



### **AIFA redefines the criteria for awarding the "innovativeness status" to medicines**

#### **Possible fast track for companies investing in preclinical and clinical research in Italy. Immediate access to the Innovativeness Fund for reserve antibiotics used against multi-resistant germs**

AIFA rewrites the requirements for the recognition of therapeutic innovativeness, rewarding medicines for diseases without real treatment alternatives or with added therapeutic value compared to those already on the market. This is defined by the Decision published in the Official Journal on 12 July which is the result of extensive consultation with patient associations and stakeholders, and which also defines the new criteria for the classification of innovative medicines and for the management of anti-infective agents for infections with multi-resistant germs, as provided for by the last Budget Law. For the first time, antibiotics to combat antimicrobial resistance are automatically included in the Innovative Medicines Fund, and national pharmaceutical research is rewarded. In fact, when assessing innovativeness, it may be considered an added value if the pre-clinical and clinical development of the medicine has been developed and conducted predominantly in Italy. This is a double advantage both for companies that invest in research in our country and for patients, since the "innovativeness status" allows immediate access to reimbursability with automatic inclusion in regional formularies, access to funding through the Fund for Innovative Medicines of 1.3 billion, of which 100 million is earmarked for reserve antibiotics, as well as a fast track for procurement by hospitals.

"The aim is to obtain innovative medicines in therapeutic areas where there is a real need, to the benefit of citizens and the NHS itself. It is essential to establish which medicines have such a therapeutic advantage as to merit economic incentives that, in order to ensure the sustainability of the system, cannot be extended to everything that is simply new," says AIFA President Robert Nisticò. "At the same time, we are strengthening our commitment to promote pharmaceutical research and development in our country and to combat antibiotic resistance".

The new rules for access to the Innovative Medicines Fund are explained in the document attached to the Decision. "The innovativeness of a medicine," it is explained, "is assessed on the basis of the production technology of its active ingredient, its mechanism of action, the way it is administered to the patient, its clinical efficacy and safety, its effects on the quality of life as well as its implications on the organisation of healthcare. The innovative medicine status, which is necessary for access to the Fund's resources and benefits, is assessed and awarded by AIFA's Scientific and Economic Committee (CSE), based on the newly introduced criteria: therapeutic need, added therapeutic benefit, quality of evidence. "Therapeutic need", as the document states, "is determined by the need for useful therapies for the treatment of a disease for which there are no available therapies or when these "present an unsatisfactory efficacy/safety profile". Innovativeness is recognised in the presence of a therapeutic need, an added therapeutic benefit and at least "moderate" quality of evidence. This is with reference to the two value scales in the same annex, which provide 5 levels for therapeutic advantage (highest, major, moderate, minor and absent), while there are 4

levels for quality of evidence (high, moderate, low and very low). In the case of medicines for rare and ultra-rare diseases “therapeutic innovativeness may be assessed even in the presence of a low quality of evidence”.

Access to the Innovative Medicines Fund will have a maximum duration of 36 months and can only be granted to medicines for the treatment of “serious diseases or pathological conditions with medium-low epidemiological impact”. The company holding the MA “may request the attribution of the therapeutic innovativeness status if the medicine, in the specific therapeutic indication, has demonstrated, compared to therapeutic alternatives (if any), to be able to induce cure or to reduce the risk of lethal or potentially lethal complications, slow down the progression of the disease, improve the quality of life of patients”. Antibiotics defined as “reserve” according to the World Health Organisation's classification, to be used only in infections with multi-drug-resistant germs, are not evaluated. Starting this year, they automatically become part of the Innovative Medicines Fund to boost efforts against antimicrobial resistance.