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AIFA approves new medicines for the treatment of cystic fibrosis

Following an in-depth investigation by the Technical and Scientific Committee and the Pricing and Reimbursement Committee, AIFA's Board of Directors has approved the marketing of **new**, **highly effective medicines for the treatment of cystic fibrosis** (CF), an inherited genetic disease that affects approximately one child for every 2,500 births. The main novelty is a combination of two medicines: *Kaftrio*, a combination of three active ingredients (ivacaftor/tezacaftor/elexacaftor), and *Kalydeco* (ivacaftor). Currently over 5,000 patients are registered and followed in our country. The medicines will be available, fully paid by the NHS, for all patients who fall within the indications approved by the EMA after publication in the Official Journal, expected by 3 July 2021.

"This is a significant breakthrough in the treatment of cystic fibrosis that has until now only been partially effective. Thanks to the agreement reached, the NHS will make this medicine available free of charge for all patients for whom there is evidence of benefit", noted the Director General, **Nicola Magrini**.

This approval represents an important improvement in CF prognosis, which is much awaited by patients with the disease, due to the innovative value of the authorised medicines.

The approval process of the new authorised medicines has led the bodies of the Agency to reflect on the ability to govern innovation and improve resource allocation efficiency as envisaged in the "Pharmaceutical Governance" document of the Health Pact 2019 -2021. In this regard, also in consideration of the tasks and functions of high technical consultancy to the Government and to the Permanent Conference for relations between the State, the Regions and the Autonomous Provinces on drug policies, AIFA will send a report to the institutional stakeholders for in-depth analysis.

"The hope is that the expenditure commitment for innovative medicines will be considered for the country not a mere cost, but an investment factor in health and research and development", concluded the President of the Board of Directors, **Giorgio Palù**.