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AIFA monitoring of pharmaceutical expenditure January-September 2025

Expenditure on medicines dispensed through pharmacies open to the public amounted to €6,425 million (6.33% of the FSN), while expenditure on medicines purchased directly by public healthcare facilities amounted to €11,811 million (11.64% of the FSN). This expenditure is net of expenditure on innovative medicines and antibiotics for the treatment of multi-resistant infections, which amounted to €580.8 million, as well as expenditure on medicinal gases (€183.8 million). This is the result according to the "Monitoring of National and Regional Pharmaceutical Expenditure January-September 2025" presented to the AIFA Board of Directors. In total, pharmaceutical expenditure (direct purchases + expenditure under the approved care regime) in the first nine months of the year amounted to €18.42 billion, with a deviation from the planned ceiling of €2.85 billion.

The current monitoring shows a reduction in the incidence of pharmaceutical expenditure on the FSN for both expenditure under the approved care regime and direct purchases compared to that recorded in the previous "Monitoring of National and Regional Pharmaceutical Expenditure January-June 2025". However, a comparison of expenditure on direct purchases, excluding medicinal gases, with the relative ceiling of 8.3% of the FSN shows an incidence of 11.64%, higher than that recorded in the same period of the previous year (11.29%), exceeding the ceiling by 3,384 million euro. The dynamics of expenditure on direct purchases with ceiling were affected by the release on 31 December 2024 of medicines with innovative therapeutic indications for a significant value of €494 million which, despite the broadening of the criteria for access to the innovative medicines fund following the publication of AIFA Decision No. Pres/966/2025 (setting out the new criteria for the classification of innovative drugs and anti-infective agents for infections caused by multi-resistant germs pursuant to Law No. 207 of 30 December 2024, Article 1, paragraphs 281-292), were only partially offset by the introduction of new innovative medicines, resulting in a reduction in expenditure of more than €220 million compared to 2024.

Conversely, a comparison of the expenditure under the approved care regime with the relative ceiling of 6.8% of the FSN shows an incidence of 6.33%, which is higher than that recorded in the same period of the previous year (6.28%), with a surplus of €478 million compared to the ceiling. However, the dynamics of expenditure under the approved care regime compared to the ceiling are affected by the implementation, not yet complete in September 2025, of the effects of AIFA Decision No. 926/2025 reclassifying antidiabetic medicines belonging to the gliflozin category from Class A-PHT to Class A, which will increase expenditure under the approved care regime on the one hand and reduce direct purchase expenditure on the other.

With regard to regional differences, this monitoring also highlights significant variability in terms of expenditure on direct purchases, with the ratio of expenditure to the National Health Fund ranging from 14.67% in Sardinia to 9.91% and 9.65% in Lombardy and the province of Trento, respectively. There is also regional variability in the comparison between the incidence of expenditure on the FSN

in 2025 and 2024, with some Regions recording a reduction in 2025 (i.e. Friuli V.G., Piedmont, Molise and the Autonomous Province of Trento).

With regard to pharmaceutical expenditure under the approved care regime, the Monitoring Report shows a +0.2% increase in the number of daily doses dispensed (equal to +41.5 million), corresponding to an increase in net expenditure under the approved care regime borne by the NHS of €194 million (+3.2%), with significant differences between Regions, eight of which exceeded the ceiling by 6.80% and five of which remained well within the ceiling (<5.4%).

'To ensure better governance of expenditure,' explains AIFA **President Robert Nisticò**, 'the Agency is currently developing a safeguard clause to manage access to reimbursement for new, high-cost, innovative medicines, as well as working on how to implement the provision recently introduced in the 2026 budget law concerning the revision of the national pharmaceutical formulary.'

'The trend in public pharmaceutical expenditure is influenced by many factors, including the introduction of innovative medicines and the ageing of the population, which in Italy has shown a growing expenditure trend over the last 20 years, similar to that recorded in other developed countries with a public health system,' comments **Technical and Scientific Director Pierluigi Russo**. 'The growth in expenditure on direct purchases of medicines in all reimbursement classes by public healthcare facilities is currently +4.9% (September 2025), compared to +9.1% in September 2024 and +15% in April 2024. In 2025, we are seeing a significant reduction in spending on innovative medicines following the expiry of the 36-month innovation licence, as required by law, with the burden being shifted to the direct purchase ceiling, which has been above planned levels for over 10 years. Over the last two years, the new rules introduced on the financing and regulation of pharmaceutical care and the administrative measures regulating access to medicines put in place by the Agency are contributing and will continue to contribute to the results achieved so far'.