



AIFA public consultation on criteria for the attribution of therapeutic innovativeness

The Italian Medicines Agency is launching a public consultation on the document 'Evaluation criteria for the attribution of therapeutic innovativeness and on the management of anti-infective agents for multi-drug resistant infections'.

The public consultation is preliminary to the definition of the criteria for the attribution of therapeutic innovativeness by the Agency for access to the Innovative Medicines Fund, as provided for by Law no. 207 of 30 December 2024 (art.1 paragraph 285).

'The discussion that opens today on issues of fundamental importance for access to treatment and the right to health confirms Aifa's propensity to listen,' says **Aifa President Robert Nisticò**. 'An openness,' he adds, 'that takes on particular relevance when it comes, as in this case, to establishing which medicines have such a therapeutic advantage as to merit economic incentives that, for reasons of economic compatibility, cannot be extended to everything that is simply new.'

'The launching of the public consultation on the criteria for the recognition of therapeutic innovativeness,' emphasises **technical-scientific director Pierluigi Russo**, 'represents an extremely important step in the updating of regulations on innovative medicines, including antibiotics, conducted by the Scientific and Economic Committee. With this step, the CSE opens up to discussion with patient associations and stakeholders, in order to acquire any contributions in full transparency'.

From today, Wednesday 12 March, until 6 p.m. on 22 March 2025, all stakeholders as well as patients' and citizens' associations will be able to send their contributions in non-anonymous/anonymised form exclusively in word format to the email address: infoinnovativi@aifa.gov.it.

The document subject to consultation is published on the Agency's portal: <https://www.aifa.gov.it/consultazione-pubblica-criteri-innovativita>