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# Sharing the benefits of genetic research

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should be the same for all submissions regardless of country of origin or type of institution.

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# Sharing the benefits of genetic research

*Will the World Trade Organization act to stop the exploitation of biodiversity?*

Campaigners are calling on policy makers at next week's sixth World Trade Organization ministerial conference in Hong Kong to make trade fairer for and improve the lives and health of the world's poorest people. This broad and important aim may dominate the headlines, but ministers will also be discussing technical issues surrounding international patenting laws. One issue with implications for the development of medical products is the tension between international patenting laws and benefit sharing requirements, which may threaten agreements on protecting biodiversity. If the biodiversity door shuts because of protests in developing countries, pharmaceutical research will be seriously hampered.

In Hong Kong the World Trade Organization can stop the exploitation of non-human genetic material and traditional knowledge by aligning the trade related intellectual property rights (TRIPS) agreement with the Convention on Biological Diversity. Over the past decade benefit sharing has become a recurrent theme in international debates on human and non-human genetics. The term arose from the Convention on Biological Diversity adopted at the 1992 earth summit in Rio de Janeiro, Brazil.[1] The convention has three objectives: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits from the use of genetic resources ("benefit sharing"). Although benefit sharing is compulsory when the biosciences industry or research centres use biodiversity and associated local or indigenous knowledge to develop new products and services, it is not covered by legally binding international trade agreements, such as TRIPS,[2] nor does it cover human genetic resources.

Benefit sharing is particularly important in three contexts in genetics: access to non-human genetic resources and associated traditional knowledge, human genetic banking, and research on rare genotypes.[3] The few benefit sharing agreements that have been signed to date have been widely criticised (see box on bmj.com).[4–7]

Concerns regarding benefit sharing for non-human genetic resources and traditional knowledge have included practical problems such as: how can prior informed consent be obtained from large communities without adequate means of representation; how can the socioeducational gap between negotiating partners be bridged; how can lack of trust between negotiating partners be overcome; and which benefits should be made available when and to whom? Principled objections have included concerns about incompatibility between the concept of communally owned traditional knowledge and the intellectual property rights system; views that sacred knowledge ought never be patented; and the fear that benefiting individual communities according to ethnic distinctions is divisive.

These concerns should not detract from the fact that 187 countries and the European Union have agreed in the Convention on Biological Diversity that benefit sharing for non-human genetic resources and traditional knowledge is legally binding.[1] It is in this context that an earlier ministerial conference of World Trade Organization members agreed the Doha Mandate in Qatar in November 2001.[8] This mandate identified the need for further negotiation on the clash between TRIPS and the Convention on Biological Diversity. This was reinforced by a series of submissions to the World Trade Organization from a group of Latin American and Asian countries which suggested how to bridge the gap between the two agreements.[9] These submissions urged that patent applicants should provide disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention; evidence of prior informed consent through approval of authorities under the relevant national regime; and evidence of fair and equitable benefit sharing under the relevant national regime.

Without the proposed revision of TRIPS, the Convention on Biological Diversity is legally binding but lacks "teeth" because it does not include the strong mechanism for dispute settlement that is provided by World Trade Organization treaties. Ministers will consider the revision in Hong Kong and are in an excellent position to stop the exploitation of non-human genetic resources and traditional knowledge.

Aside from the discussions in Hong Kong, benefit sharing for human genetic resources is an even greater challenge, as none of the relevant international guidelines are legally binding (HUGO Ethics Committee statement on benefit sharing,[10] UNESCO International Declaration on Human Genetic Data[11]). It has therefore been suggested that the Convention on Biological Diversity should be extended to include human genetic

P+ *Box showing benefit sharing agreements is on bmj.com*

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resources.[12] However, benefit sharing agreements under the Convention are negotiated locally, between contracting individuals ("I want your plant, what do you want in return?"). This market model does not sit comfortably with human health needs. Merely expanding the convention to cover human genetic resources might serve as "window dressing" for national governments and detract from efforts to make them regard health and health research as a state priority and the best economic investment they could make.[13–15] Instead the research community should make a concerted effort in cooperation with national governments to devise a legally binding framework for sharing the benefits of human genetics research that is based on equity, justice, and the spirit of the convention.

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# Is methadone too dangerous for opiate addiction?

*The case for using a safer alternative, buprenorphine, is strong*

Methadone is an effective treatment for heroin addiction, and it remains the mainstay of drug treatment for opiate dependence in the United Kingdom.[1] The lethal dose of methadone is estimated at 50 mg for an opiate-naive adult.[2] Nevertheless, many authorities recommend that methadone doses should be gradually increased to maintenance doses of 80-120 mg[1]—that is, twice the lethal dose for non-users. The greatly increased risk to users from methadone, particularly black market methadone, thus remains a major concern. Buprenorphine is a partial agonist that has a lower potential for causing respiratory depression than many other opioids, including methadone and heroin.[3] It is increasingly used in the United Kingdom to treat opiate dependence, with guidelines for clinical management in primary and secondary care summarised by Ford et al[4] and Taikato et al.[5] It is time it replaced methadone as the mainstay of drug treatment for opiate dependence.

A long running debate continues between proponents of long term maintenance treatment with methadone and the proponents of detoxification (in which the dose of a substitute drug is reduced over time to achieve abstinence from all agents). An expert US panel concluded, "although the drug free state represents an optimal treatment goal, research has demonstrated that the state cannot be achieved or sustained by the majority of persons dependent on opiates."[6] Without digressing further into this debate, we point out that that buprenorphine is at least as effective as methadone in both maintenance and detoxification.[7–9]

One mechanism to reduce the diversion of methadone on to the black market is to insist that these drugs are taken in the presence of a pharmacist rather than being given "to take away." Repeated advice to this effect is provided by the UK Department of Health and the Home Office.[1 10] We have recently contacted 120 of the 140 community drug teams in England and Wales to ask what proportion of new patients on methadone undergo supervised consumption. We found that at least 25% of people who start prescriptions for methadone are still prescribed methadone to take away. This

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