

The Economics of Advanced Therapy Products: Reasons for a New Accounting and Economic Approach

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The European Framework

1. Advanced Therapies: some clinical and economic features



ATMPs **restore and correct** compromised **physiological functions** by correcting genetic mutation



They have significant costs in the **short term**, but **benefits** over a long period of time



provide one-shot treatment (**single assumption**)



They have a very **complex valuation process**; the "traditional reimbursement schemes" are not able to recover the value of ATMPs



2 The ATMPs economic analysis: asymmetry between costs and benefits

ATMPs present **high temporal asymmetry** between the **emergence of costs** (almost all upfront) and that of **benefits**

Need **for a different (innovative) economic and accounting assessment procedure**

When upfront costs are matched with direct and indirect benefits over time = Investments

3 definition of investment

- **distinction between current and capital expenditure** is essentially based on the assessment of the "**different duration of the effect produced by** various expenditures"
- **Expenditures are current** if they related to the **purchase of goods and** services whose "*economic usefulness is exhausted in the accounting year in which the expenditure took place*";
- They are on the **capital account** when it *exceeds the year and affects several years*
- In **national accounts**, **investment** (i.e. the *purchase of tangible or intangible assets*) is known as **gross capital formation** (GCF or **fixed gross investments**)
- ATMP are 'products that can be **reused several times in production processes**. Therefore these products can be considered as "**fixed capital**"

4 Assessment of investments

- The international community (EU, OECD, UN, ..) **periodically updates definitions and rules for compiling national accounts** (as the scientific/political debate evolves)
- In 2008, we had an alignment between the system of national accounts and that of commercial activities (commercial accounting, 2008 SNA, p.433)
- **The updates of the Regulations are long processes, they pass through working groups, they can provide for intermediate phases with satellite accounts and experiments**
- **They certainly need a political boost from the Council and the European/Local Parliament.**

5 Are ATMP investments from an economic point of view?

ATMP therapies have special characteristics:

- they have a **high temporal asymmetry** between the **emergence of costs** (almost all upfront) and that of **benefits**
- This suggests a new economic and accounting approach to assess these therapies
- **direct and indirect benefits over time:**
 - In terms of **savings**: **healthcare savings**, **drug consumption** and **health services** of different kinds; the reduction of resources consumed directly in health centres, reduction of family costs (**direct and indirect care resources**)
 - In terms of **value**: the increase in **life expectancy**, the improvement of the **qualities** and the **value of human life**); the improvement of patients' health; **increased productivity, higher tax revenues...**

5 Are ATMPs investments?

- Recent technological developments have shown that there is a need to **rethink the concept of capital, both from an economic/statistical point of view, but also from the point of view of national account**
- In the traditional accounting approach, the **notion of capital usually refers to economic (physical) capital**
- it is now clear that human, **social and natural capital** (environment, health conditions, trust, etc.) is increasingly important for the future of countries
- we need **statistical and accounting innovations:**

how much of the expenses considered current today (healthcare equipment, Atmps, ...) actually have the nature of **investments**?

6 Do ATMP have the characteristics of investment for accounting purposes? 1/4

The key questions are:

1. Are ATMP tangible or intangible assets?

"An intangible asset is by definition an asset without physical substance.... They cannot be held in the hand, or tagged with an inventory system" (EPSAS, 2018). More precisely, "an intangible asset is an identifiable non-monetary asset without physical substance" (IPSAS 31). ATMP is a genetic material, but also 'algorithms', personalized and 'transfection' to people suffering from specific pathologies. Are they tangible or intangible goods?

Surely, they are goods produced thanks to scientific research with the aim of healing pathologies and therefore with lasting effects on clients, people's well-being, production potential and health costs.

But regardless of how ATMP is classified as goods, the following two requirements must be met for recognition among gross fixed capital formation.



6 Do ATMP have the characteristics of investment for accounting purposes? 2/4

2 Are ATMP the product of a production processes?

Yes, they are products of complex production processes, characterized by a relevant research component. The first requirement to be able to consider ATMs as capital goods is met

Are ATMP used multiple times or continuously within the same processes for more than a year?

The production process takes place in a first phase in the laboratory, and in a second phase within the organism, continuously over time, and with personalized characteristics with respect to the person. The second requirement to be able to consider ATMP capital goods could be considered fulfilled. In fact, a distinctive aspect of ATMP, compared to traditional drugs is that, after 'transfection' in the body, the next stage of the production process is internal to the organism and is continuous over time.



6 Do ATMP have the characteristics of investment for accounting purposes? 3/4

3 If ATMP are classifiable as intangible assets, would the other requirements set out in ISAS 31 be met?

- **Identifiable.** Is the asset identifiable, i.e. is it separable (i.e. can it be sold, transferred, leased, licensed or traded) or does it derive from legal or contractual rights? Identification does not necessarily imply transfer but may result from contracts or legal rights. In the case of ATMP, identification derives from contractual rights. In fact, the NHS when it buys an ATMP would sign a purchase contract conditional on its effectiveness. The NHS pays the installment if the drug works, so property rights on that drug only transfer to the NHS if the effects of the drug are lasting over time. The NHS buys only the durable part of the drug and not all the drug.
- **An entity's control of the asset.** The NHS currently has control over the acquisition of ATMP, i.e. it has the power to obtain future economic benefits or service potential from the underlying business and to restrict others' access to such benefits or potential service
- **Potential future economic benefits and service.** Future potential economic benefits or service are likely to flow to the entity. The requirement is met, vis-à-vis the NHS
- **The value of benefits can be reliably estimated.** This requirement is also met as the benefits can be identified and quantified and the cost value of ATMP can be reliably assessed



6 Do ATMP have the characteristics of investment for accounting purposes? 4/4

Conclusions

On the basis of the above considerations, there **appear to be sufficient evidence to consider ATMP as an intangible component of gross fixed benefits**

the **perimeter of intangible assets is a subject under study** and discussion at international level among national accountants

At European level, several informal working groups are being promoted by the Commission and Eurostat to assess intangible expenditure, environmental expenditure, accounting treatment of social benefits and welfare expenditure



The National Framework

7 The accounting of an Annuity Payment Model is already possible with the current rules, but a special regulatory mechanism is necessary

State and Regions
Accounting system

Accounting method based on the principles of financial **accrual and cash accounting**

Main accounting system of
the health companies

Economic and patrimonial accounting, based on the **accrual principle**

Financial statements of the
Regional Health System

It is also based **on accrual principle**

8 Possible solution to qualify ATMP as investment expenditure 1/2

Suggestion of some **accounting changes** for an effective implementation of the "**Annuity payment model**"

This would in fact determine an alignment between cash, financial and economic accrual, leading to the generation of "good debt"

PROS	CONS
<p>Would help:</p> <ul style="list-style-type: none">• the health bodies/centers to effectively apply payment models at result• NHS may allocate over time the expenditure for ATMPs in line with the expected benefits	<ul style="list-style-type: none">• to quantify <i>ex ante</i> the expenditure for the purchase of ATMPs• <i>ex post</i> control to keep the deficit generated under control

8 Possible solution to qualify ATMP as investment expenditure 2/2

Possible solution at national level:

To set an *ad hoc* (special) **fund for advanced therapies**, that in the medium term can be auto-financed with savings

to apply an *ad hoc* law containing a **specific multi-year expenditure authorization with legal competence** (accrual) **and economic competence aligned**, also in terms of financial coverage