LPMT - EU REGULACE

MUDr. Tomáš Boráň

Státní ústav pro kontrolu léčiv

Obsah

- Centralizovaná procedura registrace
- Komise pro moderní terapie (CAT)
- Procedury CAT
- web EMA

Centralizovaná registrace LPMT

- U LPMT – buď centralizovaná registrace nebo nemocniční výjimka (ne pro všechny!) pro všechny státy EU
- Stejná pravidla pro registraci jako pro jiné LP:

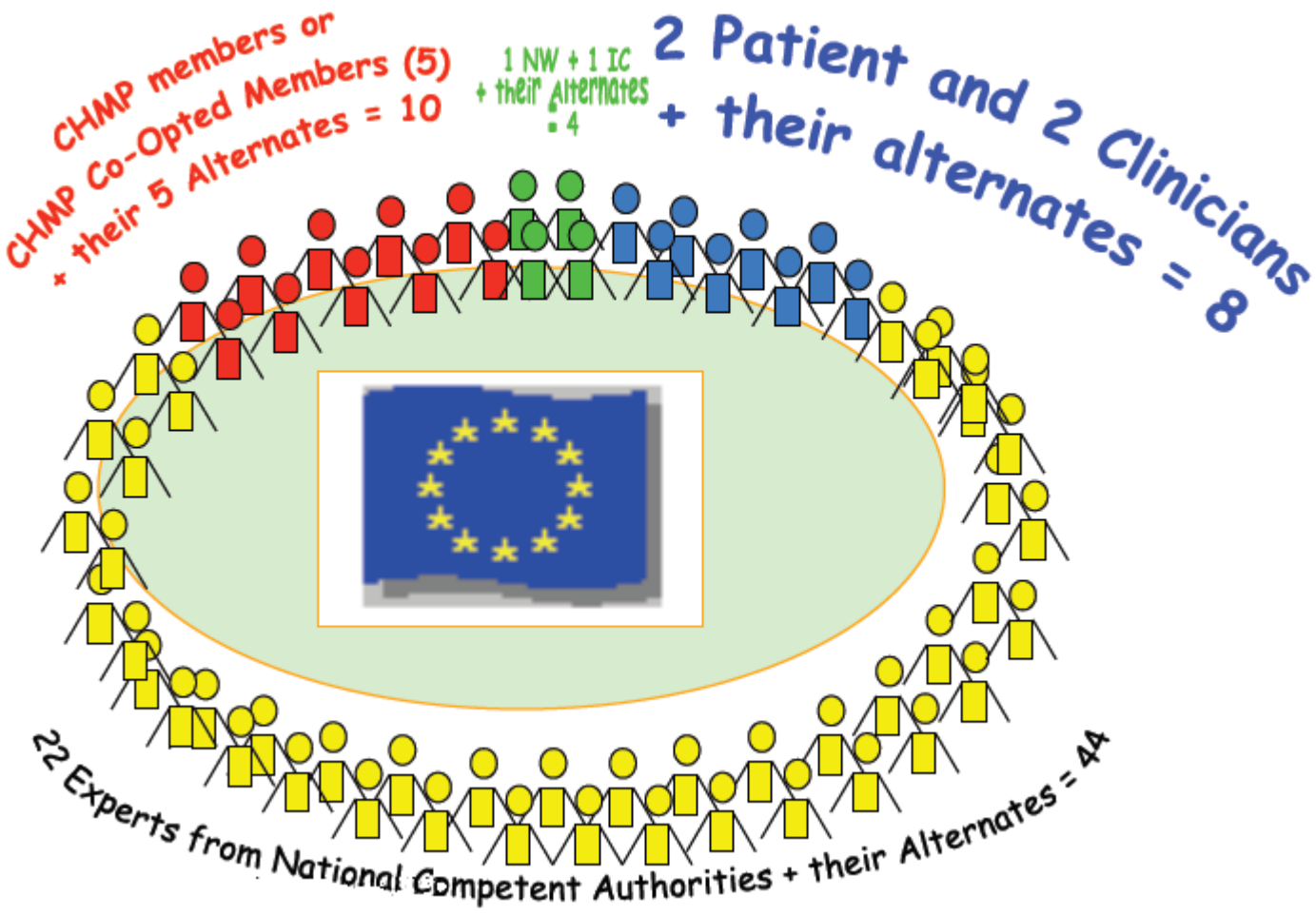
– rozhodnutí o registraci

– průkaz kvality, bezpečnosti a účinnosti

– poregistrační vigilance

Centralizovaná registrace LPMT

- Výbor pro moderní terapie (CAT)
- Mimo posuzování žádostí o registraci 2 další procedury – LPMT certifikace a rozhodnutí k zařazení přípravku
- Pobídky pro SME


CHMP members or
CHMP Co-Opted Members (5)
+ their 5 Alternates = 10
1 NW + 1 IC
+ their Alternates
= 4
2 Patient and 2 Clinicians
+ their alternates = 8
22 Experts from National Competent Authorities + their Alternates = 44

Úkoly CAT

- Hodnocení žádosti o registraci LPMT
- Certifikace
- Stanovisko k zařazení
- Scientific Advice
- Odborné zázemí pro COMP/PDCO/CHMP
- Publikační činnost
- Komunikace s regulovanými subjekty

Hodnocení žádostí o registraci

- Pro LPMT vždy centralizovaná registrace
- V gesci členského státu pouze nemocniční výjimka
- 210 dnů

– 2 nezávislé týmy (Rapp a Co-Rapp) připraví stanovisko pro CHMP, to připraví stanovisko pro EK

- Odborné diskuse na půdě CAT

Certifikace

- Pouze pro SME
- Pro kvalitu nebo preklinická data
- 90 dnů
- Zhodnocení standardů vývoje před registrací
- V případě pozitivního výstupu – certifikát EMA

Klasifikace

- Zdarma pro všechny žadatele
- CAT rozhodne, zda je LP moderní terapií či nikoliv
- 60 dnů
- Zveřejnění výsledků na stránkách EMA
- SÚKL respektuje rozhodnutí CAT

4 June 2013
EMA/341778/2013
Patient Health Protection

Scientific recommendation on classification of advanced therapy medicinal products

Article 17 – Regulation (EC) No 1394/2007

Disclaimer: This document is a summary for public release of a scientific recommendation on classification of advanced therapy medicinal products. The original text adopted by the Committee for Advanced Therapies (CAT) has been redacted to delete commercially confidential information.

The present scientific recommendation refers exclusively to the case as presented to the European Medicines Agency (EMA) without prejudice to future evaluations by the Agency.

This scientific recommendation is not binding and is without prejudice to any decision taken by Member State competent authorities on matters falling within their own remits.

Short description of the proposed active substance

Human autologous tumour-infiltrating lymphocytes (TIL).

Brief description of the proposed finished product

More than one billion of human autologous tumour–infiltrating lymphocytes suspended in 4% human serum albumin.

Proposed indication

Treatment of Stage III melanoma with one invaded lymph node

EMA/CAT comment

Consideration of Article 1(2) of Directive 2001/83/EC

- The product consists of tumour-infiltrating lymphocytes which can be considered a 'substance' in the meaning of the pharmaceutical legislation (in accordance with article 1(3) of Directive 2001/83/EC), administered to humans with a view of restoring physiological functions by exerting an immunological action.

- According to Article 1(2), the restoration, correction or modification of the physiological function is to be mediated by the substances that exert "a pharmacological, immunological or metabolic action". As the product consists of tumour-infiltrating lymphocytes it can be agreed that the product acts via immunological means.
- The product is presented as having properties for treating disease in human being. It is intended to be used for treating patients with stage III melanoma with one invaded lymph node, by exerting an anti-cancer immunological action.

Fulfilment of Article 2(1) of Regulation (EC) No 1394/2007

- The product consists of viable human autologous tumour-infiltrating T cells.
- The product is expanded ex vivo from tumour tissue, which can be considered as a substantial manipulation of the cells.
- The product is presented as acting via immunological means.

Based on the above considerations, it is considered that TILs falls within the definition of somatic cell therapy as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.

EMA/CAT conclusion

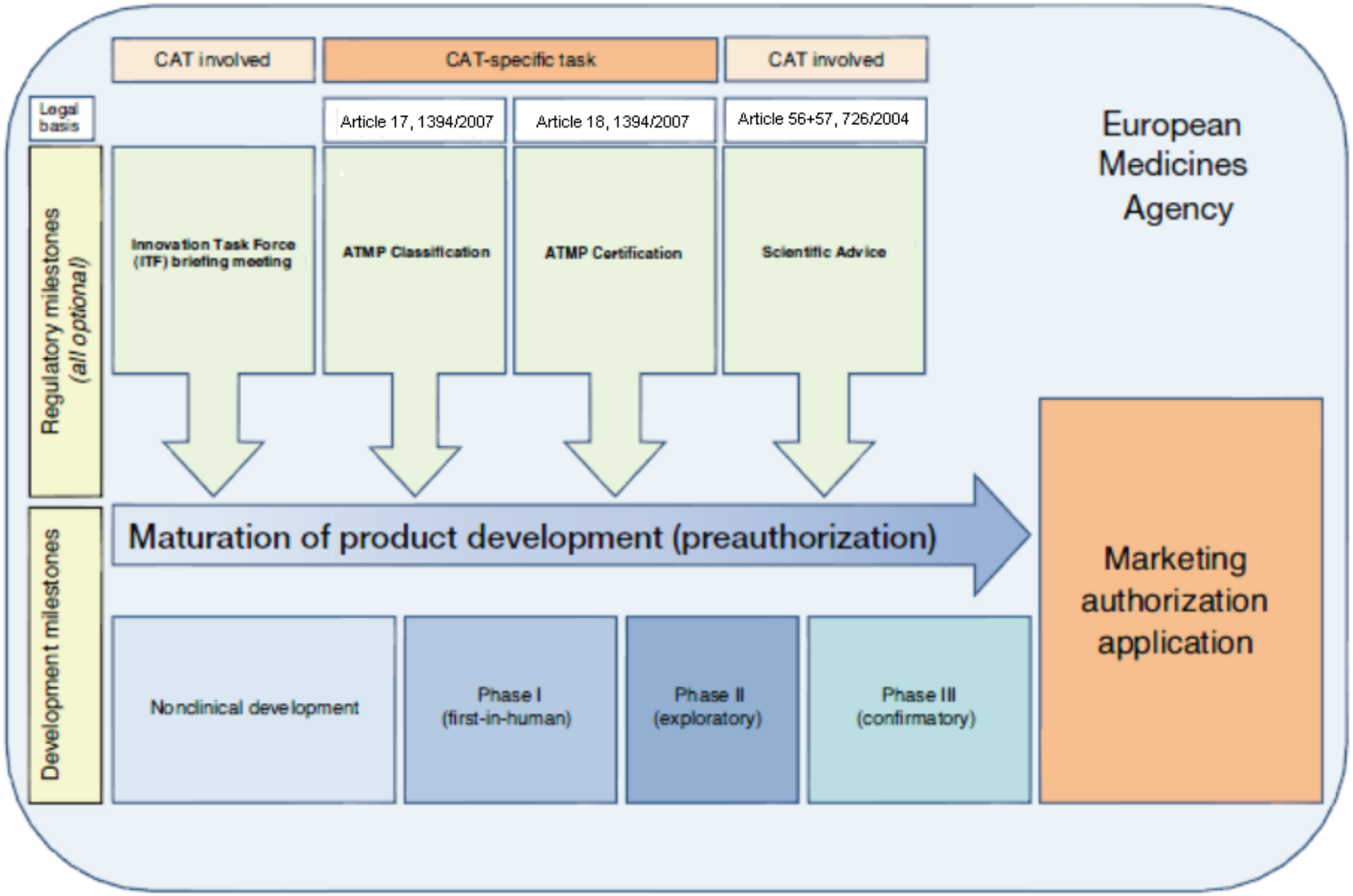
On the basis that:

- The product consists of viable cells that have been subject to substantial manipulation (i.e. expanded ex vivo from tumour tissue) so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered.

- The product is presented as having properties for treating a disease in human being

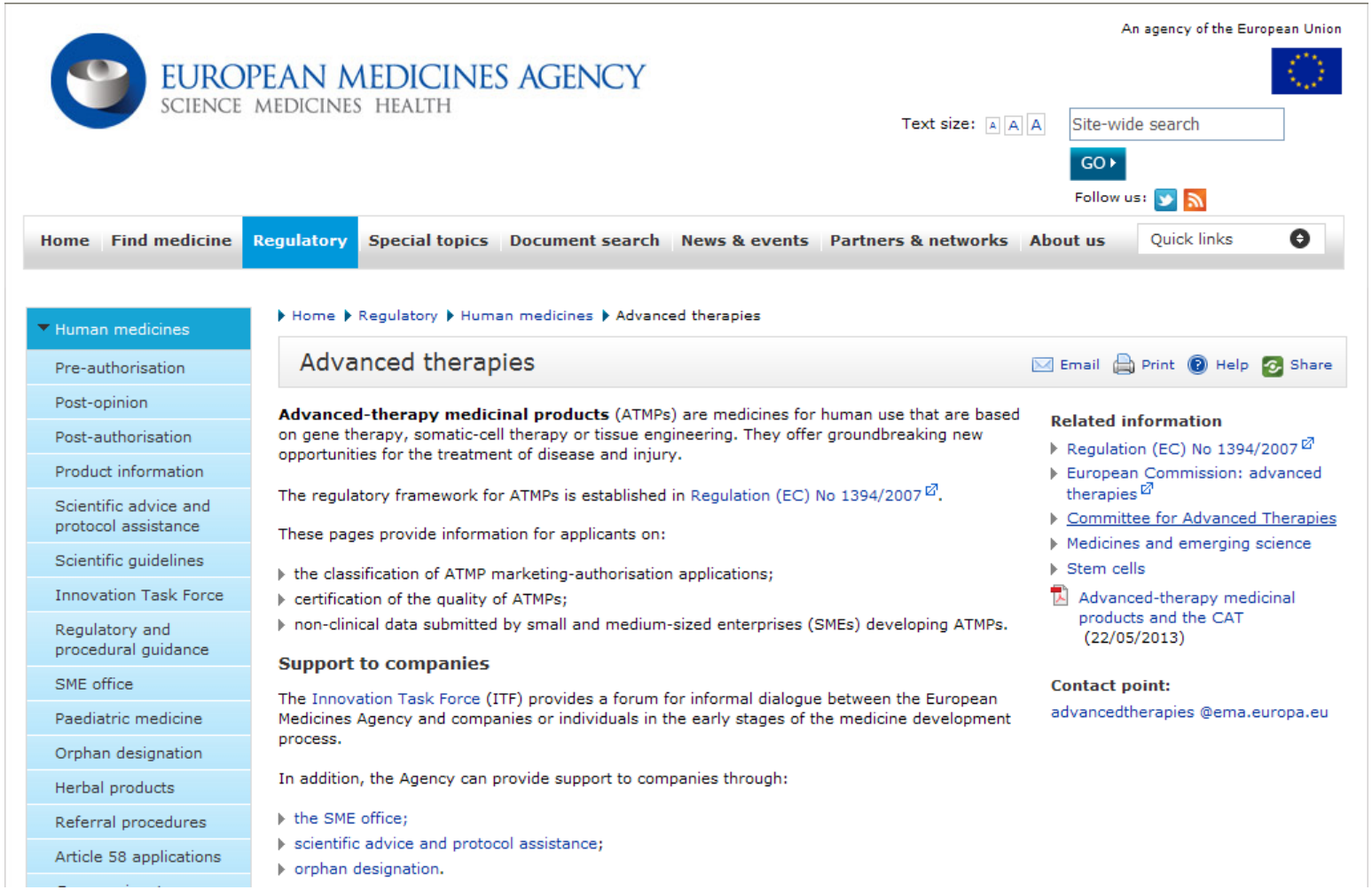
- The product is presented as acting via immunological means

The EMA/CAT considers that the product falls within the definition of somatic cell therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007.


CAT involved
CAT-specific task
CAT involved
Legal basis
Article 17, 1394/2007
Article 18, 1394/2007
Article 56+57, 726/2004
European Medicines Agency
Regulatory milestones (all optional)
Innovation Task Force (ITF) briefing meeting
ATMP Classification
ATMP Certification
Scientific Advice
Maturation of product development (preauthorization)
Development milestones
Nonclinical development
Phase I (first-in-human)
Phase II (exploratory)
Phase III (confirmatory)
Marketing authorization application

Web EMA

- http://www.ema.europa.eu
- Regulatory → Human medicines → Advanced Therapies
- Odkaz na CAT
- Odkazy na guidelines
- Odkazy na zařazení přípravku
- …


An agency of the European Union
EUROPEAN MEDICINES AGENCY
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Scientific advice and protocol assistance
Scientific guidelines
Innovation Task Force
Regulatory and procedural guidance
SME office
Paediatric medicine
Orphan designation
Herbal products
Referral procedures
Article 58 applications
Home ▸ Regulatory ▸ Human medicines ▸ Advanced therapies
Advanced therapies
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Advanced-therapy medicinal products (ATMPs) are medicines for human use that are based on gene therapy, somatic-cell therapy or tissue engineering. They offer groundbreaking new opportunities for the treatment of disease and injury.
The regulatory framework for ATMPs is established in Regulation (EC) No 1394/2007.
These pages provide information for applicants on:
the classification of ATMP marketing-authorisation applications;
certification of the quality of ATMPs;
non-clinical data submitted by small and medium-sized enterprises (SMEs) developing ATMPs.
Support to companies
The Innovation Task Force (ITF) provides a forum for informal dialogue between the European Medicines Agency and companies or individuals in the early stages of the medicine development process.
In addition, the Agency can provide support to companies through:
the SME office;
scientific advice and protocol assistance;
orphan designation.
Related information
Regulation (EC) No 1394/2007
European Commission: advanced therapies
Committee for Advanced Therapies
Medicines and emerging science
Stem cells
Advanced-therapy medicinal products and the CAT (22/05/2013)
Contact point:
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