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Health Reform Monitor

From sandbox to pandemic: Agile reform of Canadian drug regulation

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ABSTRACT

Public health urgency for emerging COVID-19 treatments and vaccines challenges regulators worldwide to ensure safety and efficacy while expediting approval. In Canada, legislative amendments by 2019 Omnibus Bill C-97 created a new “agile” licensing framework known as the “Advanced Therapeutic Pathway” (ATPathway) and modernized the regulation of clinical trials of drugs, vaccines, and medical devices [1–3]. While the passage of Bill C-97 caps off twenty years of efforts to reform Canada’s regulatory regime in order to spur innovation and competitiveness, [4,5] the significance of these legislative amendments—and the interests behind them—have yet to be recognized.

Bill C-97’s amendments are salient for several reasons in Canada and globally, as health product regulation bends to COVID-19. First, the amendments to Canada’s F&D Act are linked to pressures confronted worldwide by health product regulators to reconcile the often-competing goals of expediting access to new technologies while ensuring their safety and efficacy. Indeed, the creation of the ATPathway in Canada follows the adoption of a number of specialized regulatory review processes in the EU, Japan, and the US for cell and gene therapies [6,7]. While similarly motivated by innovation [2,3,8], the scope of Canada’s ATPathway is—in contrast to other jurisdictions—unbounded in terms of which products it encompasses, and undefined in terms of when and how evidence about the risks and benefits of Advanced Therapeutic Products (ATPs) is to be generated (Table 1). Dubbed a “regulatory sandbox,”[9] the details of Canada’s approach remain to be seen.

Second, passed just nine months before the pandemic, Bill C-97 informed Canada’s COVID-19 response in important ways, particularly in relation to clinical trials. Health Canada, the regulatory authority for health products, had planned to implement the Bill C-97 amendments by early 2021 [10]. In the context of COVID-19, however, they moved swiftly to implement select elements of this new approach. Specifically, under an Interim Order [11] issued by the Minister of Health targeting COVID-19, Canada has put into place an expedited process for reviewing and authorizing clinical trials. Another Order followed in September 2020 [12] which introduced “rolling reviews” to expedite market access to COVID-19 products. Such agile regulatory approaches were amongst the key proposals made by industry stakeholders during the development of Bill C-97 [13]. While no expedited regulatory process was ultimately incorporated into Bill C-97, and the Interim Order is a temporary measure, it is plausible that the circumstances of the pandemic will

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be used to cement—as a matter of regulatory practice—a lifecycle approach to clinical trial oversight and product appraisal that was, prior to the pandemic, pre-envisioned by the interests that coalesced in support of Bill C-97.

Third, the agenda setting and formulation of the amendments introduced by Bill C-97 were marked by a centralized policy process that privileged access by select industry stakeholders who emphasized the added value of building capacity for innovation and faster access to the market. Amid the urgencies imposed by the COVID-19 pandemic, the implementation of the amendments was hastened, while broader stakeholder negotiations that were to inform the implementation, were delayed. Despite government rhetoric of transparency, both the formulation and implementation of the amendments have occurred with little opportunity for scrutiny or public engagement.

### 1. Legislative reform

The 2019 F&D Act amendments created a distinct regulatory pathway for ATPs, exempting them from aspects of the Food & Drug Regulations [1,14] and creating a “tailored” assessment for market approval. The ATPathway was intended to be used only for the approval of novel technologies that do not fit into current regulations, such as 3D printing of tissues, artificial intelligence as well as advanced cell therapies [2,3,8]. The Minister of Health has the power to classify “emerging or innovative technological, scientific or medical developments” as ATPs and place them in a newly created Schedule G [15] according to: a) their distinguishing features based upon existing products, b) the degree of uncertainty about their risks and benefits, and c) the extent to which existing regulatory frameworks are adequate to prevent injury [16]. The amendments also include scope for additional factors that can be prescribed by prospective regulations. ATPs can be authorized by the Minister, provided that risks can be adequately managed, controlled, and outweighed by anticipated benefit [17]. In addition, two measures increase the regulator’s powers with respect to post-market surveillance of ATPs. First, the Health Minister can impose customized conditions on each product license [18]. Second, the inspector’s powers to enforce compliance with post-marketing conditions are increased [19]. The Minister can also suspend (with or without prior notice) or revoke ATP licenses when changes in the risk to benefit ratio become apparent [20].

Bill C-97 also modernized Canada’s regulatory framework for clinical trials through additions to Section 3 of the F&D Act. Conducting clinical trials without an authorization issued under the regulations is now prohibited, and holders of an authorization must comply with any terms and conditions imposed by the Minister [21]. Although the duty of sponsors to publicize clinical trial information already existed in the Act, a new provision was inserted for increasing the visibility of clinical trial information [22]. Finally, a broad definition of clinical trials was introduced that cov-
ers all types of clinical studies involving humans, beyond the gold standard of randomized controlled trials [23].

Collectively, the 2019 amendments created an “enabling structure” upon which to develop new regulations to govern future clinical trials [24]. Although consultations with stakeholders regarding such regulations are expected to take place in Fall 2021, [25] HC’s engagement with “key stakeholders” during the development of Bill C-97 has already shaped the regulator’s preferred approach. Industry stakeholders’ push for “adaptive” trial designs and novel testing methods for specific populations [3] has, for instance, been positively received by HC [2,3]. The flexibility introduced by Bill C-97’s amendments to clinical trials is not only compatible with such proposals, but according to HC officials also served as a model upon which to build the Interim Orders that were adopted during the pandemic in order to expedite clinical trial application approvals. Given the continuing influence of Bill C-97 amendments, during and potentially beyond the pandemic, it is critical to understand how they came about.

2. The centralized policy process

The legislative amendments behind the ATPathway and modernization of the clinical trials framework were enacted swiftly through a centralized policy process. From its first appearance on the agenda during early 2018, to June 2019 when Bill C-97 received royal assent, the enactment of the ATPathway took less than 16 months (Fig. 1).

Several factors drove the amendments. Powerful advocacy by an alliance of private sector firms representing biotechnology, medical technology, pharmaceuticals, digital health, and the financial services industry, including capital market actors such as private equity funds and venture capital firms, advanced the amendments. Equally important, however, has been a centralized policy process where a) agenda setting and formulation has been insulated from wider interest groups’ participation, b) policy initiation and coordination was undertaken by a federal institution other than the regulatory authority, and c) the amendments were approved through a “fast track” legislative process. Centralization was enabled by the government’s majority position in Canada’s parliament during its first term in power.

Government-appointed advisory committees from the private sector played a critical role in the policy process. Recommendations by two committees, the Advisory Council on Economic Growth (ACEG) and the Health and Biosciences Economic Table (HBSET), were central to agenda-setting and policy formulation. The ACEG was established by then federal Finance Minister, Bill Morneau, in 2016 to advise the Government on economic growth strategies. Its members included fourteen prominent individuals from a range of robust economic sectors including financial services, energy, information, and communication technology industries with long-standing connections to influential global business networks. Recommendations developed by the Council in two separate reports paved the way for the Bill C-97 legislative amendments [26,27]. The Council’s February 2017 report advised the Government to spur innovation and competitiveness of the Canadian economy through modernizing the regulations in strategic sectors with significant global growth prospects, such as life and health care sciences. The Report further suggested that the Government appointed representatives in each strategic private sector identify regulatory obstacles to innovation [26]. In its December 2017 report, the ACEG renewed demands for “flexible and agile” regulations and invited the Government to review all existing regulations to spur the private sector’s investment and innovation activities. The Council made specific reference to the life sciences and health care sector, where “stringent and detailed filing requirements” allegedly delayed the introduction of innovative drugs [27].

The Government acted on both of these recommendations in its 2017 and 2018 Budgets. Budget 2017 created six “Economic Strategy Tables” consisting of Government appointed representatives from the private sector to support innovation in strategic industries [28]. Alongside other sectors such as advanced manufacturing, agri-food, clean technology, digital industries, and clean resources, the Health and Biosciences Economic Table (HBSET) was appointed by then federal Minister of Innovation, Science and Economic Development, Navdeep Bains. Members of the HBSET were dominated by representatives of small and medium-sized biotechnology, medical technology (i.e., devices), biopharmaceuticals, information technology, and consultancy firms but also included the larger transnationals. HBSET was chaired by the managing partner of a large private venture capital firm.

The Government further announced in its 2018 Budget the proposal of regulatory reform agenda to support innovation and business investments [29]. The Treasury Board of Canada Secretariat (TBCS) was to coordinate the “targeted reviews of regulatory requirements and practices that are bottlenecks to innovation and growth in Canada” [27] in three sectors, health and biosciences, agri-food and aquaculture, and transportation and infrastructure [30]. TBCS-led reviews were held during the Spring, Summer, and Fall of 2018, focussing on regulations perceived as stifling innovation. In the Health and Biosciences sector, for example, the stakeholders were asked which regulations and practices limited innovation and were invited to propose recommendations [31]. Focussed on private sector concerns, these select stakeholders, rather

![Fig. 1. Regulatory reform timeline for advanced therapeutic products and clinical trials.](image-url)
than a broader set of healthcare actors, had privileged access and opportunity to shape policy changes.

HBSET proved central in the development of the ATPathway, and in turn, to amendments to the clinical trial framework. During the 2018 reviews, HBEST members emphasized the need to eliminate regulatory hurdles to catalyze innovation and to accelerate the adoption of technologies and commercialization [13]. Members of the Economic Tables, including HBEST, identified the complex regulatory system as the most critical barrier to innovation. They proposed greater use of “regulatory sandboxes,” which would allow experimenting with new technologies in a “safe” environment to accelerate their adoption [32]. Stakeholders thus sought a clinical trial framework and licensing that would allow earlier market access to products based on preliminary evidence. Regulatory sandboxes recommended by Economic Tables’ reports formed the basis of the new licensing system developed for the ATPs. Existing clinical trial requirements and fees were said to limit growth and deter clinical trial investments in Canada [8,31], and separate frameworks were proposed for clinical trials sponsored by small to medium-sized research enterprises, along with new study design options to allow greater and faster access to innovative health products [33].

While the extent to which the ATP policy process was coordinated by the Treasury Board was unusual, the particulars of the policy shift dovetailed with conversations that Health Canada was party to at the international level. The Treasury Board review proceeded largely independent of Health Canada’s “Regulatory Review of Drugs and Devices” (R2D2), launched in 2017 [34]. Whereas R2D2 involved enhancing the regulator’s scientific review capacity, strengthening its use of “real-world evidence,” and increasing collaboration with international partners, [35] it did not contemplate the creation of a new licensing pathway for ATPs nor the modernization of clinical trials, suggested by the Economics Table members during the Treasury Board review. But those issues were central to conversations Health Canada was participating in via the International Coalition of Medicines Regulatory Authorities (ICMRA), a platform of health product regulatory authorities, which had identified health innovation as a strategic priority in October 2017 [36]. When the government announced the Treasury Board regulatory reviews in its 2018 budget, Health Canada moved quickly to hold horizon-scanning exercises, building upon the suggestion made at ICMRA to investigate emerging technologies [3]. Reaching a set of stakeholders through the Treasury Board’s review process—university start-up firms as well as small and medium sized biotechnology companies—that were different from the organization’s traditional stakeholders (i.e. large pharmaceutical firms), Health Canada identified two proposals as critical for regulatory modernization, the ATPathway and the authorization requirements for clinical trials, during its 2018 consultations [37].

Following meetings with the stakeholders, Treasury Board led reviews also invited public input through the Canada Gazette. The Government moved quickly forward with the recommendations proposed by stakeholders. The November 2018 Fall Economic Statement promised immediate improvements to approve new products and services for Canadians faster and to simplify regulations in several key sectors, including health and biosciences [38]. Budget 2019 noted that the clinical trial framework in the health care sector would be modernized, and a regulatory sandbox would be established for the approval of new and innovative products [9].

Health Canada proceeded with the changes to the F&d Act [3] to create the ATPathway and modernize the clinical trial framework [8,37]. The proposed legislative amendments were included in the omnibus Budget Bill 2019, which was tabled in the House of Commons on 19 March, 2019. Amendments to the F&d Act were briefly discussed in the standing committees of the House and Senate but the Act was carried without amendment [24,39].

Enacting legislative changes through omnibus legislation has been a subtle but powerful tool for centralizing the policy process. Although the sitting Government had been critical of omnibus budget bills used frequently by the previous Government [40] and pledged to end their use once in power, the 2019 Budget Bill, like its predecessor in 2018, was an omnibus bill combining amendments to numerous pieces of legislation. Omnibus legislation is larger and has quicker adoption procedures that reduce the scrutiny and oversight functions of Parliament. As a rejection of budget legislation in Canada’s Parliament triggers an election, omnibus legislation, when presented in the form of a budget bill, is more potent in preventing scrutiny by members of Parliament [40].

3. Implications of the policy process for transparency and regulatory oversight of clinical trials and advanced therapeutic products

Government-appointed advisory committees from the private sector and targeted regulatory reviews allowed some industry stakeholders disproportionate privilege in agenda-setting and policy formulation processes. Other civil society organizations, such as patient groups, health professions, and health policy researchers were largely left out of this process. Even some prominent industry stakeholders, such as Innovative Medicines Canada (the country’s first-mover pharmaceutical industry association), complained that the changes were introduced without “meaningful consultation with stakeholders” [41]. To be seen as legitimate actors, the Treasury Board and Health Canada will need to show signs of fostering participation of a broader set of stakeholders affected by the legislative amendments during any further legal reforms.

Greater transparency can also address concerns about fair play and competition amongst some ATP producers [See 35, 41]. The overly broad framework of the 2019 legislative amendments lends uncertainty to how the regulations will be defined and implemented. Health Canada’s stakeholder consultations show that the ATPathway was developed for novel technologies [2–4] but industry stakeholders, who raised these concerns, were worried about its arbitrary use [37,41]. The wording of the legislative amendments is flexible, specifying an open-ended list of factors that the Minister must consider before designating a product as an ATP. Despite assurances from Health Canada officials that the new licensing framework for the ATPathway would not be used as an expedited path to authorization [37], the availability of fast track approval mechanisms in other jurisdictions [31] coupled with stakeholder demands for Canada to follow suit, leaves scope open for lobbying.

Meanwhile, the COVID-19 pandemic catalyzed the implementation of changes to Health Canada’s oversight of clinical trials. On the strength of an “Interim Order” issued by the Minister of Health, Health Canada has authorized adaptive COVID-19 clinical trial designs that combine trial phases – an approach directly informed by the legislative changes introduced through Bill C-97 [35]. In contrast to trials conducted previously, the Interim Order facilitates a broad range of multi-arm, multi-stage trials that explore multiple treatments, dosing, and duration all in the context of a single study. Further, the Interim Order allows for the suspension of a single trial arm instead of the entire trial and reduces reporting requirements, requiring only significant changes, such as to the trial protocol or chemistry and manufacturing, to the regulator [42].

Although processes are in place to transition the Interim Order to a new post-pandemic normal, the extent to which the introduction of the Interim Orders or the 2019 ATPathway will re-configure the regulator’s approach to health products beyond COVID-19 re-
mains unclear. Our fundamental point is that, even though Schedule G of the F&D Act is empty of ATPs at present, regulatory changes do not happen in a vacuum. On the contrary, as we have shown, the desire to expedite clinical trials and product authorizations was not simply a function of the current public health emergency, but rather the result of another constellation of particular interests that have long favored regulatory expediency for very different reasons.

Legislative amendments introduced to the Canadian F&D Act, and the experience of this pandemic worldwide, reveal that the fast pace of biotechnological innovations and their market push in particular, pressure regulatory authorities to make way for them faster. This amounts to a redefinition of the regulatory authorities’ roles to include facilitating product development and innovation. Rigorously ensuring the safety and efficacy of health products will always be in tension with advancing innovation and access. As regulators endure pressure to expedite access in the face of infectious or other diseases, those who are “open to innovation and also be able to adapt as needed” [36] may also enjoy increased reputational rewards. Health Canada took on a leading role internationally in ICMRa activities to develop regulatory tools and approaches for new technologies following the passage of Bill C-97 [43], and other regulatory bodies, including Singapore and Brazil, are tracking Canada’s “regulatory sandbox” approach to see how it accommodates fast emerging biotechnologies [43]. Whether this new-found agility, entrenched in the F&D Act’s exceptional approach to regulating ATPs and extended through the expedited processes developed during COVID-19, spreads aspirations of innovation within Canada’s regulator to the detriment of public health protection, must be closely monitored moving forward.

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Declarations of Competing Interest

None

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