10/09/2021

Prevention of SARS-CoV-2 (COVID-19) infections: requests for the import of unauthorized medicines used in place of authorized vaccines

Thanks to the activities of USMAF, the customs units of the Ministry of Health which are responsible for the evaluation of specific requests for the importation of medicines from abroad, the Italian Medicines Agency (AIFA) has carried out an in depth evaluation of some suspicious import requests concerning the medicine “PARVULAN”.

This medicine, containing *Corynebacterium parvum* as an active substance, is not authorized for marketing in Italy. PARVULAN is authorized and marketed in Brazil (as verified by AIFA with the competent Drug Regulatory Authority, ANVISA) for the following therapeutic indications:
Stimulant of innate immunity, adjuvant in the treatment of dermatological infections of viral, bacterial, fungal and protozoal origin, adjuvant in systemic and local infections. It has a regressive effect on solid neoplasms. Helps in the treatment of erysipelas caused by Streptococcus pyogenes. Adjuvant in the treatment of acne vulgaris.

The in-depth analyses were carried out in order to ascertain compliance with the regulatory framework and the legality of some import requests submitted to USMAF as set out in the procedures in the Minister of Health Decree dated 11 February 1997 ("Rules for the import of medicines authorized in other Countries").
In particular, the requested quantity of the product (thousands of vials) and the reported therapeutic indication (*Herpes zoster*) were considered as grounds for suspicion, also with respect to the number of authorized medicines (and molecules) currently marketed in Italy

Following requests from patients, and queries received with respect to the kind of vaccines to be considered for issuing the "Green Pass" certification, AIFA highlights that in some cases the medicine was proposed for uses that were different from the ones declared in the import request. PARVULAN was sometimes offered for “off label uses” outside the framework of the aforementioned Ministerial Decree (11 February 1997), as a therapy for the prevention of COVID-19, and as an alternative to authorized vaccines.

The competent technical committee, AIFA CTS, after having evaluated the available documentation, stated that the use of the PARVULAN in the prevention of Sars-COV-2 infection is not supported by any evidence of efficacy and safety. AIFA CTS previously declined clinical trials proposals for the use of PARVULAN. The potential use of PARVULAN as an alternative to authorized vaccines is a danger to people's health, due its uncertain safety profile and the unjustified sense of protection that the treatment could generate in the patients.
There is a lack of documented efficacy for this medicine as an alternative to authorized vaccines [to treat Sars-COV-2 infections].

In the light of the AIFA CTS advice on the use of PARVULAN, the Agency considers it essential to draw the attention of the public to the risks associated with unauthorized medicines for the prevention of SARS-CoV-2 infections (COVID-19).

The national vaccination campaign provides enhanced controls over the entire supply chain, aimed at protecting the patients. The administration of authorized vaccines for the prevention of Sars-COV-2 infection takes place exclusively at the official vaccination points, identified by each Region.

The Agency therefore considers it important to remind the public to be suspicious with respect to any alternative to authorized vaccines, or to any vaccine or medicine that has not been subjected to the evaluation of the competent authorities, since they may represent a health risk, due to the absence of any guarantee with respect to their effectiveness in the prevention of COVID-19.

Considering the current public health emergency, the public is advised to be cautious against using any unauthorized vaccine being offered to prevent COVID-19 (Sars-COV-2).

The collaboration of everyone - private citizens, health professionals, companies and associations - is essential to guarantee that suspected cases of unauthorized vaccines to prevent COVID-19 are constantly reported to AIFA. This will help AIFA implement adequate measures to protect public health.