

# One-licence solution for a one-hit wonder: Reforming Canada's Access to Medicines Regime to create a workable model of using TRIPS flexibility of compulsory licensing for exporting generic medicines

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## 1 Issues

- **Legislative initiative:** Following civil society campaigning, in May 2004, Canada implemented the WTO General Council Decision of 30 August 2003, creating “Canada’s Access to Medicines Regime” (CAMR). CAMR enables *compulsory licensing* of patented pharmaceuticals to facilitate exports of lower-priced, generic versions of medicines patented in Canada to eligible importing countries.
- **First licence:** In September 2007, the first compulsory licence was issued under CAMR, authorizing Canada’s largest generic manufacturer, Apotex Inc., to export **15.6 million tablets of Apo-Triavir (300mg zidovudine + 150mg lamivudine + 200mg nevirapine) to Rwanda**. Apo-Triavir is approved by Health Canada and was pre-qualified by WHO in August 2006.
- **International tendering:** CAMERWA, Rwanda’s central pharmaceutical procurement agency, issued an international tender in late 2007 for AZT+3TC+NVP. In May 2008, Apotex announced it had succeeded in bidding to supply Rwanda, at a price of US 19.5 cents per tablet — meaning treatment with this regimen would cost US\$146 per patient per year, lower than the then-lowest, publicly-reported price from a generic source (US\$176 per patient per year).
- **Shipment:** By agreement, Apotex shipped the authorized quantity of Apo-Triavir to CAMERWA in two separate shipments, in September 2008 and September 2009.
- **Further use?:** This is the only use to date of the 2003 WTO Decision. There is little chance CAMR will be used again, absent reform. Developing country representatives, NGOs, international experts and Apotex have criticized CAMR’s unnecessary restrictions. Apotex has indicated it will not attempt to use CAMR again in its current form; other generic manufacturers have shown no interest.

## 2 Description

Civil society is campaigning for CAMR to be streamlined to reflect needs of developing countries and generic manufacturers, as follows:

- We worked with legislators to draft and introduce bills in Canada’s Parliament that would eliminate the requirement for a separate CL for each order of a medicine, which licence is limited to a pre-determined quantity for one country, with a 2-year limit. Instead, Bill C-393 would enact a “**one-licence solution**” that grants, via a single compulsory licence, the legal authorization to generic manufacturer to produce any patented pharmaceutical product solely for export to any developing country covered by the legislation.
- We secured a public commitment from Apotex that, if CAMR is reformed as proposed, it will use it again — first to supply a paediatric formulation of Apo-Triavir.
- The Global Treatment Access Group (GTAG), a coalition of Canadian civil society organizations, campaigned for reforms using media, public education (e.g., street action, social networking), lobbying (petitions, letters/postcards/e-mails, individual meetings, Parliamentary committee hearings), and marshalling support from independent experts on intellectual property law, UN agencies and prominent public figures, including the former Prime Minister whose government enacted the legislation.

## 3 Lessons learned

Chief barriers to CAMR reform include opposition by governing party (but in a minority Parliament), and intensive misinformation by patent-holding pharmaceutical companies and some Parliamentarians about:

- the capacity of developing countries’ health systems;
- risks of diversion of medicines;
- WTO law and domestic patent law; and
- the supposed impact on pharmaceutical R&D.

Depending on outcomes of campaign, a streamlined CAMR could facilitate greater ARV access in developing countries, including for children, and could create global model for legislation elsewhere.

## 4 Next Steps

Bill C-393 must be reviewed by a Parliamentary committee (scheduled for last quarter of 2010) and enacted without significant amendments by both houses of Parliament.

► [www.aidslaw.ca/camr](http://www.aidslaw.ca/camr)

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