

AIFA GUIDE

HOW TO PROTECT YOURSELF
FROM FAKE 'MIRACLE
CURES':

AIFA recommendations

2026

Alleged stem cell treatments, sold to patients online or via social media, or administered at home in exchange for substantial sums of money by private companies and clinics based abroad. This is the worrying new trend of the so-called 'miracle cures', a business that preys on the vulnerability and suffering of those living with a serious illness for which there is still no effective treatment.

In response to these illegal practices, which exploit the vulnerability of patients, the **European Medicines Agency (EMA)** and the **Heads of European Medicines Agencies (HMA)** have already issued a [joint warning](#): unregulated cell-based products pose extremely serious health risks as they can cause severe side effects and infections, such as meningitis and encephalitis, and offer no proven benefits.

Therapies based on manipulated cells, including stem cells, are genuine medicines, defined as **Advanced Therapy Medicinal Products (ATMPs)**. Both AIFA and EMA work constantly to ensure that these therapies meet the highest standards of quality, traceability and safety, rigorously inspecting both manufacturing laboratories and the facilities where clinical trials are conducted.

At present, very few stem cell therapies have been approved by the EMA: almost all of them are based on genetically modified stem cells taken from the patient who will receive the therapy, and are indicated for genetic disorders such as primary immunodeficiencies, beta-thalassaemia and sickle cell anaemia, neurodegenerative diseases, and ocular burns. At present, only one medicinal product is based on stem cells from donor umbilical cord blood.

Once authorised, these therapies may only be administered in qualified facilities equipped with advanced clinical management capabilities. In Italy, there is a well-defined network for accessing these treatments, with centres distributed throughout the country that operate in accordance with the required standards.

Clinical trials may represent an additional treatment option alongside standard treatments. Members of the public and healthcare professionals can access information on authorised clinical trials at any time, including details of the facilities where cell therapy trials are being conducted, by consulting the [Map of Clinical Trial Centres](#) on the AIFA website.

Access to advanced therapy medicinal products that have not yet been authorised or are not currently the subject of specific clinical trials in Italy is possible only in a hospital setting, subject to specific authorisation from AIFA for individual patients (*'esenzione ospedaliera'* or 'hospital exemption'), where no valid therapeutic alternative is available, in urgent or emergency situations that place the patient's life at risk or pose a serious threat to their health. There are no other home-based or 'alternative' pathways that are compatible with the law and with the fundamental safety requirements for patients.

The work of regulatory agencies continues even after these products have been authorised: through constant monitoring of safety and adverse reactions, as required by the recommendations on cell therapies, which demand particular attention due to potential specific long-term risks.

The objective is twofold: to ensure that therapies intended for patients are based on sound evidence and to protect them from treatments that are unauthorised or lack a scientific basis.

Every year, AIFA receives numerous reports of illegal and counterfeit medicines, as well as cases involving breaches of the regulations governing the manufacture and distribution of medicines. These cases are handled in collaboration and coordination with other institutions responsible for public health protection, to ensure that all necessary measures are taken to put a stop to any illegal and, as such, dangerous practices.

Among the initiatives undertaken by the Agency, those aimed at raising public awareness of the phenomenon of counterfeiting and the illegal trafficking of medicines have been in place for some time, such as the [communication campaign](#) promoting the purchase of medicines through secure channels, which has been run in recent years on the main social media platforms.

To avoid the risk of fraud and protect yourselves from so-called 'miracle cures' based on stem cells, AIFA urges patients and their families to follow a few simple recommendations.

1. NEVER AT HOME: SAFE TREATMENTS REQUIRE QUALIFIED HOSPITAL FACILITIES

There are no legal treatments involving manipulated stem cells that can be carried out at home. The administration of these treatments requires highly qualified and accredited hospital facilities capable of managing every clinical stage in complete safety.

Always be wary of anyone offering invasive procedures (injections, blood samples, etc.) outside an authorised centre. If you have any doubts, consult your doctor or healthcare institutions.

2. THREE REQUIREMENTS FOR LEGAL AND SAFE STEM CELL THERAPIES

In Europe and Italy, all advanced therapies may only be administered legally if one of these three requirements is met:

- Therapies are authorised for marketing by the EMA.
- Therapies are administered within an authorised clinical trial.
- Therapies fall under the [non-repetitive use of advanced therapies](#) (*'esenzione ospedaliera'* or 'hospital exemption'), a special authorisation granted by AIFA for use in hospitals on individual patients in emergency situations and in the absence of therapeutic alternatives.

3. BE WARY OF OFFERS OF 'EXPERIMENTAL' THERAPIES THAT REQUIRE PAYMENT

In Italy, approved advanced therapies are provided at the expense of the National Health Service, and **participation** in any authorised clinical trial **is completely free** of charge for the patient. In any instance where payment is requested to access an 'experimental treatment', you are dealing with a scam.

4. THERE IS NO "CURE-ALL" TREATMENT

Be wary of anyone promoting stem cells as a panacea capable of curing completely different conditions (from cancer to autism to neurodegenerative diseases). Research into advanced therapies is highly rigorous: there are currently very few authorised treatments, and these are targeted at extremely specific conditions.

5. BEWARE OF ONLINE MARKETING FOR "MIRACLE CURES"

These products are often sold via websites and social media as a "last hope", exploiting families' distress. "Promoters" often describe them as "experimental" to justify the lack of authorisation and evidence, but the alleged benefits are not supported by the scientific literature. Science is not based on advertising slogans, testimonials of "miraculous cures" on social media, or links to studies of dubious value published in journals lacking any credibility.

6. ALWAYS CHECK OFFICIAL SOURCES

Before making any decision, always seek a second opinion from qualified medical specialists. If you are offered the chance to take part in a clinical trial, check that it is genuine: authorised trials in Europe can be consulted via the European CTIS (*Clinical Trials Information System*), which is also accessible via the AIFA portal, and other official registers. Always consult relevant patient organisations and report any suspicious cases to the competent authorities, who will be able to intervene to stop illegal and dangerous practices.