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AIFA Restructuring: 3 Changes to Note

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Background

The Italian Medicines Agency (AIFA) reform became active on January 30, 2024. The restructuring impacts the agency's governing bodies and top management. The new AIFA aims for a more streamlined and efficient drug approval process in Italy, and the reform introduces a wide range of changes to the organization and function of AIFA bodies.

Constitution of a new Scientific and Economic Commission (CSE)

1 This new commission merges the Technical and Scientific Committee and the Pricing and Reimbursement Committee. The CSE will be composed of ten people, instead of twenty people that sat on the two separate committees. The commission will be responsible for evaluating the efficacy and safety of drugs, as well as establishing prices and reimbursement (P&R). Despite the merge, health technology assessment and P&R procedures and evaluation criteria will remain the same.

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Abolition of the General Director role and new responsibilities for the President

2 The President of AIFA will now be the agency's legal representative and will chair the Board of Directors. The President will be appointed by the Minister of Health in agreement with the Permanent Conference for Relations between the State, Regions and Autonomous Provinces.

Establishment of two new management figures

3 The Administrative Director will oversee the administrative activity of AIFA and the Technical-Scientific Director will lead the technical-scientific activity, ensuring regulation compliance, coordinating with the European Medicines Agency, and bringing expertise in the pharmaceutical sector. Both roles will be part of the CSE.

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The impact of these changes on the Italian healthcare system and its stakeholders, as well as how the new AIFA will align with the anticipated new European health policies, is still uncertain. We can help you prepare. Let's connect!

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