

RESTRICTED

REPUBLIC OF TURKEY MINISTRY OF HEALTH Turkish Medicines and Medical Devices Agency
Number : E-628204624931227-000-013704 Subject : About Trifarma S.p.A

DOSSIER

In the Rapid Alert System notification conveyed by the Italian Health Authority on September 09, 2022; it is stated that during the inspection of the manufacturing facility of "TRIFARMA S.p.A. (Via Pavese, 2 - 20089 ROZANO (MI) – Italy)", it was found that the GMP requirements were not met.

As a result of the mentioned notification, necessary processes regarding the matter have been initiated by our Agency, and it is required that within 7 days, the member companies inform our Agency's Licensed Drugs Unit, via official letter, about the measures taken and plans made in line with the notification received, regarding the products licensed for sale, which are manufactured with active substance(s) obtained from the aforementioned facility "TRIFARMA S.p.A./Italy" and submit their applications promptly.

Your attention to promptly inform your members about this necessity is kindly requested.

Dr. Asım HOCAOĞLU Agency President

Distribution: Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Turkey Pharmaceutical Industry Association of Turkey Innovative Pharmaceutical Companies Association Association of Healthcare Products Pharmaceuticals, Pharmacy, Healthcare Sciences and Technologies Foundation 04.11.2022