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Green light from AIFA's Board of Directors to the reimbursement of four new medicinal products, five extensions of indications and two generic medicinal products

Among the reimbursed medicines are an orphan drug for certain types of female cancer and one for an ultra-rare disease.

At its session of 29 May, held in the "Sala La Torre" at the Palazzo Reale in Palermo, the AIFA Board of Directors approved the reimbursement of four new medicinal products, five extensions of indication, and two generic medicinal products.

ORPHAN MEDICINES

The National Health Service will reimburse a new orphan medicine for the treatment of adult patients with epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. The medicine, **Elahere** (mirvetuximab) is a monoclonal antibody that binds to a specific protein (FRα) expressed on the surface of tumour cells and delivers a cytotoxic agent into the cells, leading to their destruction.

The second orphan medicine to be approved for reimbursement is **Adzynma** (rADAMTS13), an enzyme replacement therapy (ERT) for congenital thrombotic thrombocytopenic purpura (cTTP), a very rare genetic blood disease. Adzynma is produced using genetic engineering and provides a recombinant version of the human ADAMTS13 enzyme, which is deficient in patients with cTTP; it is administered intravenously.

cTTP is a disease caused by a genetic mutation that prevents the production of the ADAMTS13 enzyme, resulting in the formation of microvascular blood clots, haemolytic anaemia, severe thrombocytopenia, and organ damage of varying severity. By replacing the missing enzyme, Adzynma prevents clot formation and reduces the risk of bleeding and anaemia. This represents an innovative therapeutic approach for a disease that, if left untreated, can follow a rapid and potentially fatal course.

NEW MOLECULES

Two new molecules will be reimbursed by the NHS: **Aqumeldi** (enalapril maleate), an ACE inhibitor indicated for the treatment of heart failure in children from birth to 6 years of age, and **Wainzua** (eplontersen), indicated for the treatment of hereditary transthyretin-mediated amyloidosis

(ATTRv), a progressive systemic disease that predominantly presents with cardiomyopathy and/or polyneuropathy.

EXTENSIONS OF INDICATIONS

The five medicinal products for which the reimbursed indications have been extended are: **Bridion** (sugammadex), an antidote used in anaesthesia to reverse neuromuscular blockade induced by specific muscle relaxants such as rocuronium and vecuronium, now available for use in paediatric patients from birth to 17 years of age; **Cablivi** (caplacizumab), a monoclonal antibody indicated for the treatment of episodes of acquired thrombotic thrombocytopenic purpura (TTP), in combination with plasma exchange (PE) and immunosuppression, now reimbursed in adolescents aged 12 years and older with a body weight of at least 40 kg; **Miozac** (dobutamine), an adrenergic drug used as a cardiac stimulant; **Scleryda** (dimethyl fumarate), an immunomodulatory medicine for the treatment of relapsing-remitting multiple sclerosis in paediatric patients aged 13 years and older; and **Spravato** (esketamine), an antidepressant administered as a nasal spray.

GENERIC MEDICINAL PRODUCTS

The two generic medicinal products to be reimbursed by the NHS are **Linagliptin Krka** (Linagliptin), an antidiabetic agent, and **Methotrexate Aurobindo** (methotrexate), a medicine used in oncology for the treatment of certain malignancies (such as leukaemia and lymphoma) and, at lower doses, as an anti-inflammatory and immunosuppressive agent in various autoimmune diseases, especially in rheumatology and dermatology.

The meeting also addressed the revision of the National Pharmaceutical Formulary, on which the Agency is continuing its work.