



## **From “one-size-fits-all” medicine to tailored treatments: AIFA publishes Position Paper on precision medicine and appropriate prescriptions**

Medicine is undergoing a transformation. Advances in genomics, pharmacogenomics and digital technologies are gradually replacing the standardised treatment model, which is the same for everyone, paving the way for increasingly targeted treatments based on the biological, clinical and social characteristics of each patient. This is precision medicine, a change that affects not only scientific innovation but also the very concept of treatment.

It is in this context that the Italian Medicines Agency has published its Position Paper on “Precision medicine and appropriate medicine prescriptions”, a document that identifies priority areas for action to improve the efficacy and safety of therapies and, at the same time, strengthen the sustainability of the National Health Service. The position paper is the result of work carried out by the AIFA Technical Panel on Prescriptomics, established in November 2024: a synergy between experts from the Agency, scientific societies, professional associations, academia, research institutes and patient associations, who worked in thematic groups to produce shared recommendations.

The starting point is a structural fact: the ageing population. In Italy, almost 24% of citizens are over 65 years of age, and living with multiple chronic conditions is increasingly common. According to the data cited in the Position Paper, 68% of over-65s take at least five different medicines and 28.5% take ten or more. This exposes them to a high risk of drug interactions, adverse reactions, ineffective treatment and poor therapeutic adherence.

In this context, the prescribing process becomes a highly complex exercise. “Medicine prescription can no longer be considered an isolated act,” reads the AIFA document, “but must be transformed into an integrated assessment of the ‘patient-disease’ relationship, capable of bringing together clinical data, concomitant therapies, frailty, biological and behavioural factors”.

Alongside the evidence generated by controlled clinical trials, the Position Paper emphasises the systematic use of Real-World Evidence to monitor efficacy, safety and prescribing appropriateness in the real world, with a view to continuous learning and dynamic updating of clinical recommendations.

“We can no longer accept that polypharmacy, often unavoidable in the elderly, becomes a source of risk rather than benefit,” says AIFA President Robert Nisticò. “Precision medicine is the tool that allows us to increase the likelihood of effective treatment and reduce side effects, truly putting the person at the centre.”

The Position Paper introduces the concept of prescriptomics, defined as the integrated application of clinical data and multi-omic information (genomics, transcriptomics, proteomics, metabolomics and epigenetics), integrated with digital and artificial intelligence tools, in order to personalise therapeutic choices, dosages and monitoring pathways for individual patients. This means moving

from a “medicine-based” approach to a “system-based” approach, in which therapy is constructed by considering the set of interactions between medicines, the organism and the clinical context. “Implementing prescriptomics,” the document states, “is equivalent to providing concrete tools for improving prescribing appropriateness”.

Among its operational proposals, AIFA indicates the need to encourage and systematise practices such as drug review and reconciliation, which are essential for patients undergoing polypharmacy, and to promote the use of clinical decision support software for the preventive analysis of drug-drug interactions. A central role is also attributed to pharmacogenomics, which allows the identification of genetic variations that can influence response to medicines, and to Therapeutic Drug Monitoring, which is useful for personalising dosages and preventing toxicity or ineffectiveness. The adoption of decision support systems, artificial intelligence algorithms and advanced analytical tools requires the definition of shared standards of validation, analytical quality and traceability in order to ensure their appropriate, safe and clinically reliable use.

“Technology does not replace the doctor, but helps them make better decisions”, emphasises Nisticò. “Tools such as decision support systems, if properly validated and used, can make a difference in the management of complex patients”.

The document also looks to the future, pointing to artificial intelligence and bioinformatics as strategic levers for building predictive models capable of supporting clinical practice and improving the governance of pharmaceutical spending. In order to make precision medicine structural, stable organisational models are needed, based on dedicated networks and centres, multidisciplinary integration of skills and structured training courses, ensuring equitable access and measurable sustainability of innovation.

At the same time, the position paper highlights the importance of training professionals and actively involving patients, because “appropriate prescribing is not only a technical issue, but also a cultural one”. “Precision medicine is not a luxury for the few,” concludes the AIFA President. “It is an ethical duty and an investment in the future of the National Health Service: better treatment also means better use of public resources”.

With the publication of the Position Paper, AIFA confirms its commitment to leading this transition. “In a rapidly ageing country,” concludes Nisticò, “the challenge is not to increase the number of medicines prescribed, but to prescribe them in a more appropriate, safe and targeted manner, transforming scientific innovation into concrete benefits for citizens”.