ITALY TACKLES HTA, PRICING AND REIMBURSEMENT REFORMS

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In July, new legislation set to overhaul the way pharmaceuticals are priced in Italy was finally implemented, following an announcement that dates all the way back to August 2019. The provision, which was signed by then Ministers Giulia Grillo (Health) and Giovanni Tria (Economy), has rolled out new criteria and methods by which the Italian Medicines Agency (AIFA) determines, via negotiation, the prices of drugs reimbursed by the national health service (SSN).

Italy finally rolled out the new policy this year, replacing the "Delibera CIPE" that had governed the Italian pricing and reimbursement of medicines since 2001. Nevertheless, Italy still suffers from fragmentation, specifically regarding health technology assessment (HTA), due to the autonomy of its regions, which organizations such as the Italian Society for HTA (SIHTA) have highlighted as a major area of improvement for Italy's policymakers considering the rise of new, innovative yet costly therapies.

SIHTA published a position paper dubbed "For an Italian System of Health Technology Assessment," calling for a new HTA system in Italy that can be used to more effectively evaluate the impact of new technologies and innovation while making the SSN more efficient and accessible without marring sustainability.

According to SIHTA, the implementation of a real HTA ecosystem would allow the use of robust and transparent criteria for the allocation of resources and the optimization of investments to concretely improve the equity of the NHS and appropriateness of patient care, as well as guarantee uniformity of performance on the national territory.

HTA Fragmentation in Italy

While the World Health Organization (WHO) considers HTA a "fundamental tool" that guarantees sustainability, quality and accessibility of health services, in Italy "the current architecture of the system has not been able to make this important tool available to the political-institutional and managerial decision-maker," said Pietro Derrico, president of SIHTA, in a press release.

Italy currently operates on a multiple-HTA-system basis, across various regions and bodies, such as the Ministry of Health to the Italian Medicines Agency (AIFA), The National Agency for Regional Health Services (AGENAS) and the Higher Institute of Health (ISS).

HTA is necessary for the Italian system but needs streamlining, according to SIHTA, as it is the most suitable tool for the NHS to improve its decision-making processes, improve the quality and sustainability of care and be able to guarantee its universalism thanks to some very clear objectives:

- Define and ensure the essential levels of assistance
- Optimally manage the economic resources that make up the National Health Fund in a general scenario of economic crisis
- Develop and disseminate effective and increasingly expensive technologies in clinical practice

As such, SIHTA recently suggested that the country has "too much fragmentation, too little coordination" when it comes to regulation and that a newly proposed 2019-2021 Health Pact could help provide "merging the functions into a single entity, to guarantee the authoritativeness and independence of evaluation."

At the time, Pietro Derrico, president of the organization, noted: "We proposed to establish a National Agency that would become the fulcrum of an HTA ecosystem characterized by a clear chain of production and use of reports, based on the central level, adequately equipped with multidisciplinary skills and shared methods to make its functioning

effective, and which then branches out, with clearly defined responsibilities and activities, to the local hospital.

"Having observed the evolution of HTA in Italy for over a decade, we conceived the idea that the time was ripe for such a proposal. Some reasons can be considered historical, others contingent. Among the first is the recognized importance of HTA as a method for guaranteeing the sustainability, quality, and accessibility of universal health services, a judgment that comes from the highest levels, from the WHO to the European Commission up to the national health plans."

Italy's HTA Streamlining Efforts

This is not the first attempt that the Ministry of Health has made to streamline HTA decisions, as, in 2015, the Ministry set up a control room for the HTA bodies where they could all convene and work together. The group ultimately released a document to launch a national HTA program for medical devices, setting milestones and objectives, but it never came to full fruition.

Multiple HTA bodies spoke to Italian media regarding the new proposals, which you can read here.

In early September, SIHTA published a joint paper with the Italian national HTA agency, covering regional health information about everything from phases of the HTA cycle and types of documents produced, targeting audience and regional impact of said HTAs.

In response to the paper, Italy's National Agency for Regional Health Services has noted that the survey "draws attention to the use of HTA to support decisions in our country, an issue on which the debate seemed to have died down and instead, today more than ever, it shows itself as current and central, also in light of the health emergency due to COVID-19."

In a release in Italian media, the group continued, "Over the years, the Agenas HTA Office has accumulated extensive expertise in the field of Health Technology Assessment based on the application of a rigorous and shared method, both nationally and internationally.

"There is no doubt that there are critical issues in the current structure and there is a need to activate synergies and interactions at the various institutional levels aimed at defining a new role for HTA, based on the fundamental principles of transparency and independence and based on the application of rigorous scientific research, in order to affect the governance of health technologies, as already happens in other European and non-European countries with the fundamental objective of providing citizens with the best and most effective health technologies for health protection."

The HTA society also believes that "it is necessary to use resources for activities capable of generating 'value' from an individual, technical, social, and economic point of view over a long period, the opposite of the spending review," according to Americo Cicchetti, past president of SIHTA.

Preparing for Advanced Therapies

In a similar vein, The Higher Institute of Health and Assobiotec Federchimica recently suggested that new governance is needed to avoid inequalities in access, now that advanced therapies are becoming more available.

Regulation and pricing systems around novel, innovative therapies have been a hot topic for the last few years, with various countries coming to grips with amending their systems to fit drugs that don't fit squarely within the established cost-effectiveness parameters.

SIHTA wants Italy to move away from the concept of spending in healthcare to investment, instead thinking of spending to invest in the long-term health of Italian citizens. As such, the role of HTA should be to provide a "rational methodology" to assist in decision-making when it comes to assessing the value of a medicine, said Carlo Favaretti, honorary president of SIHTA and president of the European Public Health Association (EUPHA) Section on HTA.

"In this way, the probability of optimal health outcomes is increased," said Favaretti. "HTA is, therefore, a process whose outcome is health."

HTA should consider both direct and indirect costs and the potential of new, innovative technologies in reducing costs within the healthcare system as well. At the same time, HTA methodologies should continually grow to provide decision-makers with the right basis to determine the value offered by a medicine.

COVID-19

SIHTA President Pietro Derrico addressed the COVID-19 situation when proposing the centralized agency, noting, "The dramatic experience we are experiencing has generated a unanimous sharing of political forces, health professionals and the industrial chain on the need to adequately refinance the NHS, from personnel to hospitals, from new technologies to local medicine to scientific research."

He also believes that "the current HTA system has shown, through deafening silence, that it is completely disarmed in the face of this crisis."

As such, he believes that "HTA becomes of fundamental importance to reach a rational planning, and as much as possible, rapid and shared, to make the most of the greatest resources that hopefully will arrive, a historic opportunity regardless of the nature of the sources of funding that the government and parliament will decide to activate."

Introducing the Future of HTA in Italy

In September 2020, the AIFA published draft guidelines and launched a two-week consultation where interested parties could comment on new "guidelines for the compilation of the dossier supporting the application for price and reimbursement." The deadline for the consultation was September 30, and in October, AIFA will release the final document.

The objective of the reform is to lower the costs of innovative medicines to the Italian NHS by tweaking the criteria and procedures used in pricing and reimbursement. With the reform, the price will no longer be based on a favorable cost-effectiveness ratio, thus shifting to added therapeutic value compared to treatments already available on the market.

The proposal includes new criteria in the dossier requirements, such as self-certifications attesting to production capacity and the ability to manage unexpected events to ensure a proper supply of medicines to the NHS, patent status of the relevant medicinal product, and three-year sales forecast and marketing costs incurred in Italy.

Further, it is proposed that AIFA can start the negotiation autonomously, for various reasons, and the manufacturer can request scoping meetings.

Additionally, the negotiated price would be valid for two years (to be renewed for an additional two-year period). A price increase could be implemented if there were objective difficulties in providing raw materials or increased manufacturing costs. Automatic mechanisms would favor generics and biosimilars.

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The AIFA evaluation would take 180 days, rather than 90 days, and a "stop clock" has been introduced.

New negotiation categories include the following:

- **TN1:** New chemical entity (new drugs or new indications)
- **TN2:** Drugs or indications already on the market
- **TN3:** Drugs without patent protection
- **TN4:** Reimbursement conditions revisions
- **TN5:** Special procedures

The dossier is proposed to contain different sections based on the reimbursement category.

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>
> *– Americo Cicchetti, past president of SIHTA*