Regulation of Advanced Therapy Products

Drug Office
Department of Health

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What are advanced therapy products?

Advanced therapy products (ATPs) are pharmaceutical products[1]. They are medicines for human use based on genes, cells or tissues. ATPs include gene therapy products, somatic cell therapy products and tissue engineered products.

How are ATPs regulated in Hong Kong?

Starting from 1 August 2021, ATPs will fall under the definition of pharmaceutical product in the Pharmacy and Poisons Ordinance (Cap.138) (PPO). As such, regulatory requirements for pharmaceutical products under the PPO and other relevant ordinances including product registration, manufacture, labelling, sale, supply and import and export control, will apply to ATPs.

Are all ATPs sold in Hong Kong required to be registered? How do I know whether an ATP has been registered?

According to the Pharmacy and Poisons Regulations (Cap.138A), ATPs should meet the safety, efficacy and quality criteria, and have been registered with the Pharmacy and Poisons Board ("the Board") before they can be sold in Hong Kong.

The Hong Kong registration number for a registered ATP should be labelled on the sales pack in the form of「HK-XXXXX」. Also, you can refer to the webpage of Drug Office for the registered ATPs (www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/atp_regulation.html) Unregistered ATPs have not been evaluated by the Board, and their safety, efficacy and quality are thus not guaranteed.

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[1] Please refer to the Pharmacy and Poisons (Amendment) Ordinance 2020 for the definition of pharmaceutical product (www.gld.gov.hk/egazette/pdf/20202430/es12020243019.pdf).

Are all ATPs safe and effective?

According to international standards, a new medicine should first be tested in the laboratory and in animal studies before they can be used in clinical trials for human. When the medicine is proved to be safe and effective, it can be put to general uses. Any ATP which fails in any phase of a clinical trial would be regarded as "unproven", which means that its safety and efficacy has not been established. An unproven ATP may pose serious, or potentially fatal, risks to your health including infection, allergic reactions, rejection of the cells by your immune system and development of cancer.

At the same time, the quality of ATPs can affect the safety and efficacy of the products. Therefore, ATPs should be manufactured by qualified manufacturers to ensure that the products can meet the required quality standard.

How can I acquire an ATP? Do the private healthcare facilities that provide ATP treatments need to obtain a licence?

In general, ATPs are prescription only medicines which should be supplied by registered doctors or registered dentists.

In addition, pursuant to the Private Healthcare Facilities Ordinance (Cap. 633) (PHFO), procedures involving the transplant of cell- or tissue-containing ATPs to patients (including autologous transplant) are Scheduled Medical Procedures specified under the PHFO. If such procedure is performed in private healthcare facilities, it should only be performed in hospitals or day procedure centres for which a relevant licence under the PHFO is in force. For further details, please refer to the website of the Office for Regulation of Private Healthcare Facilities, Department of Health (www.orphf.gov.hk). For the definition of Scheduled Medical Procedures, please refer to section 2 of and Schedule 3 to the PHFO (www.elegislation.gov.hk/hk/cap633).

Is all transplant of cells or tissues regarded as ATPs?

High-risk cell and tissue therapy products, e.g. cells and tissues having been subject to substantial manipulation or having changed their functions, are regarded as ATPs. However, certain cell or tissue therapies widely used in medical field, e.g. blood transfusion, bone marrow and cornea transplant, are not regarded as ATPs.

What is immune cell therapy?

The immune cells, which include natural killer cells (NK cells), dendritic cells (DCs), cytokine-induced killer cells (CIK cells) and T cells, are part of our immune system. These cells are usually subject to substantial manipulation in order to be used for medical purpose and if so, are regarded as ATPs.

Currently, there is only one registered ATP containing immune cells, which has chimeric antigen receptor T cells (CAR-T cells) as the active ingredient in Hong Kong.

What is stem cell therapy?

Stem cells are primitive cells that have yet grown into specialized cells. Examples include stem cells derived from cord blood, adipose tissue and sheep amniotic membrane. When a treatment uses stem cells, or cells derived from stem cells, to replace or repair a patient's damaged tissues or cells such treatment is known as stem cell therapy.

Stem cell therapy for medical use in humans is generally regarded as ATP. Currently, there is no registered ATP containing stem cells in Hong Kong. Please note that the safety, efficacy and quality of unregistered ATPs are not guaranteed.

What should I be cautious about if I am considering an ATP treatment?

- Is the ATP registered in Hong Kong? Or, is the product authorized for use in overseas countries?
- Is the ATP manufactured by a qualified manufacturer?
- Where will I receive the ATP treatment?
- Who will be responsible for carrying out the ATP treatment?
- Are there any risks after receiving the ATP treatment?
- Is there any appropriate long-term follow-up, and how?

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