

The new Framework Agreement between Medicines for Ireland and the State marks a major step forward in strengthening Ireland's medicines system. It delivers greater **predictability, certainty, and stability** for patients, industry, and the healthcare system. The Agreement introduces a comprehensive set of reforms across the pricing, supply, and reimbursement of medicines, ensuring that Ireland remains a competitive and attractive market while also delivering value for the State. For patients, the Agreement strengthens medicine availability by reducing the risk of shortages, supporting earlier access to generics, biosimilars, and value added medicines, and protecting the viability of older essential treatments. For industry, the Agreement provides a clearer, more stable operating environment with defined pricing frameworks, transparent processes for new medicine assessments, and structured governance.

GENERIC BIOSIMILAR & VALUE ADDED MEDICINES

€1,400,000,000

Up to €1.4 billion in value can be generated by generics, biosimilars and value added medicines for the State that can be reinvested into patient care

1.5%

Annual value maintenance price uplift for listed essential medicines

URGENT PRICE UPLIFTS

- 60** Number of days after receiving a complete application that the HSE will make a decision
- 90** Number of days an urgent price uplift will last if approved by the HSE
- 180** Maximum number of days an urgent price uplift will last



Where a medicine becomes economically unviable, the HSE will make a decision on a price uplift application within **60 days**

4 YEARS

The Agreement runs until 31 December 2029



The State and MFI will work in partnership to develop a mechanism for reimbursement of **Value Added Medicines** on a pilot basis.

3 YEARS

after launch when the first price realignment comes into effect for new on patent and VAMs

Tier 2

Allows MFI members to apply for a more sustainable price in cases where it has been uneconomical to launch certain medicines before

BVB timeline certainty

- 90** Number of days of the submission phase (day 1 - 90)
- 90** Number of days in the evaluation phase (day 91 - 180)
- 60** Number of days during pre-implementation phase (day 181 - 240)