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Advanced therapy medicines: exploring solutions to foster development and expand patient access in Europe

Outcome of a multi-stakeholder meeting with experts and regulators held at EMA on Friday 27 May 2016

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1. Introduction

Advanced therapy medicinal products (ATMPs), comprising gene therapies, tissue engineered products and somatic cell therapies, have the potential to reshape the treatment of a wide range of conditions, particularly in disease areas where conventional approaches are inadequate. Potential candidates for ATMP treatments include severe, untreatable or chronic diseases, and many clinical trials are currently underway in conditions as varied as cancers, cardiovascular diseases, musculoskeletal conditions and immune system disorders.[1] If ATMPs are to fulfil their promise of providing innovative treatments for patients, regulators must nurture a regulatory environment that encourages innovation, safeguards public health and, ultimately, facilitates timely patient access to new therapies.

In the EU, Regulation (EC) No 1394/2007 ('the Regulation') has been in force since 2008, providing a common regulatory framework for ATMPs.[2] Among the Regulation's main benefits is the automatic access to a central route for EU authorisation for ATMPs, with the goal of improving availability of these products to patients in all Member States. The Regulation also set up the Committee for Advanced Therapies (CAT), which brings together relevant expertise from across the EU, and established, among other processes, the classification and certification procedures to aid the early development of ATMPs.

The experience gained to date affords us the opportunity to take stock of how the ATMP Regulation has fared during the first decade of its implementation. One of the issues identified so far is the low number of ATMPs that have proceeded through the regulatory system,[3] impacting patient access to much needed treatments.

To explore ways to foster ATMP development and expand patient access, EMA convened a multi-stakeholder meeting on 27 May 2016, attended by leading academics and researchers, incubators and consortium organisations, and representatives from patients and healthcare professionals organisations, small and large pharmaceutical companies, the investment community, health technology assessment (HTA) bodies, national competent authorities (NCAs) and the European Commission (EC) (see appendix).

This report summarises the main ideas and solutions proposed during the meeting as well as responses sent ahead of the meeting via a questionnaire.

Main topics discussed

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

2. Research and development

ATMPs are intrinsically complex products derived from a variety of biological materials, such as cells, tissues or viral vectors, and their unique characteristics call for special approaches in research and development.[4] At the development stage, developers face the task of ensuring the homogeneity of cell starting material and maintaining continuous supply of raw materials; in addition, certain manufacturing requirements may be not be practical for all ATMPs, and there are various other

challenges related to issues such as the complexity of upgrading immature developmental production technologies to commercial manufacture, process validation and product characterisation.

The pre-clinical and clinical stages also have special requirements, among which are identifying relevant animal models and designing clinical studies able to address small populations, inter-individual variability and complex methods of administration.

Furthermore, developers of ATMPs, who are often small enterprises or spin-offs (incubators) from academia, require support to navigate the regulatory framework and would benefit from further access to capital investment and incentives (see Sections 3 and 5).

A major proposal at the meeting was for licensing requirements to take account of the unique particularities of ATMP manufacture. For example, participants noted that ATMP manufacture can take place at various sites and that, for some products, the later stages of production may need to take place close to the bedside. The implication is that all sites involved – hospitals included –would need to hold a manufacturing licence. A lack of harmonisation at national level was also noted, as some Member States allow hospitals to hold a manufacturing licence while others do not. Stakeholders therefore requested more information and harmonisation.

While industry and other stakeholders acknowledged the need for high standards, they requested authorities to make requirements more flexible during early developmental phases. Specific proposals for cell-based products included adapting requirements for low-risk (non-substantially manipulated) products, as these could be considered to fall on the borderline between transplants and ATMPs. Similarly, a more pragmatic approach should be used to address process validation requirements for many ATMPs, given the difficulty in producing the required number of batches for standard pharmaceuticals.

Other solutions proposed include promoting innovative technologies (e.g. bedside manufacturing and closed systems) and manufacturing models (e.g. decentralised manufacture), which would require more flexibility. Regulators could also promote development of manufacturing sites, as a service, using small and medium-sized enterprises (SME) and other funding, so capability is available to several parties developing different ATMPs.

These suggestions were considered timely, given that the European Commission is currently revising the guideline on GMP requirements for ATMPs and will shortly be launching a public consultation.

Another major topic was genetically modified organisms (GMOs). Stakeholders noted that the GMO Directive (Directive 2001/18/EC) is not specifically designed for medicinal products and its shortcomings in this respect are compounded by divergences in implementation in Member States. Since requirements differ among Member States, the integration of GMO assessment in clinical trials authorisation poses a challenge, particularly in the context of multicentre clinical trials. Developers called for more uniformity and suggested, as an initial step, the setting up of a central repository, in English, listing the requirements and timelines for GMO assessment in every Member State. GMO assessment should also be more closely linked to clinical trial authorisation (CTA), with timelines for assessing GMOs aligned with those of CTAs. In addition, there should be more harmonised applications and processes using the clinical trial portal and database, similar to that envisaged for ethics committees. Some stakeholders also called for changes to the GMO directive itself.

Another area that could benefit from further harmonisation relates to cells and tissues used as starting materials for the manufacture of ATMPs, with stakeholders asking for a more streamlined implementation of the Tissues and Cells Directive (Directive 2004/23/EC) and other relevant legislation. As a starting point, regulators could set up a portal for EU cell and tissue authorities to

provide information on additional requirements for testing cell and tissue starting materials at national level. Further harmonisation should facilitate the movement of starting materials between areas with different requirements (within and outside the EU) and reduce the burden of having to re-test the cells and tissues prior to starting the manufacture of ATMPs. Testing can then be focussed on aspects relevant to the nature of ATMPs.

Industry would also welcome specific guidance on excipients and a master file system for marketing authorisation purposes in relation to excipients and raw materials. They also proposed that consideration be given to novel development tools (e.g. organoids, extrapolation, modelling/simulation, biomarkers, etc.) to address non-clinical requirements.

On the question of the benefit-risk balance of products in development, stakeholders noted that current practice focuses mainly on risks and called for additional emphasis to be placed on expected but realistic benefits, particularly where patients have incurable diseases or where suitable treatments are lacking.

It was also noted that the current risk-based approach puts pressure on Qualified Persons (QPs), as QPs in different Member States may release products according to different interpretations. Stakeholders therefore called for the risk-based approach to be revisited and for more guidance for QPs.

A careful consideration of benefit-risk balance should be part of the early development strategy and discussed with regulators (including HTAs) early in the process to allow requirements to be adapted accordingly. Informal dialogue, for example, through safe harbours such as the Innovation Task Force (ITF) network and more formal discussion through scientific advice are needed. Scientific advice in collaboration with the CAT is a good tool for early dialogue and could be improved by involving inspectors, HTAs and payers. However, it was acknowledged that not all SMEs or academic enterprises have the resources to seek scientific advice.

Finally, stakeholders called for more support from regulators, particularly for academic spin-offs and SMEs with less experience navigating the regulatory system. Suggestions included better training for stakeholder groups (including healthcare professionals) and the creation of a dedicated EMA office for academia with expertise in ATMPs, using the Agency's successful SME office as a model.

Research and Development – main stakeholder proposals

- Take more pragmatic approach with licensing requirements for ATMPs
  - Apply GMP more flexibly in early development phases
  - Increase transparency of manufacturing authorisation requirements across Europe
  - Promote innovative manufacturing technologies (e.g. bedside manufacturing / closed systems)
  - Promote innovative manufacturing models (e.g. decentralised manufacturing)
  - Promote a master file system for excipients and raw materials used in the production of ATMP
  - Encourage development of manufacturing sites, as a service, using SME and other funding, so capability is available to several parties developing different ATMPs.
- Improve implementation of GMO requirements
  - Align GMO assessment with clinical trial applications as currently done for marketing

Research and Development – main stakeholder proposals

authorisation applications

  - Set up central GMO repository listing the requirements and timelines for GMO assessment
  - Harmonise Member State implementation of GMO Directive
- Harmonise cell, tissue, and blood requirements across EU
  - Create public database for EU cell and tissue authorities and approved establishments as a resource for stakeholders
  - Harmonise EU-wide requirements for cells, tissues and blood used as starting materials for ATMPs
- Rethink risk-based approach, placing additional emphasis on expected benefits
- Set up dedicated EMA office for academia with expertise in ATMPs
- Increase incentives and regulatory support
- Provide more ATMP specific guidance (e.g. on comparability), workshops and training
- Promote novel development tools (organoids, extrapolation, modelling/simulation, biomarkers)

3. Regulatory processes

The main objective of the Regulation is that developers of ATMPs, with some exceptions (see Section 4), obtain marketing authorisation so that patients right across the EU can gain access to these treatments.[3] In line with provisions of the Regulation, the CAT carries out the initial evaluation of marketing applications for ATMPs, after which EMA's Committee for Medicinal Products for Human Use (CHMP) issues an opinion. The last step, as with all centralised marketing authorisation applications, is the issuance of a legally binding decision by the European Commission.

The Regulation also introduced two incentives, an optional and non-binding ATMP classification procedure to assess whether products under development meet the strict definition of ATMPs, and a certification procedure to evaluate early quality and non-clinical data with the aim of helping SMEs secure funding during the development process.

In addition to carrying out these procedures, the CAT works closely with the ITF to interact early with ATMP developers and assists with scientific advice. To date, the committee has received 15 applications for marketing authorisation, resulting in 7 EU-wide marketing authorisations (2 of which have been subsequently withdrawn or suspended). The committee has also completed 7 certification and 211 classification procedures and has been involved in 197 scientific advice procedures for ATMPs.[5]

But the CAT is only one of several committees that ATMP developers interact with at EMA, and as such stakeholders would welcome streamlining of their involvement with the committees and support to navigate the regulatory system. One proposal was for the appointment of a single contact person at EMA for each ATMP. This person would help developers through all the necessary procedures at the Agency, providing them with relevant information on their procedures as well as incentives available to them.

Another topic touched upon was EMA's early access schemes, such as PRIME, adaptive pathways, ITF and HTA parallel scientific assessment and the certification procedure. Stakeholders recognised the

value of these schemes and advised that even more could be done to raise awareness among early developers, especially academia.

With regard to certification, some stakeholders called for this to be opened up to non-SMEs, in particular academia and spin-off incubators, as well as to larger companies, and noted that permitting certification on non-clinical aspects alone could further increase the value of the procedure to developers. Some participants raised questions about the consequences of certification, citing concerns that a certification procedure could, for example, trigger a GMP inspection. Regarding the latter, regulators clarified that the procedures do not in fact lead to GMP inspections but rather to informal site visits by experts to assist developers overcome early problems

To truly facilitate development, stakeholders reiterated the need for greater uniformity on how regulatory requirements, including classification, apply in different Member States. The ATMP Regulation is one of the many pieces of legislation governing ATMPs; several others, including the main pharmaceutical directive, GMP Directive, GMO Directive, the tissues and cells and blood directives, and the Clinical Trial Directive may apply, with subtle but sometimes significant differences in Member States.

Stakeholders urged regulators to publish, as a first step, an overview of national requirements for GMOs and tissue and cell and blood products and then to move towards greater harmonisation. It was pointed out that documents for CTAs, and national scientific advice applications could also benefit from harmonisation. Mock-ups of applications could be made available to stakeholders to help them prepare applications.

Given the global nature of medicines development today, stakeholders also called on EU bodies to consider engaging, for example through ICH, with international partners in the US and Japan to harmonise aspects of ATMP regulation. International harmonisation could enhance international research and improve the regulation of exchanging starting or intermediate materials as well as final licensing of products.

Developers would also welcome reflection on the concept of comparability as it applies to ATMPs. Comparability studies are required to prove that the quality attributes of the product, including biological activity, are maintained following changes in pharmaceutical development. This is of particular relevance when upscaling manufacturing and with novel manufacturing models (decentralised /distributed manufacturing). Regulators should challenge the existing principles of comparability and develop specific guidance and training, in the context of both standard and decentralised manufacturing of ATMPs.

Stakeholders also mentioned that orphan similarity needs to be adapted for ATMPs. This concept should also be carefully considered in the context of new active status and changes to the active substance.

Central to the discussion was also the question of process versus product: how much of ATMP treatment is product-based and how much is it a treatment process that depends more on the clinical and laboratory skills of healthcare professionals? In terms of the legal framework, the ATMP classification procedure should have more weight in determining what is considered a medicinal product and what is considered medical procedure or practice across Europe. A proposal was made to consider ATMPs more from a process point of a view, especially at the early phases of development.

Lastly, stakeholders noted that regulators could promote disease registries to monitor safety and help companies collect structured data and meet pharmacovigilance and post-authorisation requirements. Publishing lists of registries and applying common data standards would help registries provide

benefits that go beyond pharmacovigilance, though this would require greater use of electronic medical records. It was also suggested that linking registries to reimbursement could provide a strong incentive for stakeholders to take part.

Regulatory process – main stakeholder proposals

- Streamline EMA internal regulatory processes for ATMPs
- Promote use of early access tools (PRIME, adaptive pathways, ITF, scientific advice, certification and HTA parallel advice)
- Consider opening certification to non-SMEs and strengthen its value
- Publish overview of national requirements (for GMOs and tissue, cell and blood products) and move towards greater uniformity
- Harmonise application documents (e.g. CTAs and scientific advice applications)
- Harmonise global requirements (with US and Japan, through ICH)
- Develop guidelines on investigational medicinal products and comparability
- Adapt concept of orphan similarity to ATMPs
- Promote disease registries to collect structured data on efficacy and safety (publish list of registries, harmonise data standards, promote use of electronic medical records)

4. From hospital exemption to marketing authorisation

Under Article 28 (2) of the Regulation, the so called 'hospital exemption' clause, Member States can permit the use of ATMPs in their territories without the need for marketing authorisation. This clause applies only to custom-made ATMPs used in a hospital setting for a specific patient. Such products are produced under the responsibility of a physician and are only to be used within the Member State where it is produced. In addition, a competent authority must authorise hospital exemption for ATMPs and they must comply with the same national requirements concerning quality, traceability and pharmacovigilance that apply to authorised medicinal products.

The obvious advantage of the exemption is that patients can receive much needed ATMP treatments when no products have been authorised and continue to benefit from ongoing clinical research, particularly in areas of unmet medical need. Hospital exemption ATMPs can also be a valuable source of clinical experience supporting future marketing authorisation applications.

However, hospital exemption is not intended as the primary route for marketing ATMPs. The clinical trial data required to demonstrate a favourable benefit-risk balance are usually not yet available for hospital exemption products. In addition, as hospital exemption products can only be used within one Member State according to the legislation (unlike centrally authorised ATMPs), the use of hospital exemption in lieu of the authorisation route to the market deprives large groups of patients across Europe of the benefits of therapy.

At the meeting, there was broad agreement among the stakeholder groups on both the necessity and limitations of hospital exemption, and a number of proposals were made to improve implementation of Article 28(2) and help steer hospital exemption ATMPs towards marketing authorisation.

A recurring request from industry and academia was for clarification on what constitutes hospital exemption in different Member States and for greater uniformity. Because divergent implementation of Article 28(2) could have a negative impact on patient access to treatments and ATMP development, both groups called for harmonisation of criteria for hospital exemptions across the EU and for more guidance from Member States.

Stakeholder groups also called for transparency on the use of exemption products in the EU, so that industry, academia, regulators and even patients, can find out more easily which products are being used and for which indications. Specific proposals were for easily accessible registries and other electronic databases.

Another proposal in relation to information sharing was for the systematic collation of clinical efficacy and safety data and experiences from hospital exemption ATMPs. It was suggested that better data collation could help move products along the path to marketing authorisation. However, clinical trials must remain the preferred route for generating clinical data.

With regard to moving from hospital exemption to marketing authorisation, academia and industry made the point that developers need more practical assistance with regulatory, manufacturing and pharmacovigilance activities. Suggestions in this area were for centralised platforms and training and guidance via pan-European networks.

Finally, participants discussed the scope of hospital exemption. Considering the lack of adequate data on efficacy and safety in many cases, participants saw the highest value of hospital exemption in situations of high unmet medical need and where no authorised products are available. Once a licensed medicinal product becomes available in a specific indication, however, equivalent hospital exemption products should, after a set period of time, cease to exist. This approach would minimise competition between licensed medicinal products and hospital exemption products and incentivise the development of therapies with demonstrated quality and clinical benefit.

Patient representatives stressed the importance of ensuring that patients have good access to necessary treatments and that clinical research is not impeded.

Moving from hospital exemption to marketing authorisation – main stakeholders proposals

- Implement hospital exemption more uniformly across Member States
- Make details of hospital exemption products in each Member State publicly available
- Collect clinical data and experience systematically
- Provide support with manufacturing and pharmacovigilance activities
- Consider restricting hospital exemption to areas of high unmet medical need where no ATMP is licensed

5. Funding, investment and market access

Access to capital is a recurring need throughout the life cycle of ATMPs. In the early stages, academics, spin-off incubators and SMEs developing these products typically lack the funds for early research or clinical trials. At the end of the development process, the case for added therapeutic value and reimbursement needs to be made. Negotiations with HTA bodies and payers are key, but the value of

ATMPs to healthcare programmes may in some cases not yet be established or recognised. Moreover, ATMPs by their nature are more expensive and can therefore pose a bigger challenge in relation to reimbursement approval than conventional products.

At the meeting, investors shared experiences from the perspective of those funding ATMP projects and spoke about optimising funding to increase low take-up rates and decrease attrition rates. From investors' perspective, much more needs to be done to prioritise projects better, stopping failing projects early to free up funds for others and basing decisions on realistic expectations of benefits to patients. To this end, investors could benefit from information at early stages from bodies such as the CAT and the ITF. They should also encourage developers to take full advantage of incentives and advice from regulatory bodies. In addition, investors should factor into their budgets realistic costs of early development, GMP requirements and regulatory procedures, and plan for unexpected longer term funding.

Stakeholders called on regulators to do more to raise awareness among developers of the financial incentives currently available (e.g. fee reductions for scientific advice and certification) and to consider extending incentives to academia. Regulators were also urged to provide a mechanism for SMEs and academia to seek parallel EMA and HTA advice during early development and to foster meaningful collaboration with private investors. In addition, there is a need for funding and infrastructure for registries to support comparative evaluation and post-marketing data collection.

It was noted that the Directorate-General for Research and Innovation at the European Commission provides funds for several ATMP programmes, and developers were encouraged to apply for this funding. Stakeholders suggested that information on Innovative Medicines Initiative (IMI) and specific projects from Horizon 2020 needed to be more accessible and also discussed the feasibility of funding EU-wide infrastructure for specialised centres to help improve quality of care and efficiency.

Finally, participants touched on added therapeutic value and reimbursement. The overwhelming view was that HTAs from each Member State should engage with developers earlier in development process, providing informal advice (safe harbours) and guidance on how to prepare for this interaction. HTAs should also take the lead in designing and agreeing appropriate off-the-shelf models for reimbursement and payment mechanisms as well as managed access schemes at EU level to address the current lack of uniformity.

Payers were not represented at the meeting but stakeholders proposed that payers should also engage with the developers at an early stage.

Funding, investment and market access – main stakeholders proposals

- For regulators:
  - Raise awareness of financial incentives
  - Provide vehicle for SMEs and academia to seek early parallel EMA/HTA advice
  - Support and develop EU-wide infrastructure for specialised centres to improve efficiency and quality of care
  - Foster collaboration between private investors and EC (IMI, Horizon 2020) to provide continuity and complementary funding
  - Fund registries to support comparative evaluation and post-marketing data collection
- For HTAs and payers:
  - Engage earlier in development process
  - Provide platform for informal dialogue
  - Issue ATMP guidance and increase uptake of parallel advice
  - Coordinate actions in relation to reimbursement
  - Design and agree at EU level different models for reimbursement and payment mechanisms and for managed access schemes
- For investors:
  - Prioritise funding based on realistic patient benefit
  - Deploy funding more effectively, with multi-stakeholder input and monitoring
  - Build in regulatory, GMP and manufacturing costs and plan for extending funding longer term

6. Conclusions

This summary covers the main proposals from stakeholders for fostering ATMP development in the EU and expanding patient access. The number and scope of the proposals are reflective of the complexity of ATMP development, the unique needs of stakeholders developing these ATMPs and the commitment of all stakeholders to ensure that patients in the EU have timely access to much needed treatments.

Recurring themes touched upon at the meeting include the need for early interaction and guidance from regulators, more transparency and information sharing, greater harmonisation between Member States in various aspects of ATMP regulation and measures to tackle inequalities in patient access to ATMP treatments.

Although no decisions have yet been made, the European Commission, national competent authorities, and EMA have already started discussing the feasibility of these proposals. Regulators, including HTAs, welcome the contribution from stakeholders and will decide on appropriate actions. Information on these actions will be shared with the stakeholders.

7. References

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Appendix – list of attendees

Name	Affiliation
Academia	
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Name	Affiliation
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Klaus Cichutek	HMA
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Pekka Kurki *via teleconference*	EU Innovation Network
Dirk Mentzer	PDCO Chair
Hans Ovelgönne	CAT and SAWP
June Raine	PRAC Chair
Ian Rees	Inspection WG
Sol Ruiz	BWP Chair , CAT and CHMP
Simona Russo	Inspection WG
Paula Salmikangas	CAT Chair
Tomas Salmonson	CHMP Chair
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Gerard Sheridan	Inspection WG
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Robert Vanhoorde	DG SANTE
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Hilde Boone	EU Institutional Liaison
Melanie Carr	Stakeholders and Communication
Patrick Celis	Procedure Management & Committees Support
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