

3 June 2016  
EMA/388480/2016  
Media and Public Relations

## Press release

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# Regulation of advanced therapy medicines

Report details concrete proposals to encourage development and authorisation of advanced therapy medicinal products (ATMPs) in the EU

The European Medicines Agency (EMA) today published a report from a multi-stakeholder expert meeting held on 27 May 2016 to explore possible ways to foster the development of ATMPs in Europe and expand patients' access to these new treatments.

ATMPs comprise gene therapies, tissue engineered products and somatic cell therapies. These medicines have the potential to reshape the treatment of a wide range of conditions, particularly in disease areas where conventional approaches are inadequate. However, eight years since EU legislation on ATMPs entered into force in 2008, only five ATMPs are currently authorised. At the same time clinical trials investigating ATMPs appear to represent a fast-growing field of interest, underlining the need to better support innovation through a coherent and appropriate regulatory environment.

"We have organised this meeting with all relevant stakeholders to discuss concrete proposals on how we can nurture a regulatory environment that encourages development of ATMPs, safeguards public health and, ultimately, facilitates timely access for patients to much needed treatments," said EMA's Executive Director Guido Rasi in his opening address.

The meeting brought together leading academics and researchers, representatives from patients' and healthcare professionals' organisations, small and large pharmaceutical companies, the investment community, incubators and consortium organisations, health technology assessment (HTA) bodies, national competent authorities and the European Commission. In their discussions they focused on four key areas:

- Facilitating research and development;
- Optimising regulatory processes for ATMPs;
- Moving from hospital exemption to marketing authorisation;
- Improving funding, investment and patient access.

Ideas and solutions proposed by the different stakeholders are summarised in the meeting report published today. Some of the recurring themes include the need for early interaction and guidance from regulators, more transparency and information sharing, greater harmonisation between Member

States on various aspects of the ATMP legislative framework and measures to tackle inequalities in patient access to ATMP treatments.

EMA and its scientific committees, together with the European Commission and the national competent authorities, have started discussing the proposals made during the meeting. Concrete actions will be determined over the next few months and shared with stakeholders.

## Notes

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1. This press release, together with all related documents, is available on the Agency's website.
2. Although a total of seven ATMPs have received a marketing authorisation since 2009, only five ATMPs are currently authorised. One marketing authorisation for an ATMP was withdrawn by the marketing authorisation holder and the authorisation for another ATMP is currently suspended.
3. For a recent analysis on clinical trials with ATMPs see Hanna E, Remuzat C, Auquier P, Toumi M. Advanced therapy medicinal products: current and future perspectives. J Mark Access Health Policy 2016; 4.
4. More information on the work of the European Medicines Agency can be found on its website: [www.ema.europa.eu](http://www.ema.europa.eu)

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