**Health Canada’s Special Access Program (SAP)**

**Inefficiencies in the Drugs and Health Canada’s Special Access Program (SAP)**

**Special Access Program - Defined**

The Special Access Program (SAP) is a Canadian regulatory health policy established by Drug and Health Canada, which is the federal regulatory body, which governs and regulates the licensure and sale of drugs used for human treatment (Government of Canada, 2018). SAP governs access to essential medicines and other health products that are not currently sold in Canada because of the lack of licensure resulting from factors such as marker size limits and the lack of manufacturers’ urge to seek licensure because of the limited number of buyers and the lack of potential large scale commercial use. Health Canada’s mandate as a regulatory body has granted it power to formulate and enforce regulations under Canadian legislations to control the drugs and health products industry. The SAP program allows doctors and their patients to get access to non-marketed medical devices and drugs that are not yet approved in the country (Government of Canada, 2018). The health policy permits doctors to make special requests when patients have life-threatening conditions that have failed to respond to conventional therapies or in cases where such therapies are unsuitable or unavailable. The SAP health policy is currently an issue of concern because the SAP system takes too long to respond to requests for non-marketed drugs and devices, and in some cases the requests are delayed or even denied thus threatening the health and life of the patients involved (Houston *et al*., 2017). Such inefficiency is a concern and some quarters seek to have the system remedied to either quicken its response and effectiveness or to permit access to these non-marketed drugs in Canada so as to avoid delays in accessing essential medicines and medical devices. This concern is best exemplified and emphasized by a recent case in which two Canadian citizens – Zytner and Stephens – visited the Dominican Republic where they acquired hook worms, which caused a serious illness in their feet (Chen, 2018). Unfortunately, the two were unable to get prompt medication because the necessary drug (Ivermectin) was among the non-marketed drugs in Canada. Their efforts to seek SAP approval yielded no fruits because the regulatory body and policy held that there case was not severe or serious enough to warrant an approval of the importation of the drug (Chen, 2018). The two suffered serious feet damage, and they were only able to get medication through a third party that had dual citizenship, which allowed him to purchase the drugs on their behalf from another nation (Chen, 2018). Such examples of tragedy raise concerns about the effectiveness the SAP regulatory framework.

**Special Access Program’s Background**

 The WHO Model Lists of Essential drugs outline a number of drugs that are essential for healthcare, and which should be ideally available to all citizens no matter the jurisdiction (Houston, Elizabeth, & Stan, 2017). Some of these drugs include Albendazole and Ivermectin, which is an important anti-parasitic and Artemisin (anti-malarial). However, these three among others are not available in Canada. The ‘non-marketed’ label is not actually a misnomer because Ivermectin is available in Canada, but it is only available for animal use by veterinarians who treat dogs with parasites (Houston *et al.,* 2017). It is thus only available for non-human use. SAP is the only path towards obtaining such important medication, and it is in itself a non-effective and bureaucratic system that is inefficient in granting and facilitating access to essential drugs, which are not marketed in Canada. The reasons of inaccessibility in this case have nothing to do with the actual utility of the medication. Actual reasons of unavailability include business decisions by some drug manufacturers to not seek authorization or licensure in the Canadian market because it is a limited market (Houston *et al.,* 2017). Parasitic infections that need Ivermectin or malaria, which needs Artemisin therapy, are rare conditions in the Canadian context. As such, manufacturers of such drugs view Canada as a small market with a limited capacity to grow. Therefore, they often opt not to seek licensure and supply authorization to such markets, and hence the unavailability of such drugs (Houston *et al.,* 2017). Additionally, pharmaceuticals see little commercial viability in such drugs whose patents have expired and only have limited returns. As such, most of them prefer to seek authorization for new drugs rather than old ones. This implies that many drugs are left out in the regulatory limbo in Canada leading to unavailability (Houston *et al.,* 2017).

**The political will to reform SAP**

In spite of the SAP challenges, the government as the leading body under which Health Canada operates is trying to make an effort in reforming SAP regulations to ensure that there is sufficient access to essential medication. According to Houston and others (2017), Health Canada has announced reformed SAP regulations, which respond to the opioid crisis by increasing access to it and other essential drugs already available in other nations such as the USA such as prescription heroin (Houston *et al.,* 2017). The new regulations allow large scale imports of such drugs for any urgent public needs. The regulations are also expected to apply to similar cases such as flu pandemics (Houston *et al.,* 2017). This change in regulation seems to be a step in the right direction, but the government is yet to do more because most other ‘non-marketed’ essential drugs are not yet easily available in Canada.

**Federal jurisdiction on the SAP issue**

This issue relating to the access of essential medication under SAP falls within the legal and regulatory jurisdiction of Drug and Health Canada, which is the federal regulatory body under the Canadian government, which governs all matters relating to the sale of drugs and medical devices (Government of Canada, 2018). Health Canada is mandated with the formulation and enforcement of laws and regulations that govern the supply of such medical products under the Canadian government. This regulatory body consults with the industry, the public, and other concerned third parties in formulating regulatory frameworks that protect the safety and health of the populace (Government of Canada, 2018). The body also creates policies such as SAP and guidelines, which help in clarifying and interpreting procedural protocols that relate to health products and drugs (Government of Canada, 2018). The body ensures its regulatory practices are concordant to international standard. It also facilitates mutual cooperation with other jurisdictions outside Canada and ensures timely approval of medical technologies and products. Therefore, all concerns relating to SAP squarely fall under Drug and Health Canada at a national level (Government of Canada, 2018).

**Provincial jurisdiction on the SAP issue**

Regulation at the provincial jurisdictional level still falls under Drugs and Health Canada, but its provincial control and regulation does not directly occur under its sole mandate (Government of Canada, 2018). Instead, Health Canada works at the provincial and territorial levels as a department, which coordinates with the provinces and territories as well as other interested stakeholders in promoting the availability of drugs as well as optimal drug therapy and the provision of cost-effective and therapeutically beneficial pharmaceuticals. It works with all these bodies to facilitate better quality drugs, and better access to the drugs at a fair rate in terms of cost (Government of Canada, 2018).

**References**

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