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 availability 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 agencies, ending their reliance on industry user fees.
   • Less frequent use of expedited reviews.
   • Restrict membership on regulatory advisory committees to experts without financial ties to drug companies.

6. Postmarketing surveillance
   • Enforce requirements to promptly perform postmarketing 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.

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