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The value of investing in Advanced Therapy Medicinal Products: combining sustainability, innovation and respect for patients' rights

To move towards the European Health Union, we probably also need to go beyond the current narrative concerning the European pharmaceutical legislation review which – in synthesis - seems to be limited to the following statement: ["the fate of the pharmaceutical sector is at stake as well as the future of national health systems"](#). Talking about the future scenarios of the Advanced Therapy Medicinal Products (ATMPs) that the review might outline, what about the justified expectations of patients? What is holding us back from including and considering in the debate also the point of view of the so-called 'final users' of the health service, the ultimate recipients of the decisions whose effects will be experienced in practice? Travelling at different speeds, how can innovation and access be combined? To try to answer these questions, Cittadinanzattiva - through its EU branch Active Citizenship Network – has recently [presented a proposal](#) at the European Parliament, endorsed by [43 Patient Advocacy Groups \(PAGs\) from 12 Member States](#), to try to make up ground on patients' right to access advanced therapies, calling for a change in institutional mentality to classify spending on ATMPs as an investment and not as a cost.

All potential, eligible patients have the right to access Advanced Therapy Medicinal Products, and national health budget constraints cannot be an obstacle. Nowadays, traditional reimbursement and budgeting schemes are unable to amortise the value of ATMPs, whose costs and benefits are not aligned. These types of therapies need new and different payment and accounting methods, which consider the high initial costs and the large and lasting benefits over time, both for patients and for national health systems. It is time to change the institutional mindset to classify the expenditure on Advanced Therapy Medicinal Products

as an investment and not as a cost, which is possible if a decision is made to review – from Eurostat downwards – the current economic and financial classifications of healthcare expenditure. The cost of these therapies could be amortised over the years in relation to the savings generated over time. In particular, they could be entered in the state budget over several years and not all in the year of expenditure. This would significantly increase the financial sustainability of these costs by the public sector over time and promote greater and more equitable use of ATMPs in the population, without putting public finances at risk.

This proposal - realised with the unconditional support of VITA (Value and Innovation for Advanced Therapies coalition) - also received an encouraging endorsement from Italy's new Health Minister during an official Hearing at the Senate of the Italian Republic in January 2023 while, at the European level, the European Health Commissioner Stella Kyriakides, on the occasion of the [European Patients' Rights Day held in April 2023](#) emphasised that "ATMPs give hope to patients where therapeutic options are currently lacking or non-existent and they must be able to reach patients sooner. Our (European Commission's) priority is always to put patients' interest first".

Above all, we believe that the two aspects can only be better combined and find a point of connection with each other if, in the field of ATMPs, we also succeed in strengthening and guaranteeing spaces for the participation of citizens and PAGs in the decision-making process. This is also why, in Italy, we warmly welcomed the invitation of national institutions to join the [National Ethics Committee for clinical trials on advanced therapies \('ATMPs'\)](#), set up in [February 2022](#) at the Italian Medicines Agency, as the [only actor to represent the civic and patient point of view](#)

on the issue. For the same reason, we urge to overcome the extreme polarisation of the public/private debate that is accompanying the pharma legislation review, which, despite its inevitable complexity, needs to be integrated from a civic and patient perspective.

The patients' [rights to innovation and to access](#), both stated in the European Charter of Patients' Rights, should be inextricably inter-linked in every area of healthcare. Unfortunately, in many contexts this does not happen, and even in the field of ATMPs, where innovation is advancing, there are [cases of withdrawal or threatened withdrawal of existing and accessible therapies](#). So, in the presence of innovative therapeutic solutions, approved by the competent regulatory authorities, available on the market and already being used by eligible patient groups, having already proven their efficacy, we should have the courage to affirm the principle of irreversibility of access to treatment. Those who are already using them cannot be continually exposed to this situation of uncertainty. What is at stake is the credibility of the healthcare system as a whole and of all the actors involved, public and private. But above all, it concerns the medical history of so many patients who see in these innovative treatments a hope that was not even imaginable a few years ago, as well as the dreams of those who live alongside them, and the ultimate essence of ATMPs is that of being "dream savers".