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AGENZIA ITALIANA DEL FARMACO

AIFA-Farmindustria meeting

AIFA's President Nisticò: "Right away a technical committee to simplify procedures and halve the time for access to medicines"

"We are working to reduce the time of access procedures with a reduction of bureaucracy and with administrative simplification, ensuring that citizens may quickly use truly innovative medicines", so AIFA's President, Robert Nisticò at the end of the first meeting with the President of Farmindustria, Marcello Cattani. The meeting took place today at the headquarters of the Agency.

It was a constructive and immediately operational discussion, which led to establishing a technical working group, which shall identify simplification tools, so prioritising the approval of drugs capable of improving the quality of care and the therapeutic options available. It has been agreed that this objective will be achieved also by lightening the Agency's Scientific and Economic Committee (CSE) of certain procedures that could be carried out automatically.

"Through close callings of the CSE, we are clearing the considerable backlog previous to the Agency's reform – said President Nisticò – because our goal is to prioritise drugs that fill a therapeutic gap".

In this regard, a discussion was also opened on the need to provide incentives and rapid approval pathways for new antibiotics capable of replacing those that have generated forms of bacterial resistance. "An effective model is the legislation that has allowed to incentivise the research for orphan drugs for rare diseases, which can be duplicated for new antibiotics not resistant to bacterial infections. But this – so AIFA's President – will require legislative action, also at a European level, and we will commit to raising awareness among decision-makers at various levels".

To speed up the access authorisation procedures, AIFA's Technical and Scientific Director, Pierluigi Russo, announced the upcoming introduction of an online platform "to make communication between companies and the Agency more effective and transparent concerning the CSE process, in addition to updating the guideline on the dossiers for requesting the price and reimbursement of medicines".

Finally, the commitment was confirmed regarding the implementation of the European Regulation on Health Technology Assessment (HTA), which fosters a multidimensional evaluation of the drug on the health system, economic aspects and public health protection.