be less efficient and fit-for-product than option 2.2 (but still better than the status quo), as it will be difficult to keep up to date. It also leaves decisions about which practitioners can do what with medicines to Parliament, rather than professional regulation bodies. This goes against the idea that professions are best qualified to make these decisions.

How do the options compare to the status quo/counterfactual?

	Option 2.1 – Status quo under s29 of the Medicines Act	Option 2.2 – Flexible pathways via scopes of practice	Option 2.3: Expanded rights in primary legislation
Protection	0	+	+
Efficiency	0	+	+
Fit for product	0	++	++
Overall assessment	0	++	++

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

Option 2.2 is the preferred option, as it will provide more protection against substandard products, mostly through increased regulation of supply of unapproved medicines. It is likely to be more efficient, as prescribing powers of specific professions are updated to reflect the competence of those professions and modern models of care. However it will be less efficient for suppliers of unapproved medicines, who would have to be licensed. It provides a much better fit for product, as medicines will be able to be supplied by any practitioner who has the expertise and qualifications to do so. It will also provide some regulation of unapproved medicines, which appropriately reflects their risk profile. Option 2.3 has the same rating to option 2.2. Initially it will be more efficient than option 2.2, as changes to prescribing and other rights will take effect as soon as the legislation comes into force. However as time goes on, option 2.3 becomes less favourable relative to option 2.2. Option 2.2 best recognises the expertise of professions in determining what their members can do with medicines.

Example key for qualitative judgements:

++	much better than doing nothing/the status quo/counterfactual
+	better than doing nothing/the status quo/counterfactual
0	about the same as doing nothing/the status quo/counterfactual
-	worse than doing nothing/the status quo/counterfactual
- -	much worse than doing nothing/the status quo/counterfactual

What are the marginal costs and benefits of the option?

Affected groups *(identify)*	**Comment** *nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment column.*
Additional costs of the preferred option compared to taking no action			
Medicines industry	Costs from licensing of unapproved medicine supply Efficiency gains from better approval processes		
Crown	Regulator costs addressed in regulator RIS		
Health practitioners	No significant cost impact expected		
Health service providers	Efficiency gains due to practitioners working to top of scope, and more certainty about quality of medicines		
Consumers	No significant cost impact expected		
Total monetised costs		Low	
Non-monetised costs		Low	
Additional benefits of the preferred option compared to taking no action			
Medicines industry			
Crown	Reduced harm from unsafe medicines		
Health practitioners			
Health service providers	More efficient service delivery through modernised prescribing provisions		
Consumers	Improved access and protection		
Total monetised benefits			
Non-monetised benefits			

Section 3: Delivering an option

How will the new arrangements be implemented?

118. Decisions on who would implement the new regulation will be subject to future government decisions. Implementation will include development of secondary legislation which will set out details of the system, particularly elements which are likely to need to change over time.
119. The approval system will be operated and enforced by the Crown. The form of any regulator is discussed in a separate Cabinet paper.
120. Education campaigns may likely to be needed for industry and the public, if there are significant changes from the status quo.
121. Consistent with the Pae Ora (Healthy Futures) Act 2021, the Ministry of Health will retain a stewardship and oversight role.
122. As with all new systems, there is significant risk of time and cost over-runs. There are lessons New Zealand can learn from its existing regime for medicines and medical devices. In addition, comparable jurisdictions, such as Australia, have already undergone similar regulatory reform, and we can learn from their experiences. Costs can be contained in the design of the different pathways for product approval, in particular those involving reliance and notification.
123. Most of the risk comes from other elements not covered in this RIS, such as increased regulation of medical devices and the establishment or redesign of a regulator.

How will the new arrangements be monitored, evaluated, and reviewed?

124. The regulator will have reporting requirements, to be determined as part of policy work on the form and responsibilities of the regulator. The metrics are likely to include:
    1) time taken to approve medicines via the various pathways
    2) time taken to issue licences for controlled activities
    3) compliance and enforcement action taken.
125. Currently it is unclear who is responsible for detecting inappropriate prescribing. Decisions are needed on this as part of this work programme and/or the review of health workforce regulation.
126. There may be a review of the new system within five years of it taking effect.
127. The medicines industry and the healthcare sector have productive relationships with the Ministry and Ministers of Health. We expect them to be proactive in raising any problems or concerns with the new system.
128. Work will be needed on how to ensure that patient/consumer problems with the new system are heard and responded to.