

Final Audit Report

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