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Box 1: **Summary of proposed pharmaceutical reforms**

1. Access to prescription drugs

- Each nation would establish a formulary of all medically necessary prescription drugs.
- If agents with equivalent efficacy and safety were available, only the least expensive would be included.
- All residents would have full coverage for all formulary medications without copayments, co-insurance, or deductibles.
- When clinically necessary (eg, allergies), non-formulary alternatives would be covered.

2. Drug prices

- Government would negotiate with drug firms to lower prices.
- "Compulsory licensing" would allow generic manufacturers to produce essential patented medications if the patent holder refused to offer a reasonable price.
- Government would commission public production of essential drugs when price negotiation fails and no reasonably priced generic is available.
- New public divisions of the NIH and CIHR would develop non-patented drugs and make them available for low cost generic manufacture.

3. Preclinical drug development

- Preclude patents for trivial modifications of existing agents, and restrict market exclusivity for me-too drugs unless they are shown to be more effective or convenient or have fewer side effects than others in the same class.
- Repeal provisions of the Bayh-Dole Act in the US that allow private firms to obtain exclusive licenses for drugs developed through publicly funded research.
- Establish public drug innovation divisions in the US and Canada that would fund and oversee the early stages of drug development.

4. Clinical testing

- Require higher standards for clinical trials used in drug approval applications.
- Increase the transparency and public availabilty of (anonymized) clinical trial data.
- Publicly fund the majority of clinical trials through new "Clinical Trials Divisions" of the NIH and CIHR.

5. Drug approval reform

- Full public funding of the drug regulatory agecies, ending their reliance on industry user fees.
- Less frequent use of expedited reviews.
- Restrict membership on regulatory advisory comittees to experts without financial ties to drug companies.

6. Postmarketing surveillance

- Enforce requirements to promptly perform post-marketing studies.
- Increase funding and authority for regulatory agencies' postmarketing monitoring programs.

7.Promotion

- Ensure that regulatory agencies have adequate resources to review promotional materials.
- Stiffen sanctions for misleading drug promotion.
- Eliminate tax deductions for expenditures for direct-to-consumer advertising and other marketing and, in some cases, exclude advertised drugs from the formulary.
- Promote academic detailing in lieu of industry detailing.
- Reduce the role of industry funding in continuing medical education and guideline development.