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Public statement

Concerns over unregulated medicinal products containing stem cells

The Agency highlights that access to stem-cell medicinal products should only be under certain controlled conditions

The European Medicines Agency is concerned that unregulated stem-cell medicinal products are being offered to patients, for the treatment of a wide range of serious and life-threatening diseases. Stem cells are cells that have the ability to multiply and differentiate themselves into a variety of different types of cells, for example brain cells or cells that make insulin in the pancreas. There are no concerns with haematopoietic (blood) stem cells that are used for transplantation to restore bone marrow function. These are not considered to be medicinal products.

To date, no stem-cell medicinal products have received marketing authorisation within the European Union (EU). However, it is still possible to gain access to stem-cell medicinal products under certain controlled conditions. These include taking part in clinical trials or compassionate-use programmes, or receiving a custom-made medicine as part of 'hospital exemption'.

The Agency and its Committee for Advanced Therapies warn that the use of stem-cell medicinal products outside these controlled conditions may result not only in little or no benefit to patients, but could also be detrimental. This is because, outside these conditions, checks on the quality of these products may not have been carried out, and their safety and efficacy may not be properly assessed. Patients who have used unregulated stem-cell medicinal products may also find that they are not eligible to take part in clinical trials, which are needed for effective medicinal products to be developed properly.

The Agency and its Committee strongly recommend that patients who believe that they may benefit from stem-cell medicinal products should discuss all available regulated treatments with their doctor.

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Notes

1. Clinical trials can only take place after agreement with the national regulatory agency and following approval by an ethics committee. The ethics committee's role is to look at the way the trial will be run to ensure that patients' rights are fully respected, in particular the right to know about the potential benefits and risks of the treatment. Clinical trials should never involve payment from the patient or their families.

2. Compassionate-use programmes allow a doctor to obtain treatment for a given patient while the medicine is still under development. Doctors obtaining treatment under a compassionate-use programme must ensure that their patients are fully aware of the treatment they are receiving.

3. Hospital exemption allows for a medicinal product containing stem cells to be made available to an individual patient in a European hospital under the exclusive professional responsibility of a doctor. This is a custom-made product that is prepared on a non-routine basis according to specific quality standards. It is authorised for use by the regulatory authority of the Member State where the product is made.