

The response reproduced below was submitted further to a consultation held by the Nuffield Council on Bioethics on its Report: *Pharmacogenetics- ethical issues*, during November 2002 – February 2003. The views expressed are solely those of the respondent(s) and not those of the Council.

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Twin Registry

Question 1

The question was probably framed by taking into account only one model; the large multinational commercial pharmaceutical industry from developed-world manufacturing medicine.

This is not the only model of medicine manufacturing. Several countries such as China, Cuba has its own state sponsored production of medicines. Sri Lanka's State Pharmaceutical Manufacturing Co-operation also manufactures medicines. In India and Brazil there are large pharmaceutical manufacturing commercial organisations.

In development of new medicines a strong research base is necessary but is not always found in developing countries. To manufacture new medicines for the illness burden in developing countries existing R&D capacity in state and non-governmental sector has to be developed and when they are non-existent new organisations with R&D capacity to develop new medicines has to be established in the developing world.

Unless this is done there won't be any new medicines for the developing world and even if there are they will not be accessible except for the privileged few. So we in the third world won't feel any impact of the development of pharmacogenetics.

Question 2

Large-scale population based clinical and disease databases should be established by non-commercial organisations. (e.g. Sri Lankan Twin Registry) These databases will facilitate research-based pharmacogenetics. Ethical

guidelines should be in place for these databases. (e.g. bio ethics guidelines for developing world by Sri Lankan Twin Registry)

If the commercial pharmaceutical industry would like to manufacture drugs for sub groups of common diseases (like people with MODY 1 in diabetics) there should be proper ethical and scientific guidelines.

Common illness like hypertension and diabetes may differ in Europeans and Indo-Asians (People who mainly live in Indian sub-continent). Making medicines that is pharmacogenetically tailor made for Europeans (which is already being done-major Big Pharma clinical trials are mainly done on racially pure populations in developed countries) may make even common illness like diabetes and hypertension in the developing world an “orphan illness” like most other tropical illness where hardly any new scientific advances are made either therapeutically or diagnostically. Of 1223 new drugs developed between 1975 and 1997, only 13 were for the treatment of tropical diseases.

16% of the world population spent 89% of the total money spent on health care globally. More than 50% of money spent on health is being spent by USA only where 5% of the world population live. There is widening disparity between rich and poor countries in health expenditure, research and outcome, which is evident by declining life expectancy and other health indicators in Africa. From 1982 to 1990 “South” received US\$ 927 million in aid, grants, trade credits, direct private investments and loans....but the “South” paid out US\$ 1.3 trillion in interest and principal on debt (excluding royalties, dividends, repatriated capital, brain drain and under priced raw materials) Without addressing this huge disparity and inequality between developed and underdeveloped nations whatever regulatory mechanisms wont work.

The only way to encourage production of new economically unprofitable medicines is to invest in R&D of Bio-medical sciences in non-profit making non-governmental organisations and academic centres in developing countries.

Question 3

This clause may impede new drug development from developing world. In “orphan diseases” like tropical disease this may cause further restrictions.

Question 4

Ultimately each individual should have the right to know about his gene profile. But in developing countries, where there is minimal scientific literacy and no public debate on these issues, there should be a mechanism of regulation.

Question 5

In developing countries health care providers work under enormous strain. Before discussing about legal liability, universal provision of basic health care is a necessity.

Question 6

Yes.

Question 7

In the public health care system efficacy and safety should be considered in a professionally formulated clinical guidelines. It is better if cost is not a limiting factor in following clinical guidelines. But in a developing country this has to be invariably taken in to account.

Question 8

In universally free public health care system in Sri Lanka, there is an inequality between city and village, wet zone and dry zone. This inequality between mainly urbanized Western Province and rural North Central, Uva, Southern and Eastern Provinces is evident not only in health care but in all the other socio-economic indicators. Future application of pharmacogenetics is not going to tilt the balance either way significantly.