

Generic competition, price and access to medicines

The case of antiretrovirals in Uganda

Access to treatment is a key part of national strategies to combat HIV/AIDS. Antiretrovirals can increase the length and quality of life, and the productivity of patients. Research in Uganda shows that poor people will use ARVs if the price is right and if a delivery system is place. It also shows that the price of brand-name drugs fell significantly only when generics entered the market. Generic competition, the use of the public-health safeguards in the TRIPS Agreement, and urgent funding for health-service delivery are essential parts of the fight against HIV/AIDS in developing countries such as Uganda.



Summary

John, a local fisherman near Kampala, has felt much better since he started antiretroviral therapy. He can work and provide for his family. John's wife has also recently been diagnosed with HIV. 'I do not have the money to pay for medicines for both of us.' If he pays for his wife, his children cannot go to school and 'they will not have a future.' If he stops taking the ARVs to enable his wife to be treated, he will die. 'What will happen to my family?' he asks. Like many others, John says a more affordable price would be around 10 per cent of income. This would allow both John and his wife to access treatment. John believes that the government should help those in need by cutting the price of ARVs.

The dramatic decrease in morbidity and mortality seen in industrialised countries due to the use of antiretroviral therapies has not happened in developing countries, which account for 90 per cent of global HIV infection. The principal barrier to these life-saving medicines is their high cost, in the context of low family incomes and public-health budgets. Out of the 1.5 to 2 million HIV-positive Ugandans, only between 5,000 and 10,000 (0.3 – 0.5 per cent) are currently receiving antiretroviral therapy. Most of those on treatment have to sacrifice other family needs in order to pay. Women tend to go without when families have to make choices about who gets treatment.

This paper outlines the findings of Oxfam research into the accessibility of ARV therapy in Uganda since 2000. During that year two important events improved access to these medicines. First, five drug companies agreed to reduce the price of some ARVs under a UNAIDS scheme. Second, the Joint Clinical Research Centre (JCRC), the biggest provider of this therapy in Uganda, imported low-cost generic ARVs from India.

The study's conclusions are:

- **The crucial role of generic competition.** When generic medicines entered the market, the price of patented medicines fell dramatically. This finding reinforces the view that an important determinant of price, and therefore accessibility of ARVs, is competition from generic medicines:

‘...we had been promised price cuts since May 2000 and didn't see them until we started to import generics in October,’ Cissy Kityo, Research and Clinic Deputy Director of JCRC.
- **The need for a systematic tiered pricing mechanism.** The difficulties that Oxfam researchers encountered in obtaining information about the offer from the five companies reinforces the need for a transparent system of tiered pricing in developing countries. Generic competition provides the vital benchmark for low prices.
- **Poor people can use ARVs if the price is right.** Interviews clearly showed that relatively poor people in low-income countries do buy medicines for life-threatening diseases, but that they have to make huge sacrifices to do so. As a result of price cuts and generic importation, JCRC was able to increase the number of patients treated by ARVs from 962 to 3000.

- **The need to maximise the use of TRIPS safeguards and ensure that public health takes precedence over patent rights.** After 2005, Uganda will no longer be able to import generic versions of newly patented medicines because generic-producing countries, such as India, will no longer be allowed to export them. Rich-country trade ministers committed themselves at Doha in November 2001 to find a solution to this problem by the end of 2002, but are backsliding on this pledge by putting forward temporary, impracticable, and highly restrictive solutions.
- **The urgent need to fund health services to deliver treatment.** Funding health services should go hand-in-hand with massive cuts in prices. The Global Fund provides opportunities for countries such as Uganda to deliver comprehensive programmes which include treatment using ARVs.

1 Introduction

'I feel embarrassed because of my medicines and the burden on my family; I have to constantly struggle to get the money and keep the family going. It's a tug of war.'

At the beginning of his treatment James, a police officer in Kampala, paid \$247 per month. Now that the price of ARVs has decreased he pays \$127, which accounts for all his income and most of his wife's. She has not been tested, and the family could not afford her treatment if she needed it.

Uganda is considered a success story in combating HIV/AIDS, due to its early recognition of the implications of the disease and its vigorous public-education programme. Yet there are between 1.5 and 2 million Ugandans infected by HIV who need treatment. The Accelerating Access Initiative (AAI) began in May 2000 with an agreement between the UN and five pharmaceutical companies to use price reductions to secure a rapid increase in access to antiretrovirals (ARVs) in developing countries. However, significant price reductions were not observed until the importation of generic ARVs by the Joint Clinical Research Council (JCRC), the major centre among 14 accredited centres for the delivery of treatment in Uganda.

This paper draws on research by Oxfam in Uganda to understand the current situation in terms of access to ARVs and to describe the role generic alternatives to these branded medications have played in increasing accessibility. The research also reviewed Ugandan patent laws, including the newly proposed Industrial Property Bill 2002 (IP Bill). The paper presents an overview of the AAI and price trends, the affordability of treatment, and its impact on patients' lives, followed by a review of the IP laws and some recommendations.

2 Accelerating Access Initiative (AAI)

'My children do not know that I am sick. I want them to go to school, and I do not want them to know that I can die if I do not have my medicines.'
Agnes, a shopkeeper and AIDS widow.

Global public pressure led to a partnership between the UN and five pharmaceutical companies to make a rapid increase in access to ARVs in selected developing countries by introducing significant price reductions. Just before the Durban conference on HIV/AIDS, which focused on treatment, the five companies announced their intention to cut the prices of ARVs. Apart from GlaxoSmithKline, which announced a 90 per cent reduction in price, the other four

companies (Boehringer Ingelheim, Bristol-Myers Squibb, Merck, and Hoffman-La Roche) did not specify the level of price cuts.

The cuts were welcome, but prices were still too high. Moreover, the AAI gave no guidance concerning relations between the pharmaceutical corporations and developing countries. Companies negotiated directly with governments on a country-by-country, drug-by-drug basis. Uganda was the first to sign an agreement.

‘Competition is what brought prices down. There was an 80-90 per cent price cut when JCRC brought in generics on an emergency basis.’
Programme Advisor for UNAIDS in Uganda.

Although the AAI was signed in May 2000, the most significant reductions in prices for branded ARVs in Uganda coincided with the importation of generics from an Indian company (Cipla) by JCRC in October 2000 (**Annex 1**).

The introduction of generics led to a fall by December 2000 in the prices of brand-name medicines to between 22 per cent and 70 per cent of the May 2000 price. By March 2001 the price of AZT and abacavir to between 44 per cent and 48 per cent of the September 2000 price respectively. The largest decrease was for D4T, which fell from US\$173 for a monthly dose of 40 mg to US 118 in December 2000, to US\$ 23 in February 2001, and then eventually to US\$6 in April 2002 (**Annex 2**). In November 2000, the price of lamivudine was almost half what it was a month earlier. The price of Combivir, an important basic double combination, fell from US\$220 in May 2000 to US\$71 in February 2001 – 32 per cent of its original price.

Given that antiretroviral medicines are prescribed in triple combination, a decrease in the price of just one of the components prompts an overall decrease in the price of the cocktail. A combination of Combivir and efavirenz, both branded drugs, costs \$119 per month. By substituting Combivir with the generic equivalent (Duovir), the cost decreased to \$83 per month. The monthly cost of the triple cocktail of brand-name stavudine, lamivudine, and indinavir is US\$114. By replacing the first two drugs with generic equivalents, this is reduced to US\$85 per month. However, the cheapest triple-ARV cocktail is Triomune – a generic drug imported from India – which costs \$40 per month. It also has the added value of combining three drugs patented by different companies into one medicine, making it easier for patients to comply with the treatment.¹ JCRC estimates that 700 of its patients are currently taking Triomune.

3 Impact on access

'Over half of our patients would stop treatment if we were unable to import generics.' Dr. Cissy Kityo, Deputy Director of JCRC.

The progressive price cuts were reflected in an increase in the number of patients receiving ARV therapy at JCRC Centre. With the importation of generic drugs, JCRC increased the number of patients on ARV therapy from 962 in 2000 to 3000 in 2001 – a 200 per cent increase in the numbers of patients taking ARVs at one treatment centre alone. JCRC is the largest provider of ARVs in Uganda, dispensing roughly 40-70 per cent of all ARVs.

More patients are now accessing treatment beyond the centre, because JCRC has started providing medicines to some government regional hospitals. It has already dispensed approximately 2500 doses of generic ARVs, including Triomune, to the Mbarara hospital between October 2001 and March 2002.

Price reductions also helped patients improve significantly adherence to their treatment regimen, thus reducing the risk of HIV drug resistance. However, there is still a long way to go for the thousands who need the treatment but cannot yet access it.

4 Patents and access to medicines

Seven ARVs are patented in Uganda, five of which have generic equivalents imported from India. Although these drugs are patented in Uganda under current IPR law, no lawsuits have yet been filed by the patent holders. An additional 15 generic ARV registration applications have been filed with the national drug authority, which will enhance competition and lower prices.

Under current Ugandan law, patents must be granted for products and processes for 15 years. Uganda is also a member of the African Regional Industrial Property Organisation (ARIPO), which has been frequently used by companies to obtain patents for HIV-related products. Between 1989 and the end of 2001, 61 ARIPO patent applications relating to HIV were filed, including the triple-combination Trizivir.² The generic equivalent of Trizivir may not be allowed in Uganda if the patent holder decides to enforce the patent rights. This would deprive patients of the option of a fixed-dose combination, which improves adherence.

The Patents Bill 2002 will make Uganda comply with the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights

(TRIPS) even before it is obliged to do so. The Agreement requires a minimum of 20 years' patent for new pharmaceutical products and their processes. If the proposed IP Bill is enacted, not only will Uganda lose its transition period for TRIPS compliance (until 2006), but also the further extension until 2016 granted in Doha for pharmaceutical products.

The TRIPS safeguards, such as compulsory licensing (over-riding a patent in the public interest) and parallel importing (buying a patented drug from the cheapest international source), are restricted under the new Bill. The grounds for compulsory licensing are unclear and require a judicial process, which opens the door to endless litigation by companies, and inhibits countries from using this safeguard. The option of compulsory licensing gives governments a vital bargaining tool when negotiating lower prices with pharmaceutical companies.

The Bill also restricts parallel importation to imports by the patent holder, or with the holder's expressed consent. This will prevent importation from a third country where the medicine may be on the market at a much cheaper price.

Over 95 per cent of drugs consumed in Uganda are still imported (33 per cent from India alone), of which 80 per cent are generics.³ Patents on pharmaceuticals (such as ARVs) can be used to prevent the importation of cheaper essential medicines and the local manufacture of similar products.

5 Affordability and funding

Most patients who were interviewed by Oxfam researchers are spending 50 per cent or more of their monthly incomes on ARVs. People are making great sacrifices to pay for treatment. The research found that women with HIV-infected partners are often not tested if they are not ill, partly because the family could not afford medicines anyway. It is clear that patients appreciate the value of medicines. 'I must continue to pay or I will die,' said Charles, a civil servant. 'Before I was sick, and now I am fine.' In Violet's case the treatment meant that she could work as a shopkeeper, earn money, and send her children to school.

However, prices are still beyond the means of the majority of patients who need them. Patients interviewed said that they could pay around 10 per cent of their income for treatment, and recommended that the government intervene for further price reductions. Accredited health centres focus primarily on treating opportunistic

infections and providing palliative care because the majority of patients cannot afford ARV therapy.

‘Why should we tell patients about ARVs when they will not be able to buy them? It will just make them more depressed.’ Dr. Moses Kanya, Co-director Mulago hospital HIV clinic.

Many patients are not aware of generic options available at lower cost, since the medical profession gets information mainly from the large pharmaceutical companies’ promotional material. In addition to the cost of ARVs, patients have to pay for lab tests. Health centres must also be equipped, and resources found to pay staff to deliver treatment services.

6 Conclusion and recommendations

Access to treatment is a crucial element of national strategies to combat AIDS, and should co-exist with prevention and care. ARVs can increase the length and quality of life, as well as the productivity of infected patients, and thus their contribution to the national economy. Treatment can also offer hope for the future, which is often a necessary motivation for testing and accepting of safe sex education. But the high price of medicines is still an impossible barrier for the very poor, and women are severely disadvantaged in gaining access to this life-saving treatment.

It was only when generic equivalents to branded drugs entered the market that the price of brand names came down significantly. This study showed that, where an organised treatment system was in place, generic competition led to a 200 per cent increase in the number of patients using the medicines.

The Ugandan government should ensure that the new IP Bill takes full advantage of the existing public-health safeguards as confirmed at Doha, to ensure that Ugandan HIV/AIDS patients can benefit from the importation of cheap generics in the future.

However, the great majority of HIV-infected Ugandans still cannot afford to pay for therapy. The international community, especially the Global Fund to Fight HIV/AIDS, TB, and Malaria, should support national treatment programmes.

In order to help Ugandan patients to get access to medicines essential to their survival, donors, the Global Fund, pharmaceutical companies, and the Ugandan government need to:

- Apply a systematic tiered-pricing system whereby developing countries pay the minimum price of medicines based on the

marginal cost of production. This will not unduly affect drug companies' profits as these are earned in rich countries. Generic competition creates price competition, an essential element in setting the benchmark for low prices.

- The Ugandan government should revise the draft Bill to take full advantage of the public-health safeguards in the TRIPS Agreement and Doha declaration, including the extra allowable transition period.
- WTO members must agree to an effective solution to the predicament of countries lacking the capacity to make their own medicines. Regardless of the TRIPS safeguards, after 2005 they will have nowhere from which to import them.
- The Global Fund should recognise that access to affordable medicines to combat AIDS includes the delivery of treatment services. The Fund should support regional and multi-country bulk purchase of medicines, including generics.
- Government and donor programmes should create awareness among the medical profession and the public regarding the value of generic medicines.

Notes

¹ Triomune is a combination of generic versions of lamivudine, developed by GSK, stavudine, developed by Bristol-Myers Squibb, and nevirapine, developed by Boehringer Ingelheim.

² A fixed-dose combination of AZT, lamivudine, and abacavir produced by GSK.

³ National Drug Register, Uganda, December 2001.

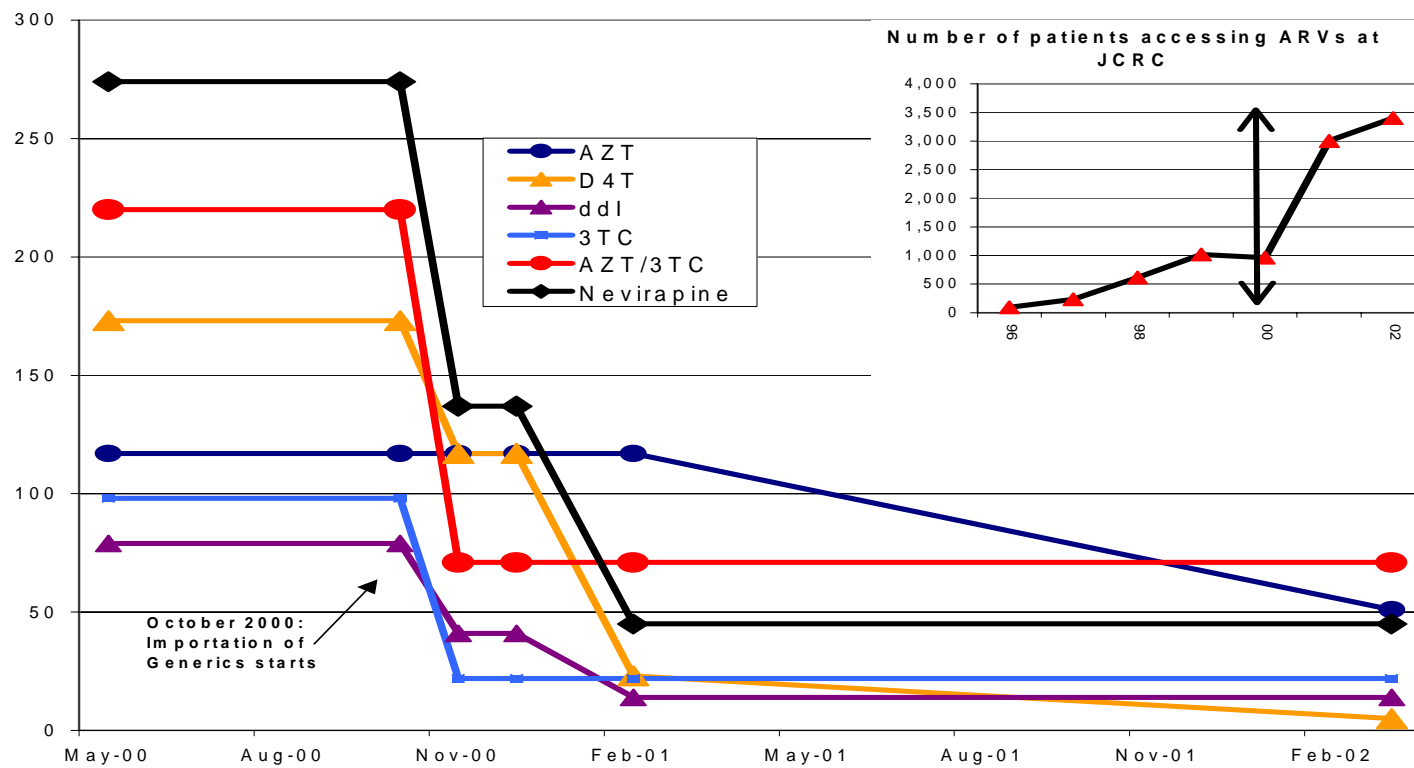
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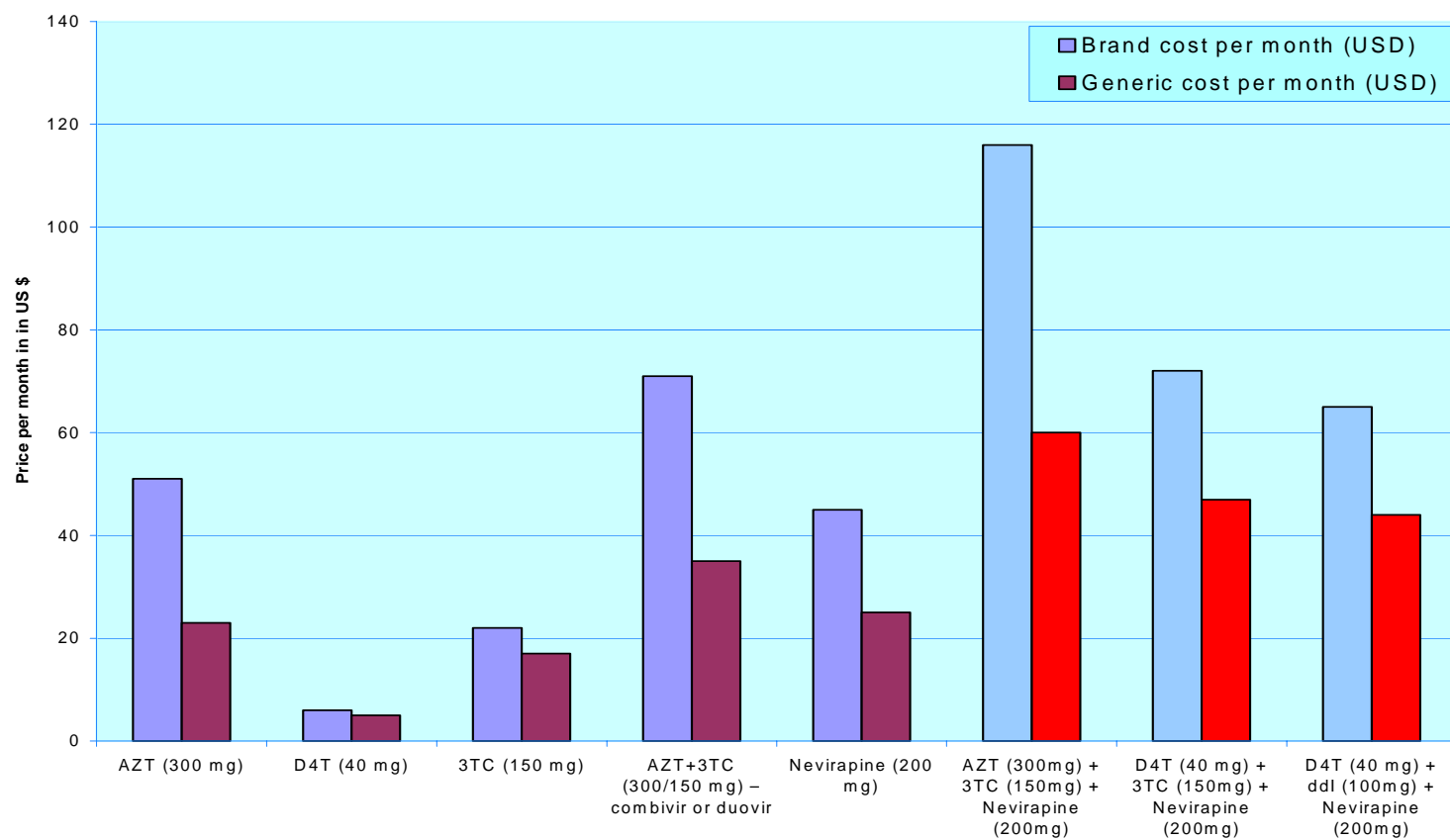
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For further information please email advocacy@oxfaminternational.org

Impact of introduction of Generics on prices of ARVs and number of patient treated



Comparison of prices of brand name and generic ARVs in 2002



Non-Proprietary Drug Name (Dosage)	Chronology of Prices of brand name ARVs							
	May – Oct. 2000	Nov. 2000	Dec.2000	Dec. Cost as % May/Sept 2000	Jan – Feb 2001	Jan/Feb cost as % May/Sept 2000	Mar – April 2002	Mar/Apr cost as % May/Sept 2000
NRTIs								
Zidovudine/AZT (300 mg)	117	117	117	100%	117	100%	51	44%
Zidovudine/AZT (100 mg)	81	81	81	100%	81	100%	30	37%
Stavudine/D4T (40 mg)	173	118	118	68%	23	13%	6	3%
Stavudine/D4T (20 mg)	160	112	112	70%	15	9%	5	3%
Lamivudine/3TC (150 mg)	98	22	22	22%	22	22%	22	22%
AZT+3TC (300/150 mg) – combivir or duovir	220	71	71	32%	71	32%	71	32%
Didanosine/ddl (100 mg)	79	41	41	52%	14	18%	14	18%
Didanosine/ddl (25 mg)	20	10	10	50%	8	40%	8	40%
Abacavir (300 mg)	266	266	266	100%	266	100%	127	48%
NNRTIs								
Efavirenz (200 mg)	207	207	103	50%	104	50%	48	23%
Nevirapine (200 mg)	273	137	137	50%	45	16%	45	16%
PIs								
Nelfinavir (250 mg)	400	400	400	100%	400	100%	311	78%
Indinavir (400 mg)	289	289	96	33%	96	33%	57	20%
Lopinavir/Ritonavir (133.3/33.3 mg)							62	

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Oxfam International Advocacy Office, 1112 16th St., NW, Ste. 600, Washington, DC 20036 Tel: 1.202.496.1170, E-mail: advocacy@oxfaminternational.org, www.oxfam.org

Oxfam International Office in Brussels, 60 rue des Quatre Vents, Brussels, B1080 Tel: 322.501.6761

Oxfam International Office in Geneva, 15 rue des Savoises, 1205 Geneva Tel: 41.22.321.2371

Oxfam International Office in New York, 355 Lexington Avenue, 3rd Floor, New York, NY 10017 Tel: 1.212.687.2091

Oxfam Germany

Greifswalder Str. 33a
10405 Berlin, Germany
Tel: 49.30.428.50621
E-mail: info@oxfam.de
www.oxfam.de

Oxfam-in-Belgium

Rue des Quatre Vents 60
1080 Buxelles, Belgium
Tel: 32.2.501.6700
E-mail: oxfamsol@oxfamsol.be
www.oxfamsol.be

Oxfam Community Aid Abroad

National & Victorian Offices
156 George St. (Corner Webb Street)
Fitzroy, Victoria, Australia 3065
Tel: 61.3.9289.9444
E-mail: enquire@caa.org.au
www.caa.org.au

Oxfam GB

274 Banbury Road, Oxford
England OX2 7DZ
Tel: 44.1865.311.311
E-mail: oxfam@oxfam.org.uk
www.oxfam.org.uk

Oxfam New Zealand

Level 1, 62 Aitken Terrace
Kingsland, Auckland, New Zealand
PO Box for all Mail: PO Box 68 357
Auckland 1032
New Zealand
Tel: 64.9.355.6500
E-mail: oxfam@oxfam.org.nz
www.oxfam.org.nz

Intermón Oxfam

Roger de Lluria 15
08010, Barcelona, Spain
Tel: 34.93.482.0700
E-mail: intermon@intermon.org
www.intermon.org

Oxfam America

26 West St.
Boston, MA 02111-1206
Tel: 1.617.482.1211
E-mail: info@oxfamamerica.org
www.oxfamamerica.org

Oxfam Canada

Suite 300-294 Albert St.
Ottawa, Ontario, Canada K1P 6E6
Tel: 1.613.237.5236
E-mail: enquire@oxfam.ca
www.oxfam.ca

Oxfam Hong Kong

17/F, China United Centre
28 Marble Road, North Point
Hong Kong
Tel: 852.2520.2525
E-Mail: info@oxfam.org.hk
www.oxfam.org.hk

Oxfam Quebec

2330 rue Notre-Dame Quest
Bureau 200, Montreal, Quebec
Canada H3J 2Y2
Tel: 1.514.937.1614 www.oxfam.qc.ca
E-mail: info@oxfam.qc.ca

Oxfam Ireland

9 Burgh Quay, Dublin 2, Ireland
353.1.672.7662 (ph)
E-mail: oxireland@oxfam.ie
52-54 Dublin Road,
Belfast BT2 7HN
Tel: 44.289.0023.0220
E-mail: oxfam@oxfamni.org.uk
www.oxfamireland.org

Novib

Mauritskade 9
2514 HD. The Hague, The Netherlands
Tel: 31.70.342.1621
E-mail: info@novib.nl
www.novib.nl

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