Trade and Gender Series

Paper-II

The Current Trade Paradigm and Women's Health Concerns in India: With Special Reference to the Proposed EU-India Free Trade Agreement

Centad
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The Current Trade Paradigm and Women's Health Concerns in India: With Special Reference to the Proposed EU-India Free Trade Agreement

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Foreword

Achieving gender equality worldwide has been a part of the international development policy agenda for some time now. Gender mainstreaming or including the gender dimension in all economic and social evaluations has been an objective of many international initiatives.

The role of trade in creating long lasting impact on development in general and on human development in particular has already been established. Therefore, it is pertinent to ask how trade impacts the already present gender bias in developing countries. While this question is being increasingly raised by development specialists and women's organisations, the link between trade and gender is complex and multidimensional. While it is increasingly clear that trade policy is not 'gender-neutral', the nature and extent of linkages is yet to be studied in detail. The issue is made more complicated by the fact that evaluation of what is absolutely good or bad is impossible in the context of complicated socio-economic structures. Therefore any study of gender and trade must be more nuanced than simply a fact based or data based study using conventional indicators. This is more imperative since current data in most developing and even some developed countries do not include a gender dimension. In addition, it is next to impossible to estimate inequalities within households by the current data estimation methods. In addition, the trade policy spectrum is itself changing continuously, with the WTO model being supplemented and even partially replaced by Free or Regional Trade Agreements, which are often more ambitious than the WTO system.

Keeping these issues in view, the Trade and Human Development Programme of Centad, in partnership with the Heinrich Boll Foundation, has undertaken a sub-programme on 'Trade and Gender', which looks at the linkages between trade liberalization and gender, from India's perspective. The special focus is the impact of the EU-India FTA, which is being currently negotiated, on women in India. The programme intends to come out with four reports as part of its initial research output. While the first is a literature overview, the following three study the gender impact of the EU-India FTA on agriculture, services and health. These research outputs are to be followed by advocacy at various levels.

This report is the second of the publications under the 'Trade and Gender Series' brought out by the programme. Health is an area of special concern in the context of gender inequalities. Since the EU India FTA covers many areas which are known to have serious implications for health, this needs detailed analysis. Liberalisation of health services coupled with investment liberalization, TRIPS plus provisions in the IPR chapter are some concern areas and can affect the access to medicines and treatment, as well as to food. Health hazards posed by working conditions in export based industries and domestic policy space at the disposal of the Indian government to address gender inequalities and change the social structure, are also areas of concern. The need to indicate suitable policy interventions, both in the trade agreement and in the domestic socio economic environment, to maintain and encourage women's access to health and healthcare, is undeniable. This study is an attempt to provide such an analysis in simple terms.

I also take this opportunity to thank our partner, the Heinrich Boll Foundation for supporting our activities and for sharing our vision. Without their continuous encouragement and wholehearted participation, this would not have been possible.

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Abstract[1]

India is currently negotiating a Free Trade Agreement with the European Union, which includes not only liberalization of commodity trading, but also a wide range of chapters including deep services trade liberalization, full investment liberalization, and stricter IPR conditions than the TRIPS norms. As trade is an engine of growth and development, India's trade policy has many goals to meet. India shows high poverty level, increasing income and social inequalities as well as deep seated gender inequalities. Health is an area of special concern in the context of gender inequalities. Arguably, where there is a constraint on health care access, whether due to education, income or location, women experience a greater constraint compared to men. Since the EU India FTA covers many areas which are known to have serious implications for health, this needs detailed analysis. Liberalisation of health services coupled with investment liberalization, TRIPS plus provisions in the IPR chapter are some concern areas and can affect the access to medicines and treatment, as well as to food. In addition, the way deep trade liberalization uses women's labour and imposes adverse working conditions on them is another aspect which must be taken into account. Domestic policy space at the disposal of the Indian government to address gender inequalities and change the social structure, can also be undermined the FTA. Therefore, an analysis and evaluation of health impacts of this FTA on Indian women is necessary. The need to indicate suitable policy interventions, both in the trade agreement and in the domestic socio economic environment, to maintain and encourage women's access to health and healthcare, is undeniable. This study is an attempt to provide such an analysis in simple terms.

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Introduction

India is currently negotiating a Free Trade Agreement with the European Union, which includes commodity trading in agriculture and industrial sectors. In addition, there are a wide range of chapters including deep services trade liberalization, full investment liberalization, stricter IPR conditions than the TRIPS norms. The FTA also has liberalization of public procurement, competition policy on its agenda. In commodity trade, tariffs on 90% on goods are supposed to be brought down to zero. A major problem with this FTA negotiation, as with others, is the fact that it is taking place is secrecy, and draft agreement documents are not available to the society at large. This makes it difficult not only for conducting impact analysis, but also for getting feedback from involved stakeholders. There is also limited dissemination of general information on the impact of these FTAs until now. This makes it much more difficult for stakeholders to realize the benefit or cost of such agreements on their lives. Given that most FTAs go way beyond the liberalization visualized under the WTO, and this FTA in particular, is very ambitious in its coverage, it is imperative that analysis and information of possible impacts of such FTAs is understood by our society.

In particular, India is a country with high poverty levels, increasing income and social inequalities, and deep seated gender inequality. Broad based development still remains out of reach of most of India's vulnerable population; which includes not only the poor, but the old, women and children. Women's socio economic achievement, in particular, remains a matter of concern, which despite efforts from many sectors, still lags far behind that of men. Their constrained access to resources, both physical and human, in terms of land, water, capital, health and education, is evident even from a cursory glance at gender based data. Literacy rate is 53.67 compared to 75.26 of men, and work participation rate 25.6 compared to 57.9 for men (2001 Census). Women seem to contribute only 17.2% of organized sector employment in 2001. Health is an area of special concern in this context. While gender based health indicators have shown improvement over the past, the achievements are still far from optimal. While life expectancy has improved from 58.1 in 1990 to 65.3 in 2001, this seems to be the only indicator which is better than that of men. Infant Mortality Rate (IMR) for women is 65 to 62 for men, the sex ratio is still 933 (2001 Census). Gender inequalities in health indicators in India clearly also has a relation with location, employment, education and income group status[2]. Arguably, where there is a constraint on health care, whether due to education, income or location, women experience a greater constraint compared to men.

Since the EU India FTA apparently covers many areas which are known to have serious implications for health, this is an area which needs detailed analysis. Liberalisation of health services coupled with investment liberalization, TRIPS plus provisions in the IPR chapter are some concern areas. Not only do these threaten the access to medicines and health care facilities, these affect

2 See more details on this in Section I.

the access to food, a basic requirement for the maintenance of health, as well. In addition, the way deep trade liberalization uses women's labour and imposes adverse working conditions on them is another aspect which must be taken into account. In addition, we see that that the domestic policy space that the Indian government must have to address gender inequalities and change the social structure, can also be undermined the FTA. Therefore, an analysis and evaluation of health impacts of this FTA on Indian women is a must at this point. The need to indicate suitable policy interventions, both in the trade agreement and in the domestic socio economic environment, to maintain and encourage women's access to health and healthcare, is undeniable.

This study is an attempt to provide such an analysis in simple terms. The study provides a brief overview of gender inequalities in health indicators in India in Section I. Section II provides a survey of the main issues of interest in North South FTAs from a health perspective, examines the available experience on these linkages worldwide, and attempts to connect it to the provisions in the EU India FTA. Section III takes up these provisions in the EU India FTA and examines what these imply for women's health in India, given the socio economic context in the country. TRIPS plus provisions, liberalization of services and investment in the health sector, health impact in export based industries, the impact of IPRs on food security, and domestic policy space are the issues examined in this section. A conclusion and policy suggestions are provided at the end.

I. Trends in Health Indicators and Gender Concerns in India

India's health Statistics remain dismal, even compared to many other developing countries. If we compare to the European region, the gap is enormous (Table I.1). Among cause specific mortality rates, maternal mortality rate in India is 16.6 times, TB among HIV positive population is 2.8 times, and age standardized mortality rate from non communicable diseases is 1.2 times the comparable indicators in Europe. Only the incidence of cancer in India is significantly lower than in the EU.

According to NFHS-3 data for 2005-06, at least 47.85 of women in India experience some kind

Table I.1: Cause Specific Mortality and Other Health Indicators, India and EU

	Cause	India	European Region
Cause Specific Mortality rate	Maternal Mortality Rate (MMR), 2005	450	27
	HIV/AIDS (2005)		10
	Malaria (2006)	1	
	TB among HIV Negative population (2005)	26	6
	TB among HIV Positive population (2005)	2.5	0.9
Age-Standarised Mortality Rate by cause (per 1 lakh population)	Non-Communicable (2004)	713	590
	Cardio-Vascular (2004)	382	332
	Cancer (2004)	100	142
	Injuries (2004)	116	79
Distribution of years of life lost by broader cause (%)	Communicable (2004)	56	56
	Non-Communicable (2004)	30	30
	Injuries (2004)	14	15
	Incidence of T.B per 1 lakh population (2007)	168	49

Source: WHO Statistics, 2009

of a problem during giving birth, only 50.2% of women giving birth went to a doctor for antenatal care, 22.85 received no ante natal care and 57.6% of women giving birth accessed no post natal care at all. 26.9 and 21.55 of urban and rural mothers reported 'costs too much' as the reason for not delivering their child in a health facility. Maternal care in India has definitely improved in India since 1992-93, but with only 76% women accessing any ante natal care and only 40.85 of births happening in a health facility, there is a long way to go. There is also a clear rural-urban gap in maternal care in India.

Anaemia and Tuberculosis are two diseases with considerable impact on women, and have a stronger impact on poorer women in rural areas. 56.2% of ever married women in India experienced some form of anaemia in 2005-06, an upward trend compared to 51.3% in 1998-99. This is also clearly related to location, education and wealth index (see table I.2). Women in rural areas recorded a higher incidence compared to their urban counterparts, while women with no education recorded the highest incidence of anaemia (58.7%). The incidence of anaemia has also receded as incomes increase (Table I.2). TB is another disease with significant impact on women. While the incidence among women is about 60% of men's, the incidence is significant and higher in rural areas (371 out of 1 lakh population) compared to urban (247 out of 1 lakh population) according to NFHS 3.

Three other diseases, Diabetes, Asthma and Goitre, show up interesting patterns where urban women do worse than their rural counterparts. Women obviously suffer from Goitre much more than men, both in rural and urban areas, by about 1.93 and 3.62 times, while urban women suffer more from Asthma than their male counterparts. In respect of diabetes, women seem to be doing better than men.

Table I.2: Percentage of Women with Any Form of Anaemia in India 2005-06

Maternity status	
Pregnant	58.7
Breastfeeding	63.2
Neither	53.2
Residence	
Urban	50.9
Rural	57.4
Education	
No education	60.1
<5 years complete	58.1
5-7 years complete	56
8-9 years complete	52.4
10-11 years complete	49.2
12 or more years complete	44.6
Wealth index	
Lowest	64.3
Second	60.3
Middle	56
Fourth	52.2
Highest	46.1
Total for ever-married women	
2005-06 (NFHS-3)	56.2
1998-99 (NFHS-2)	51.8

Source: NFHS 3

Though incidence of cancer is still low in India compared to developed countries, incidence of breast and cervical cancer, apart from other forms of cancer, are becoming increasingly significant. According to NSS data (2004), out of every 1000 women, 33 in urban areas and 39 in rural areas were hospitalized due to cancer.

Even in case of HIV/AIDS, a largely male

dominated disease, Indian women are increasingly becoming victims. Over time HIV infection shifts from high risk groups to the general population, and Mitra (2009) argues that this has already happened in six states in India. In 2005-06, the incidence of HIV positive people among women in urban areas is 0.29%, in rural areas this is 0.18%. Among pregnant women, 0.11 per cent is currently affected. The Regional Human Development Report on South Asia (UNDP 2003) ascribes unequal gender relations in South Asia to this phenomenon. 'Poverty and gender inequality are the strongest enhancers of risk exposures to HIV, a subject that has been relatively ignored in both bio medical and social science research (Mitra 2009). While HIV is not limited to the poor, poverty plays a major role in enhancing the contribution of each of these factors. Difference in power relations between men and women is another major cause of the spread of HIV/ AIDs among women (Mitra 2009). Pressures of migration, violence against women including trafficking and domestic violence are manifestations of this problem which in turn subjects women to HIV/AIDS risk. Lack of information and denial of access to safe practices during sex are additional reasons for this situation.

Finally under nourishment among women in India is high, contributing to the status of India as one of the worse achievers in ensuring food security but adequate nutrition. In the Global Hunger index list calculated by IFPRI (2008), India ranks 66 (among 88 ranks, with higher hunger showing a higher rank) with a score of 23.7 with an 'alarming' hunger incidence. Interestingly, India is one of the only two net exporters of food to face alarming level of hunger. Women's nutritional levels are lower as women face discrimination right from the time of breastfeeding to their adulthood (Pandey 2009). Pandey also finds evidence of discrimination in other early childhood feeding practices in her study of West Bengal. Complementary food given between 6 to 18 months of birth, showed difference in food and content of protein, vitamin and minerals, given to girls. The contrast was sharper in protein rich food items like eggs, meat and fish. This has to do with education, awareness as well as with a lack of resources.

This is also the reason why India shows up the highest figure for underweight and under height children for age. IFPRI ascribes this, among other things, to the high poverty levels and the "the lower nutritional and educational status of women" (IFPRI 2008, P.12). Under nourishment of women is also the single largest contributor to the high level of Anaemia among Indian women. In fact NFHS-3 shows that there is a clear relation between children's height-for-age, weight-for-height and weight-for-age conditions and the mother's nutritional status (NFHS-3). In addition, the mother's literacy level also shows a clear relation with children's nutritional status (Borooah 2009).

Women also suffer from a reduced access to health care in terms of ability to pay. Table I.3 below shows that medical expenditure for both hospitalization and non hospitalization is much lower for women. The rural urban dimension of this phenomenon is also interesting. While rural women face relatively more disparity (compared to urban women) in non hospitalised

treatment as evident in a lower female to male expenditure ratio, urban women face more disparity in hospitalized treatment. Assuming non hospitalized treatment forms the larger bulk of health care of rural women, and hospitalized treatment for urban women, it seems they face more disparity in the more critical areas of care. Gender disparities are also evident in the utilisation of health services, both for in-patient and out-patient care. This is evident from data from the NSSO and from numerous studies (Saha and Ravindran, 2002, B. S. Ghuman and Akshat Mehta, 2009)

Table I.3: Gender Dimension of Medical Expenditure in India

Average total medical expenditure (Rs.) for non-hospitalised treatment per ailing person during last 15 days (Jan-June 2004)				
Gender	**Rural**	**Urban**		
Male	275	322		
Female	240	291		
Person	257	306		
Female as % of Male	**87.27**	**90.37**		
Average medical expenditure (Rs.) per hospitalisation				
Gender	**Rural**		**Urban**	
	2004	**1995-96**	**2004**	**1995-96**
Male	5946	3778	9535	4185
Female	5406	2510	8112	3625
Person	5695	3202	8851	3921
Female as % of Male	**90.92**	**66.44**	**85.08**	**86.62**

Source: NSS (2004)

The deep gender inequality in education, employment and economic category seem to be reflected in the determination of women's access to health care. Income inequality, of course remains a primary determinant. As table I.4 below shows, only one fifth of births in poorer households is attended by skilled health professionals compared to richer households. Incidence of children under height for age, and both infant and under five mortality rates, are 2.15 to 3 times higher in poorer 20% of households compared to the top 20%. The under-performance of children's health indicators is also an indication of deep gender bias, caused by under nutrition and lack of medical supervision in pregnant mothers. Therefore a higher inequality in incomes also represents a greater inequality in access to proper and balanced food and healthcare. Women's decision making regarding their own health care and ability to go alone to a health facility also clearly improves with the wealth index (Table I.5).

Women's empowerment and health are clearly related but still has a long way to go. Only 27.1% of women in India seem to take decision about their own health care according to NFHS-3 (2005-06) while 30.1% of decisions are taken by the husband. While 62.2% of women take decision on their own or jointly with husband about their own health care, this seems to improve with education levels (NFHS 3). Only 60.3% of urban women and 41.5% of rural women are allowed to go alone to a health facility. This improves, apart from age, with education and employment status (see Table I.5), especially with cash employment. This indicates the need for both economic and educational empowerment for improving basic access to health.

From a survey of health indicators of women in India, it seems evident that location (rural/urban) has a significant role to play in its determination. Given the traditional structure of rural societies, the lack of general access to health facilities, coupled with a lack of education and employment opportunities, translates into a severe restriction on health improvement opportunities for women in rural areas. Education, employment and general income class all appear to play significant role in

Table I.4: Inequality and Maternal & Child Health in India

	Poorest 20%	Richest 20%
Births Attended by Skilled Health Professionals (%)	16	84
One Year Olds Fully immunised (%)	21	64
Children under Height for Age (% under age 5)	58	27
Infant Mortality Rate (per 1000 live births)	97	38
Under Five Mortality Rate (per 1000 live births)	141	46

Source: Data Compiled and Calculated from UNHDR (2007/08)

empowerment of women and therefore, in the determination of health conditions for both rural and urban women. Inequalities in income also have a direct impact on access to health services. The lack of access to food and nutrition also has significant impact on women's and children's health in India. This is also reflected in the high rate of anaemia, goiter (due to lack of iodine), and high rate of underweight children in India. Therefore, gender inequalities in health indicators are significant and seem to be strengthened by income, regional and social inequalities (social relations) and a number of issues need to be kept in mind for proper redress.

II. North South Free Trade Agreements, Health Issues and Implications for the EU-India FTA[3]

The literature on FTAs and in particular their impact on women's health is still marginal but existing analyses raise concern about the direct and indirect impacts on health of economically and socially vulnerable groups, including women. Analysts point out that much of the rationale behind FTAs ostensibly improving health conditions in developing countries is arguable false.

Provisions in the FTA chapters directly related to health can cover multiple areas and impact health in a multitude of ways. The more invasive FTAs in this regard are seen to be the FTAs with Northern countries like the US and the EU which include not only liberalization of commodity trade, but attempts to cover areas like services, investment, IPRs, completion policy and public procurement. Some of these also include labour and environmental standards, which can also impact health. Provisions in the FTAA, for example, raise serious concerns about health (Shaffer et al, 2003). In fact the impact of trade on health may be felt in ways not even foreseen, without even the possibility of assessment or evaluation. Among some of the more immediate concern areas, we can classify TRIPS plus standards in intellectual property rights; services sector liberalization and investment liberalization in the services sector; standards for plants and seeds (e.g. the UPOV convention) which threatens the access to seeds and food; lax labour laws and adverse working conditions in export industries and labour standards in FTAs; and the limitations on governments policy space.

3 This section largely draws on relevant sections in Sengupta and Gopinath (2009) which is the first (a background study) of a four part project study from the Centre for Trade and Development, funded by the Heinrich Boll Foundation.

The most obvious impact, of course, relates to TRIPs plus provisions in intellectual property rights. While the TRIPS regime included in the WTO agreement already lays down strict standards[4], the TRIPS plus provisions in many North South FTAs go beyond those provisions. Some analysts argue that the developed countries, in particular the US, EU, EFTA and Japan, attempt to capture market and satisfy economic aspirations through the imposition of strong intellectual property rights on developing economies. Horn et al (2009) show that deeper commitments under TRIPS are included in all of EU and US FTAs. In addition, strong WTO extra IPR provisions in the form of 'accession to international treaties not referenced in the TRIPS Agreement' are contained in all of EC's FTAs and 13 of 14 US FTAs with WTO members (till October 2008). For example US's completed and proposed FTAs with the Andean countries (Peru, Colombia and Ecuador), Chile, Jordan, and Morocco, all contain TRIPS Plus provisions.

Restriction of pre grant opposition, data exclusivity or protection of trial data, patent market linkage, patent term extension, constraints on compulsory licenses and parallel imports, ever-greening are some of the TRIPS PLS provisions which severely impact access to critical medicines and treatment. By making generic production more costly or delayed, in effect, the price of medicine is increased, in addition to the delay in supply of critical medicines at affordable rates in developing countries (Correa 2009). A study by Shaffer et al (2003) examines the adverse impact of the FTAA (Free Trade Agreement of the Americas) on health based on several grounds; by reducing public spending in health and access to affordable medicines; reducing protection from harmful substances such as tobacco and alcohol, and effective standards for patient safety. Increasing costs in water and medical insurance will add to costs of healthcare while the drain of health professionals and the reduction in government's policy space to address health concerns can also aggravate health concerns. This added to the fact, that patenting does not necessarily encourage innovation in neglected diseases like TB, Malaria which are not seen to be 'profitable', adds to the gap in necessary treatment in developing countries.

Data exclusivity, or strict restrictions on public disclosure of trial data even before a patent is granted, has been a key feature of North South FTAS. TRIPs Article 39.3 provides for protection of undisclosed test or other data submitted for obtaining marketing approval. However this has been interpreted in different ways by developing and developed countries. In fact many developing countries, for example India, opt for minimum 'data protection' but developed countries enforce a 'data exclusivity' regime which implies that national regulators cannot refer to trial data submitted by the original manufacturer to grant marketing rights to a generic producer for a certain period of time. This implies that generic producers will now have to submit their own data and therefore will have to repeat clinical trials if they have to enter the market. Not only is this costly and often unaffordable for small producers,

4 See Sengupta and Gopinath (2009) for details on TRIPS provisions and gender implications

it also involves unethical wastage of resources in repeating trial of already established treatment. Oxfam (2007) analysed price rises resulting from data exclusivity provisions in the US-Jordan FTA. The study found that between 2002 and mid 2006, "data exclusivity has delayed generic competition for 79 per cent of medicines newly launched by 21 multinational pharmaceutical companies that otherwise would have been available in an inexpensive, generic form" (ibid P.2). The study also compares prices of medicines in Jordan to that in neighboring Egypt where no such provision is in place. It finds that new medicines to treat diabetes and heart disease cost anywhere from two to six times (200-600%) more in Jordan than in Egypt. The problem with data exclusivity is that even if a patent is not granted (and patents are a more difficult process), a producer has to just submit trial data in order to get a minimum five years of protection and prevent generic competition (Correa 2009). In addition, there is often data exclusivity on new uses of old medicines, even on incremental modifications. The Jordan study finds that at least 25 medicines received additional three years of protection for new indications.

Another provision that is often seen in North South FTAs is 'patent term extension' to beyond the TRIPS' stipulated 20 years. This is granted on grounds of 'unreasonable delays' in granting patent and/or in registering the medicine. CAFTA (Central American Free Trade Agreement) for example, by Article 15.9 provides such a clause (CAFTA document, cited in MSF 2004). This again effectively delays generic producers from producing it at cheaper cost.

'Patent linkage', is another controversial inclusion that links the patent status with the process of registrations of generic drugs. For example, the US-Chile Free Trade Agreement, Art.17.10.2(c), prevents granting of marketing approval to any third party prior to the expiration of the patent term. This gives rise to many complications as up to date information on patent status may not be accessible to the registering authority, or they may not have the wherewithal to know which patent they are infringing on. This generally tends to make the registering authority more stringent than required and cover all patents. This linkage also implies that instead of private patent holders protecting their own right, it now becomes the government's legal obligation to protect patent rights.

'Border measures' are a set of provisions which relate to IP enforcement and apparently establish stringency of IP standards of even goods in transit. This has recently become a highly controversial issue with EU seizure of not counterfeit but genuine drugs from generic producers in India to Brazil. Such provisions are often found in EU FTAs and undermine the supply of genuine and cheap medicines for treatment of critical diseases (Heumber, 2009).

Finally, limitations on the use of TRIPS flexibilities such as the use of compulsory licenses and parallel importation, deny developing countries the right to protect public health. For example, Jordan has amended its law which now requires it to ask for prior permission of patent holders in order to have parallel imports. This effectively eliminates the use of such provisions (Oxfam 2007).

A report on impacts of the possible TRIPS plus IPRs in Thailand (WHO, 2006), finds that "for 42 top selling medicines in 2003, the introduction of competition would have saved approximately 260 million US dollars. Thus, TRIPS plus provisions could, by postponing the introduction of competition, result in significant additional expenses. Alternatively, the consumption would be about 35% lower" (ibid P.5). The Report also points out the harmful effect of TRIPS plus provisions on treatment of critical diseases like HIV/ AIDS. In a preliminary analysis, the study shows indications that expenditure on Anti Retro Virals (ARVs) may increase by 3 to 7 times under a TRIPS Plus regime as opposed to the current TRIPS compliant one.

The reach of TRIPS Plus conditions covers traditional medicines and forestry products as well. As Srinivasan points out (2005), for example, CAFTA's IP provisions cover traditional medicines, which make it difficult for rural and indigenous communities to continue to use and protect such systems of healthcare. Women often act as main keepers of traditional knowledge, and benefit from both the sale and use of traditional medicines, thereby protecting the health of their families and communities. All over the developing world, women plant, transplant, and maintain trees, collect fruits, oils, and medicines from trees to use in the home or sell in local markets, and maintain subsistence farms and traditional agro-forestry systems (UNDP 2007). The TRIPS plus conditions also contradict the efforts made by many developing countries to develop an effective National *sui generis system*[5] .

Further many studies point out that though the goal of strict IPRs in generating innovation by sharing benefits of knowledge generation with the inventor is often elusive. Oxfam (2007) point out that conforming to the highest form of IPRs has not encouraged generic producers in Jordan to innovate in new medicines. In addition, Jordan has seen only a fraction of new products being launched in the US or the EU (Cohen-kohler, Foreman and Lipkus 2008).

As argued before, any constraint on access to medicines and public healthcare acts as a stronger constraint on women. First, women are generally economically poorer than men, both across and within households. Second, in situations of constraint in access, it is most often the women who forego treatment. For example, in treatment of critical diseases like HIV/ AIDS in couples, the woman often gives up the medicine if supply is limited or expensive. In a US based study of HIV treatment and AIDS opportunistic illnesses (OI), it was found that even in an advanced country like the US, there is a clear gender difference in OI rates and trends, as well as in prescribed HAART[6] (Highly Active Anti Retro Viral Therapy). The study suggests differences in access to care and

5 For example, the Philippines enacted the 'Traditional and Alternative Medicine Act', passed in 1997, which established the Philippine Institute of Traditional and Alternative Health Care and a Traditional and Alternative Health Care Development Fund. India has created a public database that catalogues traditional herbal medicines, plants and yoga practices (UNDP 2007).

6 For example, HAART was prescribed for 74% of men and 70% of women overall (adjusted OR=0.88, p<.01), and for 67% of male and 61% of female IDU (adjusted OR=0.79, p<.01).

prevention services and socioeconomic status as some of the reasons behind this difference (McNaghten et al 2004). Third, as discussed, women in developing countries also practice and use traditional medicines extensively. All this add up to a serious impact on women's access to medicines, and health.

In addition to the giant reach of IPRs, trade in services, including vital services such as health care, water, waste, and energy; standards for the safety of plants and food; and constraints on domestic policy to provide universal access to affordable healthcare can all affect health conditions of women in developing economies.

Health service is an area where FTAs can mark a sharp movement away from the WTO scenario. Health and social services is the only services sector where no negotiating proposal and no collective request have been tabled at the WTO. There is very little commitment in this segment. According to the WTO, less than 50 WTO members (the EC-27 counting as one) have undertaken commitments in one of the four health services sub-sectors; most of the commitments concern hospital services. Mode 1 commitments on health-related professional services are also low (WTO website). Some movement in Mode 1 (tele medicine) and Mode 2 (medical tourism) has been visible.

However under an FTA, this sector is likely to get fully open, and while only about 40 countries have currently made commitments under Mode 3 in the WTO, this is likely to gradually increase with increasing number of FTAs. Services liberalization can come combined with widespread investment rights under FTAs. Mode 2 poses certain problems as domestic regulation of areas like medical tourism will be severely restricted and the government may be unable to bring in major changes in regulation without infringing on FTA provisions in the future. Surrogacy, for example in India, has been a much debated area where activists have asked for more regulation. This is problematic as many of these issues are new issues and there is very little existing domestic legislation in many developing countries on these areas. It is also argued that medical tourism increases the constraint on access to health services for domestic citizens, especially the poor, women and children by making them share domestic supply of health services with foreigners. On the other hand, foreign investment in foreign owned hospitals, for example, also provides undue competition to domestic and state run hospitals, drives up user prices and necessitates a switch from public to private expenditure on health. It increases private facilities at the cost of public ones with cost to the poor.

Mode 4, on the other hand, seems to still remain under committed. While it has been acknowledged that for full potential of trade to be realized there needs to be movement of labour across borders, as well as of goods, countries remain hesitant to offer much. Most EU FTAs offer minimum commitments under 4, keeping the restriction vis a vis skilled professionals intact. Women workers are unlikely to see real gains in this segment for example in EU-ASEAN FTA (WIDE 2007). However, the developed countries are not only ones cautious in this area. Even developing countries, for example, India, has been wary of opening borders to workers from

other developing economies. In the SAFTA for example, Mode 4 does not yet find a place. On the other hand, as Mode 4 also tends to produce drain of skilled and semi skilled professionals, for example in nursing and care services, it has been seen to cause significant supply shortage in source economies (WIDE 2007), resulting in a so called 'care drain'.

In addition, an increasing concern with FTAs may be the direct impacts on health in export based industries. While this is problem relevant for trade liberalization in general, with real protection in terms of actual tariffs coming down significantly under the FTAs, competition increases manifold. Therefore, the pressure on labour force and the use of flexible labour supply with adverse working conditions can also increase, with significant impact on the health of its work force. Since women dominate these sectors in many of the Asian economies, including in India, this is a matter of serious gender concern. While trade with the EU is expected to boost employment, but job pressures in export sectors like textiles and garments can add to adversity for women's health conditions. However the EU does attempt to include labour standards in its FTAs. While seen as an invasion of domestic space and a non tariff barrier to trade by many developing countries including India, it may have the potential to offset some of the negative impacts on health stemming from adverse work conditions for women workers.

The TRIPS plus provisions on IPRs affect not only the access to medicines but access to food as well. In the field of agriculture or food security, strong IPRs are seen to dictate developing country governments to; a) implement or join the UPOV 1991 Convention; b) grant patents on plants or animals; c) join the Budapest Treaty on microorganisms; and, d) conform to "the highest international standards" of IPR protection (GRAIN 2004). Some US FTAs also insist that signatory countries join the Patent Cooperation Treaty (Choudry, 2007) which allows a single patent application to be recognized in all countries. The precedence to trademarks over Geographical Indicators (GIs) is another example of a strict IPR regime. These provisions affect access to seeds, plants, production materials and therefore livelihoods, by imposing stringent IPRs and commercial control on a wide variety of natural resources/products (e.g recognizing the seed breeders' rights under UPOV 1991 as opposed to the farmer's rights). GRAIN (2008) has provided a list of such provisions in North South FTAs which are currently in operation, signed or under negotiation. Among the African and Middle Eastern economies, 8 such FTAs are with EFTA, 16 with EU, and 7 are with the USA. In the Asia Pacific region, 5 are with EFTA, 8 with EU, 3 with Japan, 1 with Switzerland, and 10 with the USA. Similar examples can be found in Latin America and the Caribbean (GRAIN 2008).

There are other issues as well. The use of GMO seeds, often pushed by FTAs, for example, are not only fraught with health and safety questions, but also have to be bought each season, thus reducing the farmers' ability to freely exchange, reuse. The use of GMO seeds also reduces the farmer's ability to protect traditional seeds from extinction.

These combined restrictions on the use and exchange of seeds and genetic resources undermines women's role as seed keepers, users of traditional seeds and propagators of bio diversity. It obviously reduces their ability to engage in agricultural production, maintain livelihoods and food security. In fact, given lower access to knowledge, resources and skills, their ability to register and access patents is much lower than even that of the ordinary farmer. Simultaneously, since women often produce for subsistence rather than the market, the higher costs resulting from such control of knowledge & technology in general and of products in particular, can be heavier on women's access to food and therefore to nutrition and health. All these provisions also impose limitations on bio diversity and encourage bio piracy. These harm women and small farmers by harming their genetic heritage and their natural right to use it (Damian and Graz 2001).

Finally, the constraint on domestic policy to regulate and intervene in the health system to address key health concerns, especially for vulnerable groups, is a matter of increasing concern. This is a cross cutting issue and comes up again and again throughout North South FTA chapters. For example, government policy space to regulate domestic health conditions may be affected by the TRIPS plus provisions and its constraints on compulsory licensing, parallel importing etc. The establishment of competition policy and full liberalization of public procurement also affects domestic country governments' ability to address inequities in health care and ensure the availability of medicines and treatment.

In particular, the EU is known to include health related provisions in some of its FTAs. According to Horn et al (2009), the EC cover provisions in the areas of health and energy, crucial service sectors which are not generally included under GATS. Health is covered in 3 of EU's 14 FTAs signed with WTO members till October 2008. The type of provisions is non trade related. For example, provisions under health cover "monitoring of diseases; development of health information systems; exchange of information". These are also often non enforceable; only 1 FTA of these 3 actually includes legally enforceable conditions. However the fact that the EU is keen to include these provisions in its FTAs, thus bringing it under a legal and structured framework as well as intrinsically link health issues to trade, can be read as a pointer to its eagerness to exert control over these service sectors. These attempts can turn into significant intrusion on domestic policy space initiated through a trade regime.

From the above discussion, it is clear that there are concerns that we must address in the light of the proposed EU-India FTA. Being a North South FTA, it includes similar provisions as described above. Even though documents are not circulated openly, leaked documents on the IPR chapter points towards the usual IPR plus provisions. If we look at other EU FTAs, for which documents are already available, India is likely to be no exception. In particular the EU sees India as an almost developed country with a thriving pharmaceutical and services sector. The following section looks at the likely (through similar agreement texts) and known (through

leaked texts) provisions in specific areas of the EU-India FTA, and explores India specific impacts on gender lines.

III. The EU India FTA and Possible Impact on Women's Health in India

a) IPR Provisions in the EU India FTA and the Impact on Access to Medicines: Some Concerns on Gender Lines

i) Pharmaceuticals

Even with a large generic industry in pharmaceuticals, medicines are already out of reach for much of India's poor population. Medicines constitute 50 to 80 per cent of health care costs in India making healthcare is the second highest cause of indebtedness in India (AIDAN 2009). The AIDAN study also shows that to treat multi drug resistant TB, a labourer has to work 4.5 to 6.5 years, to treat anemia, he has to put in daily wages of 62 days (ibid, P.4).

The available material on the EU India FTA lists most of the TRIPS plus provisions described in the previous section (Correa 2009, Leaked Text, IPR Chapter, 2009) though it also professes to adhere to the Doha Declaration on the TRIPS Agreement and Public Health (November, 2001) by the Ministerial Conference of the WTO' (article 9.2.1).

- By article 2.2, EU also includes provisions to safeguard the creation of a Sui Generis system for protecting 'non-original' databases, which will affect scientific and librarian communities.
- Article 10 pins down this provision to the test data submitted for approval of pharmaceutical products. The period of such exclusivity is unclear but in EU this is usually ten years.
- Evergreening by allowing for extension of patent for new indications on existing products is also on the cards, and even data exclusivity is extendable by one year for new indications.
- Article 9.3 allows patent term extension by up to five years to compensate for time in approval of marketing.
- In addition, the EU has also embarked on a mission of strong IP enforcement through detailed provisions in Articles 12-28. The draft text contains provisions on 'border measures' includes not only importation but exportation and good in transit. The recent seizure of drugs from India going to Africa, seized by Netherlands, is also a pointer towards the EU's zeal in this direction though its provisions in the FTA may be technically or legally inapplicable. India has resisted most of these provisions.
- On the omission side, the draft text does not include any commitment on EU's part to ensure transfer of technology to India. Its article 3.1 limits itself to exchange of views and creating of enabling environment for technology transfer.

Though the Indian government has apparently rejected both data exclusivity and patent term extension, it remains to be seen what the final IPR chapter will contain.

In terms of the TRIPS flexibilities, while the text provides for parallel imports (article 4) where the rights of the original patent holder is exhausted once the product is placed on the market in

any part of the world, it makes it subject to the provision of the TRIPS Agreement. This, points out Correa (2009), is a matter of concern as article 6 also excludes exhaustion from being challenged under the WTO Dispute settlement mechanism, thus creating a contradiction. It also challenges India's ability to create its own system for exhaustion, while making it subject to unspecified provisions. The provision on compulsory licenses is also unclear though the draft text does include provisions to include CL. The ECORYS (2009) report suggests that IPRs in the FTA will not substantially have any impact on health. However, the Report does suggest that "commitments made in this FTA on IPR should therefore be construed in a way which does not impair the capacity of both parties to promote access to medicines in line with the relevant flexibilities built into the TRIPs agreement" (ECORYS et al 2009, P. 266).

As a result of the FTA, the prices of new drugs will be much higher than ever before, in addition, the entry of cheaper generics will be significantly delayed, both because of data exclusivity and patent term extension, if allowed after the FTA. It these go through they will contravene the interpretation of TRIPS Article 39.3, of the Satwant Committee report (2007) which recommends data protection and not data exclusivity for India in the current context[7] . The US and EU on the other hand have opted for a data exclusivity regime. In addition, market availability of drugs will be adversely affected by patent linkages and constraints on use of TRIPS flexibilities like compulsory licensing. Therefore both prices and availability, in effect, will be affected. All this adds up to a constraint on drug availability not only in India but all over the developing world as 67% of India's drug exports go to the developing world (Centad 2009).

This pressure to increase IPR standards is clearly linked to the global pharmaceutical trade patterns. FDI inflow into India does not currently show up any European countries and comes mainly from Mauritius, Singapore, US, UAE. However the first two countries are often used for recycling FDI through backdoor channels. EU has a large presence in the global pharmaceutical market. Medicaments (HS 3004, excluding bulk drugs) represent EU's fourth largest export amounting to 4.35 of total exports (2008). EU also imports pharmaceuticals with medicaments (Hs 3004) showing up as the ninth largest import accounting for 1.37% of EU's total imports (WTO Trade Statistics). India has been a major exporter of pharmaceuticals with exports in 2008-09 amounting to Rs. 38433 Crores, with annual growth ranging between 14% (2007-08) to 25% (2008-09) over the last few years. The domestic pharmaceutical market has been evaluated at Rs. 55454 crores (2008-09)[8] (GOI, 2009). It is in EU's interest to dampen India's large generic industry to gain access to this large market and the FTA will naturally be a battleground for gaining market access.

7 The Satwant Committee suggested however that India may go for data exclusivity in the long run but it is not in India's interest to include data exclusivity in the current scenario.

8 This includes retail pharmaceutical market at Maximum Retail Price (MRP), generic and companies not tracked by ORG, hospitals and institutional sales excluding government procurement, direct doctor purchases, over the counter (OTC) products and diagnostics

The current Patent Law in India, effective from January 1, 2005 to meet with TRIPS norms, put in place a regime where not only processes but products could also be patented in pharmaceuticals. By this amended law; a) medicines patented before January 1, 1995 (irrespective of the date of launch by Indian companies) can be freely marketed without any arrangement with the innovator company irrespective of the expiry date of the patent; b) Drugs patented subsequently up to January 1, 2005 (when the new Patent Law came into force) can be launched by manufacturers in India with approval from the innovators only; c) if the drug has already been launched prior to January 1, 2005, the Indian manufacturer is required to make arrangements with the patent holder for continued manufacture and marketing; d) no compensation can be claimed by the patent holder for the preceding period when the drug was being manufactured and sold without consent of the patent holder; e) In the Indian law, the effective date of start of patent is important and not the date of launch of a medicine or the expiry date of the molecule (Srinivasan, 2005).

However, making use of the TRIPS flexibilities, the Indian Law has tried to ensure considerable safeguards for public health. First it lays down very strict patentability criteria (Section 3 (d)). In addition, it allows; Indian generic companies to continue to produce drugs already marketed before the enactment of the law, even if a patent is granted to another company subsequently. It also allows both pre-grant and post grant-opposition i.e. anyone to challenge a patent application before or after it is granted; and also restricts the use of ever greening (section 3 (d)) or the extension of the patent after the expiry of the initial patent period (MSF, 2009a). On the other hand, after the FTA, new drugs will now be patented by pharmaceutical companies and Indian generic manufacturers will not be free to develop more affordable versions of these drugs. These are likely to be sold by the patent-holding pharmaceutical companies only, and priced out of reach of most of the poor in India. This also conflicts with Article 3(d) which prevents evergreening and restricts the patentability criteria.

India has 74 listed bulk drugs and combinations thereof which are price controlled, accounting for only 20% of the pharmaceuticals market (AIDAN 2009). But the rest are non-scheduled drugs which can be sold at any price determined among other factors by patents. The Indian government does not have the authority to dictate prices of these drugs except to put a cap on the annual price increase. In India, prices of non scheduled drugs can increase only at the rate of 10% per year. But this does not prevent manufacturers from introducing a drug at a steep initial price, higher than in other markets. If a stricter patent regime results in the wake of this FTA, the scope for increasing initial prices further increases substantially. In addition, the company is allowed to increase prices up to 9.99% each year.

The problem is compounded by the fact that the pharmaceuticals market does not operate on a market rule. It is a highly distorted market. The fact that in the pharmaceutical market, the consumer does not prescribe the medicine, leads to a breakdown of the market principle (AIDAN

2009). It is often seen that drug producing companies pass off a share of the price to doctors and pharmacists, thereby ensuring high prices which is to be paid by the patient. There is nothing in the domestic regulation mechanism to stop the prevalence of such high prices of non scheduled drugs.

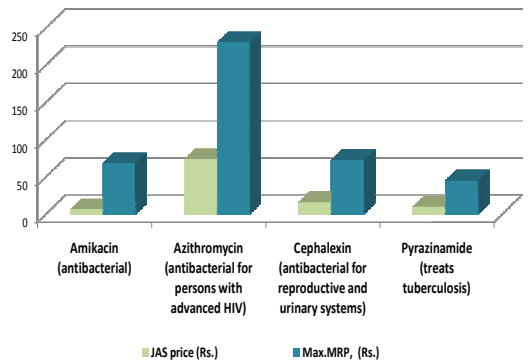
In fact, prices of low priced generics (public sector) and branded medicines (including branded generics) already show a large gap in prices. There is also a large variation within branded prices. We compare a few drugs which is sold by Janaushadhi,agovernment run low priced generic medicine store, with the prices of comparable branded medicines that are available in the market for diseases relevant for Indian women (Table III.a.1 below).

Table III.a.1: Some Drugs of Relevance for Indian Women and Prices of Generic Medicnes sold at Jan Aushadhi Store (JAS) Compared to Maximum and Minimum Market Price of Selected Branded Products

Therapeutic Group/ Indications	Generic Name	Max/ JAS Price (%)	Min/ JAS Price (%)	Max/Min Price (%)
Paracetamol/ Reduces fever	Paracetamol	424.53	235.85	180.00
Antibacterial/ Treating serious bacterial infections.	Amikacin	1214.29	214.29	566.67
Antibacterial/ Treats or prevents infections in persons with advanced HIV infection.	Azithromycin	313.57	40.90	766.67
Antibacterial/To treat urinary tract infections, gonorrhea, and prostate infections.	Norfloxacin	328.85	148.08	222.08
Antibacterial/ Treats mild to moderate infections, may also be used to treat or prevent certain infections in persons with advanced HIV infection.	Azithromycin	534.37	56.33	948.72
Antibacterial/Treats infections in respiratory tract, the middle ear, the bones, the skin, and the reproductive and urinary systems.	Cephalexin	463.51	192.06	241.33
Antiinflammatory	Diclofenac Sodium	398.67	398.67	100.00
Antimalarials	Chloroquine Phosphate	178.08	90.14	197.57
Antiprotozolas/Treats bacterial infections of the vagina, stomach, skin, joints, and respiratory tract	Metronidazole	175.21	152.99	114.53
Tuberculostatic	Ethambutol	296.81	54.44	545.15
Tuberculostatic		152.78	50.98	299.71
Tuberculostatic		159.72	50.53	316.11
Tuberculostatic	Streptomycin	151.15	151.15	100.00

Source: Calculated from Data provided in 'Comparative Analysis of Jan Aushadhi & Average Branded
Note: For details of prices, manufacturers, brand name, strength, type, see Table A.2 (Appendix)

Fig. III.a.1: Variation in Drug Prices in India: Janaushadhi and Branded



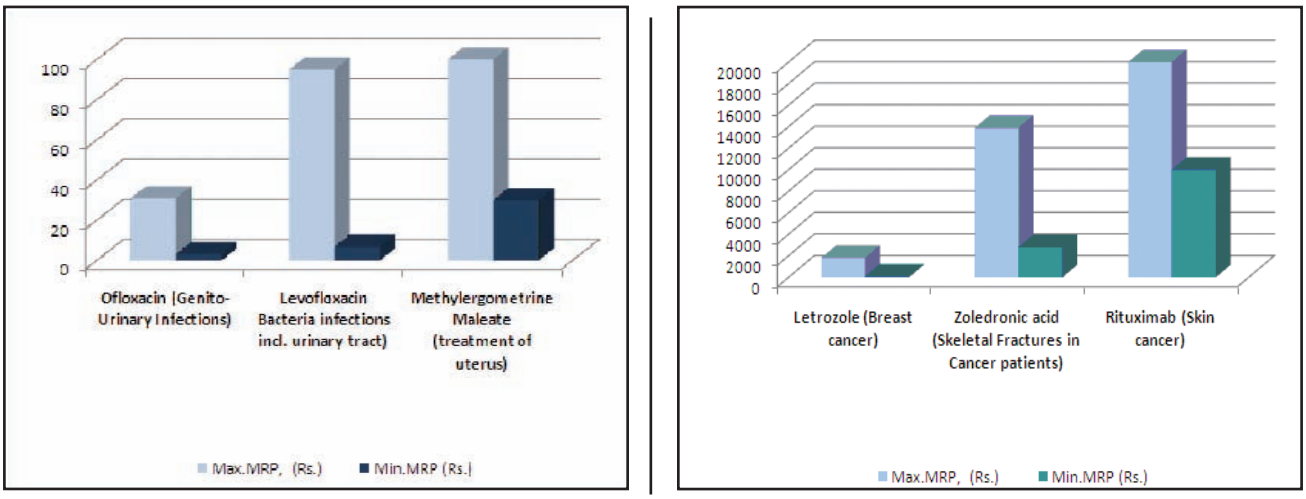
Source : Same as Table III.a.1

It is clear that branded medicines can be cheaper even than the JAS prices, but both the ratio of maximum to minimum branded prices and the ratio of maximum to JAS prices are very high. Amikacin, for example, shows 1214% higher price for maximum price of branded medicine compared to JAS equivalents. Even the ratio of minimum branded price to JAS price is also often pretty high. For Paracetamol, for example, it is 236%. Fig III.a.1 shows the drugs with the highest variation within the list compiled.

Even for drugs for which no low cost equivalents are often present, for example, in drugs for cancer, arthritis, neurological disorders, there is still a high variation in branded prices. Table III.a.2 illustrates this variation. The price of Letrozole, a treatment for breast cancer, shows a variation of 1833.33 per cent. Fig. III.a.2 shows the drugs with higher variation, with the high price drugs on the right.

In addition, drugs and treatment for fertility related problems and for assisted delivery for women are

Fig. III a.2: Variation within Branded Prices of Selected Drugs



Source : Same as Table III.a.2

becoming an increasingly large business for the pharmaceutical companies. Methylergometrine Maleate, used for prevention and treatment of postpartum and postabortal haemorrhage, sold as Methergin by Novartis and as Ingagen-M by Inga shows a variation of over 300 per cent (see Table III.a.2). Fertility related medicines are often initiated at very high prices without significantly cheaper generic equivalents. Women are also encouraged to use these medicines extensively.

These gaps/ variations in prices reflect, to a large extent, the extent of over pricing due to market

Table III.a.2: Some Drugs of Relevance for Indian Women and Ratio of Maximum to Minimum Price of Branded Products

Therapeutic Group/ Indications	Generic Name	Strenth	Max Price/ Min. Price (%)
Post Partum and post abortal haemorrhage, other treatment of uterus	Methylergometrine Maleate	0.125 mg	333.33
Breast cancer	Letrozole 2.5mg	2.5mg	1833.33
Skin Cancer	Rituximab	100mg	200.00
Breast Cancer	Tamoxifen	10mg	703.70
Skeletal Fractures in Cancer patients	Zoledronic acid	4mg	496.43
Rheumatoid arthritis	Leflunomide	10mg	550.00
Viral infections including HIV/AIDS	Zidovudine	100mg	264.94
Worm infestation	Albendazole	400mg	283.33
Depressive disorder	Escitalopram	10mg	233.33
Peripheral vascular disease	Flunarizine	10mg	208.00
Neurological disorder	Gabapentin	300mg	319.39
Nausea & vomiting	Metoclopramide	10mg	178.57
Blood Pressure	Valsartan	80mg	594.20
Genito-Urinary Infections	Ofloxacin	200mg	968.75
Bacteria infections incl. urinary tract	Levofloxacin	500mg	1392.96
Bacteria infections incl. urinary tract	Ciprofloxacin	III.b.2	251.28
Bacteria Infections	Azithromycin	250mg	460.47

Source: calculated on data from MIMS, Sept 2009, AIDAN (2009)

control. After the introduction of TRIPs plus norms, market control, in terms of the ability to enter the market and control the entry of others, will increase manifold, sometimes facing no limit at all. Therefore, prices of new drugs are likely to reign at ranges much higher than these maximum prices, without generic equivalents for a long period. The example of Jordan (Oxfam 2007), discussed in the previous section, demonstrates this phenomenon.

The use of TRIPs flexibilities and especially compulsory licenses will be severely restricted under a TRIPS plus framework. CLs allow national governments, the judiciary or even institutions like the Competition Commission to allow licenses to a non patent holder to produce, market and supply generic versions of a patented drug, without permission from the patent holder. The Indian Patent Act 2005 allows CLs to generic producers even when another country wants to import drugs (Centad 2009). This can help to ensure that India continues to supply generic drugs to developing nations with critical public health needs. But India has already included TRIPS plus provisions in its Patent Law with a possible view to encouraging FTAs. For example, it requires that generic producers wait for 3 years after the grant of a patent before they can apply for a CL, not only in the case of non working of an invention (as required by TRIPS) but on other grounds as well. It also prevents CL for purposes of importation thus prohibiting importing of active pharmaceutical ingredients necessary for production of drugs. Under the EU-India FTA, these restrictions may become stronger as its provisions on CL and parallel imports are not clear. Widespread investor's rights, coupled with IPRs, as expected under the EU-India FTA, will mean more stringent protection of patented drugs, and will surely undermine the ability of the government to use TRIPS flexibilities, e.g. compulsory licensing, if it is seen to be infringing upon the investor's rights. In addition, the already existent TRIPS Plus conditions will become irreversible.

The exact impact of the TRIPS plus provisions in the EU-India FTA, if these are passed, is difficult to quantify and any attempt to measure price and availability differentials arising from such TRIPS plus provisions is complicated, given India has a large generics industry. Some indications lie in the new drugs that have been patented since 2005. The prices are much higher compared to earlier branded prices. In a Centad Policy Brief on Compulsory Licensing in India (Centad 2009), Leena Menghaney provides the example of two drugs patented so far by the Patents Act 2005. *Valganciclovir* is a drug essential for the treatment of acute *cytomegalovirus*, an eye infection which HIV patients are susceptible to, and if untreated, can lead to blindness. The patent for this drug was granted to Roche in 2007 and the drug now costs Rs. 1040 for 450 mg tablet of one dose. Menghaney estimates the cost of a four month treatment at Rs. 2,74,560 per patient. Pegylated Interferon is another drug for Hepatitis C, which is a growing concern area for HIV/AIDs patients. After a grant of Patent to Roche in 2006, the cost for a single vial of 180 mcg is Rs. 18,200, with the cost coming to Rs.8,73,600 for a standard 48 week course. The rise in prices resulting from the Patent Act itself is evidently going to be much higher than in the past, TRIPs plus conditions will exacerbate this tendency. Prices and variations thereof are likely to be even higher than before.

It is clear that women will bear a large burden of this additional cost. Section I of this paper already establishes the large gap in treatment that faces Indian women today. This is made more difficult by poverty and lack of adequate income, lack of access to health institutions, especially in rural areas, the lack of education and awareness. It is evident from Section I that women face a more severe constraint in access to medicines and treatment compared to their male counterparts. TRIPS plus conditions make medicines more expensive and affects availability (for example, distribution in rural areas), and therefore both these factors will hit women comparatively more.

Constraints on access to medicines are going to prove especially critical for HIV/AIDS treatment, a disease to which an increasing number of Indian women are succumbing. Anti Retro Virals (ARVs), used for this treatment, have to be used in several lines of treatment as patients grow immunity to primary lines. Costs increase more than proportionately. For example, while the first line of treatment is available for about Rs. 950 a month, the second line is available at 6-10,000 Rs. From the third line, medicines are largely patented by multinationals and are available at Rs. 20-30,000 per month. National AIDS Control Organisation (NACO) provides free treatment for HIV/ AIDS patients but it is highly restricted. This shows the impact on costs, of patents. Till date the Indian government has not issued a compulsory license for ARVs and the number of ART service centres, providing ARV treatment to patients is highly inadequate compared to the need. Women patients have more to suffer from price rises in ARVs. Women suffer not only from a disproportionate vulnerability to contracting the disease but to treatment as well. Health activists argue that, firstly, women face more adversity in accessing treatment because of social stigma which in turn generates a culture of silence around the disease and a reluctance to seek healthcare. This is further aggravated by the hike in costs and lowering of availibility. In addition, in case of couples with both having HIV/AIDS, the women usually foregoes the medicine if access to drugs is constrained, either due to high prices or non-availability. This is critical as these medicines must be taken on a regular basis and even a single dose should not be missed. Another problem that women HIV patients face is that many of them are widows (as husbands often succumb to the disease), often poor, with the burden of supporting their family alone. They also encounter higher social ostracization. Several studies documented by Mitra (2009) argue that women have particularly disproportionate access to healthcare in general and treatment of diseases like STD, HIV in particular.

Another issue with additional provisions for patent protection is its failure to bring cures in neglected diseases. In spite of the fact that the IPR system was ushered in on the grounds that it encourages investment and innovation in new medicines, the diseases that have a large prevalence in India and in the developing world has been largely neglected. Treatment of TB and Malaria, are still to see private innovation on a large scale as these diseases mainly afflict the poor which limits the potential for commercial gains from development of new drugs. Most research is still undertaken by public research institutions (Dinesh Abrol et al 2009).

ii) Traditional Medicines

In India, the traditional system of medicine has been an important source of treatment, which has provided cheap treatment for ages, especially to the poorer rural population in India. The Department of Ayurveda, Yoga and Naturaopathy, Unani, Siddha and Homeopathy (AYUSH) of the Government of India, shows that in 2007 there were 4011 practitioners of Ayurveda, 412 practioners of Unani and 58 practioners of Siddha in India for every crore of population, with 277 hospitals catering under these streams of traditional medicine. Leaving out Homeopathy, the Indian system of medicine (Ayurveda, Unani and Siddha) had 506820 practioners and 3124 hospitals in 2007, spread over all the states in India. At the end of 2007, rural District Hospitals (DH), Community Health Centres (CHC) and Primary Health Centres (PHC), co located with AYUSH facilities, served about 39.8 lakh, 9.1 lakh and 2.1 lakh of rural population in India. The Indian System of medicines is dependent on the medicinal plants that are cultivated in India. The Annex provides a list of 32 prioritised medicinal plants listed by AYUSH, GOI.

The traditional system has been practiced as well as used extensively by women, especially in rural areas. A vast majority of community folk healers in India are women (World Bank 2006). While the exact extent has not been fully documented, case studies show that rural women in India, especially in tribal communities carry the main responsibility of collecting forest products, including medicinal plants. For example, in Uttar Pradesh, poor women were found to derive 45% of their incomes from forest products compared to only 14% for men (UNDP 2007). Many women's diseases, too, are treated by the ISM (See Table III.a.3). In rural areas, where the reach of modern medical facilities is poor, traditional medicines and its practice play a large role in delivering healthcare. A Women's research group on alternative medicines and women's health, called Shodhini, came out with detailed research work on which kind of women's diseases are treated by traditional medicines and found that many herbs, for example, *Shatavaru*, *Atibala*, *Mimosa Pudica*, *Amruthavalli*, *Sarsaparilla*, cures simple vaginal problems to difficult uterine problems, regulates hormones, and acts as tonics (Shodhini, 2008).

Apart from domestic use, India plays a significant role in the global trade in traditional medicines. The US and the EU are large importers of Indian traditional

Table III.a.3: List of diseases for which women patients generally visit AYUSH Govt. Hopsitals & Dispensaries

Ayurveda		Unani		Siddha	
Hospital	**Dispensaries**	**Hospital**	**Dispensaries**	**Hospital**	**Dispensaries**
Vandhatya (Infertility)	Vandhatya (Infertility)	Cervical spondolosis	Gynaec. disorders like leucorrhea, metrorhagia, memrorhagia, infertility	Ventheettu (White Discharge)	Ventheettu (White Discharge)
Menstrual Disorders/Leucorrhoea				III.b.2	
Infertility	Leucorrhoea				
	Gynae related disorders				
	Gynaecological conditions				

Source: AYUSH in India 2007, GoI. PP:246--254

medicines. This shows the interest in this field of medicine. In fact trade statistics from AYUSH shows that net exports amounted to Rs. 1926.14 crore rupees in 2006-07 and this shows annual growth rates of 12-39% from 2004-05 to 2006-07. Of this export, 'plants or parts of plants including seeds and fruits used for perfumery, pharmacy or insecticides (HS 1211) and 'vegetable saps and extracts, pectic substances' etc (HS 1302) form the bulk, and indicate the importance of these varieties.

TRIPS as included under the WTO, does not specifically refer to traditional knowledge but its article 27.3(b) provides for the patenting of life forms, or biological material. While the debate on conforming TRIPS to the CBD (which protects biodiversity and recognizes community rights and proposes the sharing of benefits as well as prior informed consent or PIC) is still going on, the TRIPs regime at least provides possible options for certain flexibilities like Special and Differential Treatment (SDT) (though its provisions are very limited); a sui generis system; disclosure of source of origin to ensure PIC and benefit sharing; strengthen the protection of Geographical Indications (GIs) of traditional medicines; and other exclusions to patentability. Many of these are still highly debated, but if agreed upon, these offer some escape routes for TK protection in the interest of communities.

The EU-India FTA does not currently have any specific provisions on traditional knowledge and genetic resources (Correa 2009). This seems a deliberate attempt on the part of India to protect traditional medicines and genetic resources. However, until the negotiations are over, the final provisions will not be known. India may have to trade concessions in one area with another. In addition, experts also point out that India could have tried to use this opportunity to make EU comply with the Convention on Biological Diversity (CBD). India could have also included an obligation on patent applicants to disclose the origin of biological materials claimed in a patent application (Correa 2009).

However, the TRIPs plus conditions in this trade agreement do ask partner countries to sign the UPOV treaty. In India's case, this will override India's own Plant Varieties Protection Act (PVP), which provides more benefits to traditional users of plants compared to the UPOV system. India has also used the Sui Generis system to develop a legally valid catalogue of traditional medicines, plants and yoga practices. However, full documentation of the entire system of traditional medicines and plants, is difficult and costly and is also refused by many communities. There is also inadequate inclusion of women's traditional knowledge which is not well documented. India also needs to develop its capabilities, both in research and legal practices, in order to use and counter the TRIPs Plus standards for its own benefits, a process it is highly unlikely to surpass the EU in, at least in the near future. Another problem with this FTA could also be that India may not be able to apply 'performance requirements' on access to resources and transfer of technologies which makes use of these resources (UNDP 2007).

There are two important effects of strong IPRS in this area. First, it can take access away from traditional users once these are patented by large multinationals. Second, over harvesting can lead to extinction of such varieties. This also conflicts with women's role as protectors of bio diversity.

The TK system is usually held on a community basis, making it difficult to patent by communities. It is also difficult for traditional communities and research institutes, given their limited access to resources and technology, to develop the medicines in ways to satisfy patent requirements. Difficulty also arises with keeping traditional knowledge a secret, as product composition has to be necessarily disclosed as a prerequisite for the registration of herbal medicines before the product can be sold (UNDP 2007). In addition, the IPR system comes into conflict with community held knowledge as IPRs protect individual rights. As pressures to commercialise grow, there is the tendency for increasing bio piracy. India has faced these problems before, as is most evident in the cases of legal battles it had to fight over Neem and Turmeric. Patenting of Neem for biopesticidal properties which are known for centuries, Turmeric as anti-infective, bittergourd (karela), Phyllanthus Niruri (for hepatitis) are few examples of biopiracy (Srinivasan 2005).

b) Liberalisation of Services and Investment in the EU India FTA and Impact on Gender

i) Health Related Services

Health services trade can potentially take place under all 4 modes. There are a number of activities which takes place under different services which relates to health. The following table (III.b.1) provides a classification. Some of these are not included under health services in GATs, and are included under other services like professional services (Mode 4), medical education under education services etc. Currently services trade is open under all 4 modes in the health sector. In terms of investment, 100% FDI is allowed through the automatic route, or through approval of Foreign Investment Promotion Board. Under GATS, India has made offers on Mode 3 in medical and dental services which allow local incorporation with a foreign equity of up to 74% subject to certain conditions. In hospital services, similar provisions apply to Mode 3 but without any conditions imposed. This sector has received FDI of Rs. 29687 million (April 2000-July 2009) which represents 0.715 % of total FDI received

Table III.b.1: Services Covered under Different Modes of GATS

Mode of delivery of the service	Kind of service delivered
Cross-border service (mode 1)	Shipment of samples, diagnosis, clinical consultation via traditional mail channels. Electronic delivery of health services like telemedicine, telesurgery, telediagnostic services; medical back office services, medical transcription services and online medical education services.
Consumption abroad (mode 2)	Medical tourism for super specialty medical services and alternative systems of healthcare.
Commercial presence (mode 3)	Establishment of super specialty hospitals and clinics, diagnostic and treatment centres in collaboration between domestic and foreign health services providers, health insurance services and hospital management services.
Movement of natural persons (mode 4)	Services of doctors, surgeons, nurses and midwives in foreign countries.

Source: Rupa Chanda, 'Liberalising Trade in Health Services: Issues and Concerns for India', presentation made at the National Workshop on Health Services Liberalisation under WTO/GATS - Whither and How?, organised by the Ministry of Health and Family Welfare and the WHO India Office, 15 Feb 2006.

by India. The EU does not seem to have a major interest in health services currently, but the FTA does give EU investors the ability to freely invest in India and this must be kept in mind while planning for healthcare services in the future. In fact India is looking forward to increased FDI in this sector.

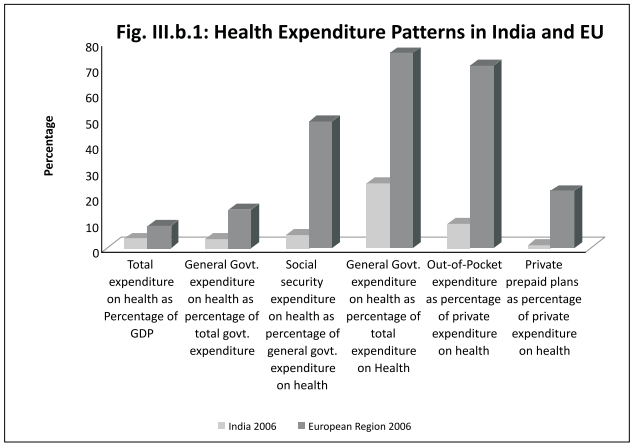
The impact of trade liberalization in this services sector through an FTA will work through some of the following impacts; inequalising nature of FDI and increases in inequity in access; private –public trade off in health services and impact on equitable access; the availability of health care professionals and facilities for addressing needs of women and other vulnerable groups; the freedom of domestic regulation to ensure access; the impact of technological advancement on women. Among these, the impact on policy space is discussed separately under section d) as it is a cross cutting issue.

FDI, Public-Private Tradeoff and Equality

A significant problem with health services trade liberalization is that the role of foreign investments in addressing domestic equity concerns is yet unclear. As Section A shows, currently there is severe inequity in access in India and this also has a clear gender outline. So increases in inequity in income, infrastructure, and other indicators increases inequity for women patients and others, like pregnant and infertile women, in need of care. First of all, foreign investments in India, like in many other sectors like banking, have been seen to be in-equalizing as they have been further aggravating the urban orientation of private services. FDI has traditionally chosen 'safe' areas as its destination and it is no surprise that most out of the 62 cases of foreign investment in hospitals or diagnostic centres approved between 1991 to May 2001, most have been concentrated in cities, and even within cities to large metropolises like Delhi, Kolkata and Chennai (Gopakumar 2009) where medical services are already well developed.

In spite of the fact that additional hospitals and facilities in the health sector may increase overall facilities and therefore access, the equity question remains a crucial one. For example, even the positive outcome envisaged under the India EU FTA, for example investment in health sector (Mode 3), may not be of use to the poor. At the primary level this adds to the public vs. private debate in meeting health needs. For health services to reach the poor we need extension of public health facilities, not private health. Even in the developed countries the % share of public expenditure is 75.6% whereas in India this is mere 25% in 2006 (See Table A.1, Annex). The primary responsibility of the government is to provide healthcare for all and this cannot be replaced by private facilities.

Interestingly, the share of public expenditure on health is much higher in the EU (75.6% in 2006), therefore, avoiding dependence on the private

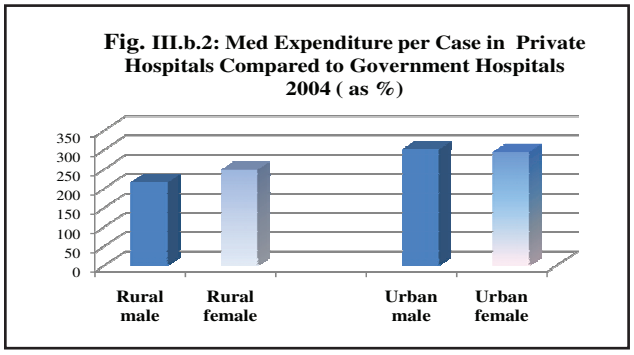


Source: Based on Table A. 1(see Annex), Data Source: WHO statistics 2009

sector for basic health security of citizens. Private pre-paid plans' coverage is also much better in the EU. The government's total expenditure on health as a percentage of total government expenditure in India remains an abysmal 3.4% compared to EU's 14.8% in 2006 (see Fig. III.b.1 below).

The services provided by private agents are always costlier and cannot be afforded by much of India's poorer population. The table below shows that expenditure in private hospitals per case, is more than double that in government hospitals. This in fact seems to have increased between 1995-06 and 2004, with the proportion reaching nearly 3 times in urban areas in 2004.

This also has an interesting gender and urban-rural dimension. The ratio of expenses in private to government hospitals is higher for women in rural areas, compared to their male counterparts (See fig. III.b.2). This may have a significant impact on deterring rural females from getting treatment in private hospitals. In urban areas, the ratios are higher compared to rural rates, for both males and females, implying that private facilities are more expensive in urban areas for both males and females. But males seem to incur proportionately higher expenditure in private hospitals compared to females.



Source: Based on data from NSS (2004)

In addition, 75% of specialists and 85% of technology lies with the private sector. But simultaneously, despite its very high share of resources used, the private sector covers a much smaller population. It still provides only 49% of total beds and has a much lower bed occupancy ratio of 44% compared to the public sector's 62%. Further, the private sector which accounts for the largest chunk of health service resources in terms of infrastructure, technology and personnel, has a much smaller presence in rural areas as opposed to urban which accounts for 2/3 rd of the total health professionals and 88% of overall resources (GOI 2006).

In spite of increasing gaps which needs to be filled in by the Indian government to meet the health needs of the vulnerable and women, the government's ability to address such health disparities may get severely limited by the FTA if

Table III.b.4: Average Medical Expenditure (Rs.) Per Hospitalisation Case in India

	Rural		Urban	
Type of hospital	**2004**	**1995-96**	**2004**	**1995-96**
Government hospitals	3238	2080	3877	2195
Private hospitals	7408	4300	11553	5344
Any Hospital	5695	3202	8851	3921
Expenditure in private hospital as a % of that in govt. hospital	**228.78**	**206.73**	**297.99**	**243.46**

Source: NSS (2004)

full services trade liberalization, with uninhibited FDI entry and the rise of private foreign investment into the health sector goes through.

Medical Tourism

Another issue is of medical tourism which comes under Mode 2. India has been trying to encourage medical tourism and is by now well known for acting as a major destination for providing high quality medical services at cheaper rates compared to the developed countries. Trade under this mode is currently free but as a result of this FTA, there may be increased flow of this service, in addition to foreign investors setting up facilities in India with the key purpose of attracting foreign patients/ service seekers, by using India's domestic facilities and rich supply of healthcare professionals. However, there are issues linked to medical tourism that one must consider. The first is that it takes critical facilities away from domestic needs. Second, it exerts an upward pressure on costs of healthcare and therefore on government budgets if government hospitals have to stay competitive. Otherwise, user fees in government facilities must go up. This has been pointed out by the National Commission on Macro Economics and Health (NCMH) (GOI 2006). While medical tourism may generate significant revenues for private players who naturally promote medical tourism, the rationale of using India's limited resources for promoting cheaper medical facilities for others may imply a trade off that India cannot afford, especially as its own costs will be likely to rise. Women, especially poor women, are likely to be a disproportionate sufferer because of shrinkage of access.

Medical tourism also involves significant ethical issues. For example, surrogate motherhood, much touted as a front runner in India's medical tourism boom, has serious ethical questions which must be resolved by Indian policymakers, in India's socio economic context. The Indian Assisted Reproductive Technology (Regulation) Bill, 2008, has been passed recently though it still leaves most questions unanswered. It clearly protects the rights of the private service provider by allowing medical surrogacy for commercial purposes. While this may remove legal barriers to surrogacy, and therefore encourage it, the Bill faces widespread criticism on the point that it provides inadequate protection of the rights and health of the surrogate mother. The bill attempts to ensure commercial gains for the surrogate mother, but the provisions on regulating this sector are highly inadequate. However later attempts to interfere with such practices may be taken as a violation of the FTA and may be severely disputed by EU. Many FTAs now have a stability clause by which policy regulations at the time of signing of the FTA must be held unchanged for an unknown period, and new regulations to protect vulnerable groups cannot be enacted if it infringes upon the provisions of the FTA (Ramanathan, 2008-9).

The liberalisation under Mode 2 of medical tourism, on the one hand, coupled with uninhibited foreign investment in health sector under Mode 3 on the other, pose the critical problem of crowding out of public hospitals and services from the health sector. In the era of declining public expenditure, public services represent a crucial policy instrument to address critical health needs. The public health system can survive and operate in rural areas and provide care to the poor, women and patients of critical

diseases if they make enough profit in other areas.

Mode 4 Liberalisation and Concerns from a Health Perspective

A critical issue is the liberalization of Mode 4 which further encourages the outflow of doctors and nurses from India's already significant outflows. If EU's significant barriers to entry are removed as part of this FTA, while it will give benefits to the trained health professionals, it will further adversely affect the health condition of the public sector which has witnessed the highest outflow due to low wages, adverse working conditions etc. while it must be acknowledged that unless domestic pay and work conditions in public services is improved, this outflow is inevitable. But in the absence of such prior improvements to domestic conditions, whether India is in a position to further encourage outflows of health professionals is a question that must be answered. Signing an FTA at this juncture, where the possibility of outflow is very real given the much more attractive working conditions in EU, seals the possibility of addressing this issue later on. Movement of health workers to the UK is already high.

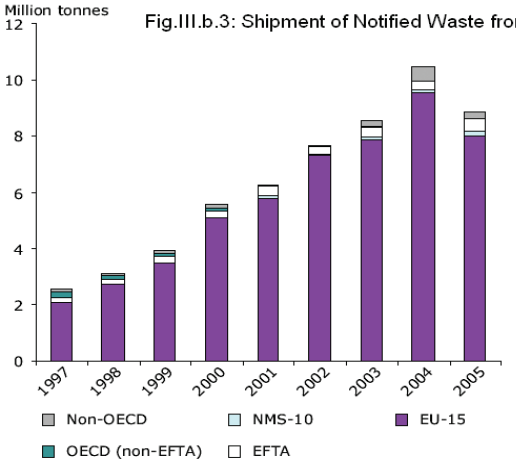
However, the EU currently has very high barriers which are unlikely to be significantly removed even after the FTA. There are entry barriers in terms of border measures related to immigration regulations, and domestic regulation in the form of accreditation and licensing requirements. From documents of the European parliament, it seems evident that the EU is cautious on promising too much in this chapter (EU Parliament document, March 2009). Currently gains are expected to be limited to employees of BPO services located in EU under Mode 3. Though this means that there will be minimum gain to health service providers seeking employment through Mode 4 liberalisation under the FTA, it may mean that further drain of health professionals will not be a major concern in the immediate future.

ii) Solid Waste Management: Hazardous Waste from the EU

An area that the EU is interested in within the services sector is the waste management services and waste trade. The EU is interested in investing in these services in India, but from a health point of view what is of concern is the export of hazardous waste from the EU for disposal in India. From experiences in Thailand, it is evident that it has been an issue of concern in the Thailand-Japan FTA (FTA Watch, 2009).

"Hazardous wastes are defined as toxic, inflammatory, reactive, explosive, or infectious; and include such wastes as heavy metals in batteries, electroplating sludges, paint solvents,

Fig.III.b.3: Shipment of Notified Waste from the EU



Note: Shipment of notified waste from the EU Member States relates to: old EU Member States (EU-15) (5); new EU Member States (NMS-10); EFTA countries; other OECD countries; and non-OECD countries. Romania and Bulgaria are classified as non-OECD countries. The 1997 and 1998 figures do not include export out of NMS-10.

Source: European Commission, 2007; Secretariat of the Basel Convention, 2007.

pesticides, and infectious healthcare wastes" (Cointreau, 2006, P. 5). Among the amount of hazardous waste generated by countries, the UK, Germany, France seem to be among the top few. Germany, France, UK, and Italy produced 21705400, 9621600, 8448500 and 7464673 tonnes of hazardous waste in 2007, while the EU in total produced a mammoth 88731340 tonnes. EU accounts for approximately 35% of World's hazardous waste generation (Eurostat 2004). Export of notified waste (mostly hazardous or problematic waste) to EU or Non EU countries is still a small proportion of EU's total generation. However, even though EU has strict rules about the export of hazardous waste to non OECD countries and each shipment has to be notified to the European Commission, the shipment of notified waste has been steadily increasing. For example, from 5% of total hazardous waste in EU in 1997, shipment increased to 13% of EU's total hazardous waste in 2005 (EEA 2009). What is of concern is that even proportion of shipments to non-OECD countries has been increasing (EEA 2009)(see figure III.b.3 below). The notified data given to European Commission is of a very general nature (EEA 2009).

Shipments of waste do provide raw material to developing countries, the problem arises because developing countries, including India, do not have the wherewithal to manage hazardous waste in an environmentally sound manner. Imports are also closely linked to the work of the ship breaking industry. In addition, India lacks the ability to adequately address health problems arising out of such waste. In spite of the 'Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal', the trend has continued. In fact the case of the French aircraft carrier "Le Clemenceau", which was sent to a shipyard in Alang, India with unknown amounts of toxic waste, including asbestos shows the problem of inequalities in addressing this issue (Sonak et al 2008). The study by Sonak et al (2008) also documents reports that large quantities of toxic waste are still being imported by India from countries that ban the use of this waste (See Table III.b.5). An FTA between FTA and EU may considerably ease norms for the shipment of such waste. This poses a health hazard in general but may also pose a threat to women and children who work in this sector. In fact the ship breaking industry in India is a main receiver of such waste and health of workers in this labour industry should also be a matter of concern.

Table III.b.5: Import of Hazardous Waste into India

Year	Imports (tonnes or rupees)	Hazardous material
2004–2005	1123.9 tonnes	Mercury
	30.06 tonnes	PCBs
	216.6 tonnes	Asbestos brake linings and pads
	101.1 tonnes	Clinical and related wastes
	107 crore	Ash and residues of arsenic
2003–2004	32.8 tonnes	Asbestos material
	20 tonnes	PCBs, PBBs
	54.35 tonnes	PCTs
	5.25 tonnes	Asbestos brake linings and pads
	1200 tonnes	Hazardous waste No 38249036 Incinerated ash

Source: Sonak et al (2008)

PCBs, Polychlorinated biphenyls; PBBs, polybrominated biphenyls; PCTs, polychlorinated terphenyls

iii) Technology and Implications for Women

One issue is also of technical advancement. While India is looking forward to advancements in technological knowhow and this is likely to be realized, one must also be aware of the pitfalls of

new technology. In a society which is characterized by traditional sociological attitudes to women, technology has often been used to perpetuate these. For example, many of the high growing states in the Northern part of India like Punjab and Haryana have witnessed worsening sex ratio because of advancements in technology. The point is after an FTA, will the government have enough control to restrict the use and transfer of such kind of technology? Any technology transfer needs to effectively monitored and regulated on the basis of its impact on vulnerable groups like women.

c) Working Condition of Export Industries and Labour Standards

The increasing pressure of catering to a competitive global market has its costs. This is why labour in general and women's and children's labour in particular, has been used to meet trade's demands. The low requirement of skills in this sector also encourages the hiring of women workers. These groups of workers agree to work on flexible terms, are not registered and hired at lower rates of pay. A large proportion of them are also migrant workers who are less organized and easier to employ. In spite of some improvements in productivity, women's wages have often been kept unequal, and not increased in tandem with productivity gains. In addition, it has been seen that working conditions in export based industries in developing countries has been compromised to retain profit margins and ensure competitive prices. The workers are made to work in cramped rooms, without even adequate toilet breaks and are not granted leave. The pressure to retain jobs means that the workers cannot ask for a betterment of terms of work. Health adversities, for example, include physical and mental stress, inhalation of dangerous material (for example fibre in textile and garments units), inadequate light and air, inadequate meal breaks or toilet breaks. This issue has been a matter of some concern in civil societies in developing countries, especially relating to segments like textiles, garments, tobacco production (Mazumdar 2003, see also Sengupta and Gopinath 2009 for a short survey).

These pressures are likely to go up after the EU India FTA and will affect more women workers as labour is expected to shift to these sectors. The Impact Assessment study by ECORYS et al (2009) on the EU-India FTA also predicts adverse results on health in export based sectors. While the Report shows nominal impact on health in its broad conclusions, it does show adverse impact on health in export based sectors, especially where the informal economy is large. It specifically points out that these sectors are women intensive sectors and therefore the impact on women's health will be worse. Of course, these findings work to the advantage of EU which has been arguing to include labour standards in the FTA.

The Indian government has been criticized by labour activists for not implementing even national labour standards, for example the Factories Act, in export based sectors. The SEZs in particular enjoy higher labour law flexibilities. This is ostensibly to maintain comparative advantages in its export market. The EU has asked India to conform to ILO labour standards which India is yet to ratify. India, in return, has strictly asked EU to not mix issues like labour standards

and human rights with trade agreements. This represents one of the most contentious areas in the negotiations with both taking a strong stance. India has signed the ILO convention, but has not ratified all the conventions. In particular, India does not ratify rights to organize and bargaining, discrimination and elimination of child labour. India looks upon labour standards, like many other developing countries, as non tariff barriers to entry in the EU market. However, while it is true that tackling labour standards is complicated in a bilateral forum if other countries in similar situations do not do so, it also is clear that India needs to take its labour standards, and the health and safety of its workers seriously. The EU should also ensure that it follows a uniform policy as regards its own investments in India.

Interestingly, labour activists point out (Interview with Resmi Venkatesan, Cividep India, 4th September 2009), that even if there is growth in trade in sectors like textiles and garments in the wake of the FTA, it does not matter to the average woman worker who will still have to work under adverse conditions. In fact, even the so called technological improvements, which is advanced in favour of trade liberalization is discounted in this context, as it does not necessarily translate into better work conditions. For example, an improved machine may produce double the items it produced before but the worker may still have to stand and use it. Labour activists point out the importance of social audit to evaluate such conditions and implement improvements.

d) Patenting of Plant Varieties and the Impact on Food & Health

The current PVP Law in India has included a chapter on farmers' rights, after much pressure was exerted by NGOs. But TRIPS plus provisions, like pressure to join UPOV 1991 which mainly protect breeder's rights has been included under EU-India FTA (Correa 2009) under Article 11. This will eliminate the element of protecting farmers' rights contained in the current law. UPOV 1991 prevents the farmers from saving, using and freely exchanging seeds, which is traditionally practiced by Indian farmers, especially smaller ones. In addition, provisions under the present law, such as the registration of extant and farmers' varieties and benefit sharing provisions to compensate farmers' for their innovations will also be threatened. This provision, though not strictly obligatory in text, as it imposes an obligation to 'cooperate to promote and reinforce the protection of plant varieties' according to UPOV 1991, may still turn out to be pretty stringent in implementation. As a concession, the draft text refers to the possibility (article 15(2) of UPOV 1991) of introducing an exception for the use, in their own exploitation, of seeds saved by farmers. However this will be inadequate to protect farmers' rights to use seeds freely and the Indian government needs to resist any such attempts.

Even the pressure to push GIs does not really work for our farmers as they are still ill equipped to secure GIs. In addition, the IPR text also includes patent term extension by five years which also refers to plant protection products (Correa 2009).

Another area of concern is that the domestic policy regime is already being conformed to international pressures. The Seed Bill also allows sale of seeds by farmers, but it has to meet certain quality standards, which makes it necessary to get

it registered. It also has to be sold under a brand name. This makes it impossible for small farmers and women, who are traditional seed keepers and protectors of bio diversity, to sell in the market while competing with seed companies.

The constraints on access to seed, production and consumption of crops, including food crops, is also exacerbated by the investment liberalization provisions in the FTA. Land is a natural resource of critical importance for maintaining production capability, and access to land is now protected as investor's rights. Therefore if the FTA allows, EU investors may have to be given national treatment over Indian land, countering the current Indian policy of protecting FDI in agriculture. However, EU's outward FDI in agriculture does not seem to be a very high proportion of its total FDI, though in volume terms, it is not insignificant. EU's outward FDI stock is 1229 million Euros (2005) and has shown a steady growth. FDI in land ownership may also be showing up in forms other than as agricultural FDI, for example as industrial investment.

e) Domestic Policy Space and Health Concerns

With the advancement of Free Trade Agreements, domestic policy space left to developing country governments to independently address their development priorities has been increasingly compromised. Throughout this paper, this phenomenon has been pointed out in each section, under every issue. This is evident not only in the field of health but other critical areas as well. For health, it appears as an important constraint on ensuring access.

One of the key areas affected by the liberalisation and non discrimination of public procurement in India, as demanded by EU, will be the ability of the government to protect the field of public health. In the field of pharmaceuticals for example, the public procurement system in India, is used extensively for ensuring the availability of medicines for public health purposes. AIDAN (2009) points out that in the field of pharmaceuticals, government tender procurement prices are 1-3% of retail market prices, often from low cost generic producers. A number of efforts have been taking by Indian government like "Jan Aushadhi" generic stores and Tamil Nadu Medical Services Corporation Ltd. (TNMSC) drug procurement model. Jan Aushadhi generic stores are government run outlets for getting drugs at affordable price. Tamil Nadu Medical Services Corporation Ltd., (TNMSC) was set up with the primary objective of ensuring ready availability of all essential drugs and medicines in government medical institutions throughout the State by adopting a streamlined procedure for their procurement, storage and distribution. These are done through discriminatory procurement. A non discriminatory commitment through FTAs in the case of government procurement in the field public health will be self destructive.

What is of additional concern is that the Indian government is already enacting policies that eliminate small producers from public procurement. A new rule on Public Procurement now bans small producers from bidding for public procurement has recently been passed. These are seen as efforts to meet international free trade norms in addition to pressures exerted by domestic big pharmaceutical industry. There are many others. For example, the Food Safety Bill

which lays down high standards unlikely to be met by the small producer and retailer; the Seed Bill, which makes seed sale impossible for small farmers because of complicated requirements, are just a few examples from an increasing set of policy regulations gone awry. Critical health related issues also remain unresolved. As discussed before, the field of surrogate motherhood is an area that gender health activists have been asking the government to regulate. The Surrogacy Bill has been recently passed but hardly protects the rights and health of the surrogate mother. This area is yet to see effective regulation.

In addition, many of the provisions entered under an FTA may be irreversible. Therefore, whatever guidelines for health sector is not currently in place may never be implemented if they conflict with FTA provisions. As mentioned before, the stability contractor stabilization clause, often included in FTAs to protect investor's rights, ensure that certain domestic policies have to be held fixed including tax concessions. Investors can take recourse to stringent dispute settlement actions if these are found to be violated. This will prevent new regulations from being enacted or applicable to FTA partners if it infringes upon signed FTA provisions. For example, the FTAs between Canada-Colombia, US-Peru FTA contain these provisions.

IV. Conclusion and Policy Suggestions

This study finds that there are many likely provisions in the EU-India FTA that can adversely impact women's access to healthcare in India. Some direct impact may also be felt as a result of increased pressure on female-labour intensive export based sectors. In addition, the government's ability to address health concerns through its policy space may also be constrained. While the government has apparently rejected many of these provisions (e.g. strong IPRs), it may be forced to give in to some provisions while bargaining for others. It is of importance to resist TRIPS plus provisions like data exclusivity, patent term extension so that its generic production of pharmaceuticals and access to medicines is not compromised further. Retaining TRIPS flexibilities and using these extensively is also a policy option that India must pro actively pursue, irrespective of the FTA. It can for example, use compulsory licensing and price control more effectively. India must also resist strong and unjustified provisions on IP enforcement, in particular, border measures, as it affects not only India's domestic supply but supply of critical medicines to other parts of the developing world.

Pressures to join UPOV 1991 that works against Indian farmers cannot be justified either. In the field of traditional medicines, India has been prudent to drop provisions, and India can take a more proactive role in imposing CBD provisions on EU. At the same time, India's own Sui generis system of protection of plant varieties needs to be defended both for traditional medicines (plants) and food security. Though health services liberalization may not be high on EU's agenda right now, India needs to guarantee access to such services to all its' people even in the future, and replacing public services with private ones is a costly solution. India also needs to protect its policy space to ensure health access to all, and be able to make suitable regulatory intervention to resolve health related issues.

India must also take a proactive role in safeguarding the health of its workers, and ensure that trade liberalization and export growth does not come at the cost of its workers health and wellbeing. Finally, gender disparity in health indicators is strengthened by existing inequalities in incomes, employment, regional divide in health infrastructure and gaps in education and social consciousness. Until these are addressed domestically, women will somehow lose out from ambitious trade liberalization. Therefore, attaining certain minimum equality in socio economic indicators is a policy measure that India must consider seriously before increasing possibilities for further exacerbation in such inequalities through bilateral trade liberalisation. Attaining a balance between growth and equitable development, between men and women, between rural and urban areas, between metropolitan cities and other areas, and between private and public provision of healthcare should be, in some ways, a prerequisite for attaining a just and equitable trade agreement. Broad-based social security programmes covering job security, income security, health and education guarantee, are proactive options in this regard. Finally, India must keep in mind the impact of its stance in the EU India FTA on WTO negotiations. India cannot afford to weaken its own position or that of developing countries as a whole, by giving concessions for commercial gains, especially ones that can harm the basic health needs of its citizens and vulnerable groups like women.

Appendix

Table A 1

Health Expenditure Indicators, India and EU

Expenditure on Health	India		Europen Region	
	2000	2006	2000	2006
Total Expenditure on Health as Percentage of GDP	4.3	3.6	8	8.4
General Govt. Expenditure on Health as Percentage of Total Govt. Expenditure	3.3	3.4	13.7	14.8
Social Security Expenditure on Health as Percentage of Gen. Govt. Expenditure on Hea	5.8	4.9	50	49.2
General Govt. Expenditure on Health as Percentage of Total Expenditure on Health	21.8	25	73.6	75.6
Private Expenditure on Health as Percentage of Total Expenditure on Health	78.2	75	258	24.4
External Resources for Health as Percentage of Total Expenditure on Health	0.6	1	0.2	0.1
Out-of-Poclet Expenditure as Percentage of Private Expenditure on Health	92.1	9.4	68.6	70.8
Private Prepaid Plans as Percentage of Private Expenditure on Health	1	1.1	22.4	22.1
Per capita Total Expenditure on Health (US$)	19	29	936	1756
Per capita Govt. Expenditure on Health at Average Exchange Rtae (US$)	4	7	704	1350

Source: WHO Statistics, 2009

Table A.2: Some Drugs of Relevance for Indian Women and Prices of Generic Medicnes sold at Jan Aushadhi Store (JAS), and Details of Maximum and Minimum Market Price of Selected Branded Products

Therapeutic Group/ Indications	Generic Name	JAS price (Rs.)	Strenth	Type	Packsize	Brand Name (Max.)	Manufacturer (Max.)	Max.MRP, (Rs.)	Brand Name (Min.)	Manufactur er (Min.)	Min.MRP (Rs.)
Paracetamol/ Reduces fever	Paracetamol	2.12	500mg	Tablet	10s strip	Reemol	Remedy Healthcare	9	Cofamol	Cfi pharma	5
Antibacterial/ Treating serious bacterial infections.	Amikacin	5.6	100mg/2ml	Vials/Ampoul	2ml vial	Deomic	Semsun Pharma	68	Mikanova	Raphael Pharma	12
Antibacterial/ Treats or prevents infections in persons with advanced HIV infection.	Azithromycin	73.35	500mg	Tablet	10s strip	Azila	Alpha Lab	230	Azalyd	Custodian	30
Antibacterial/To treat urinary tract infections, gonorrhea, and prostate infections.	Norfloxacin	13	400mg	Tablet	10s strip	Unbid	Lupin	42.75	Nogit	Alde	19.25
Antibacterial/ Treats mild to moderate infections , may also be used to treat or prevent certain infections in persons with advanced HIV infection.	Azithromycin	34.62	500mg	Tablet	10s strip	Eazythrot	Pramukhswami	185	Aziral	Gnosis Pharma	19.5
Antibacterial/Treats infections in respiratory tract, the middle ear, the bones, the skin, and the reproductive and urinary systems.	Cephalexin	15.62	250mg	Capsule	10s strip	Phexin	Glaxo-Smithkline	72.4	CD Phex	Cyper Pharma	30
Antiinflammatory	Diclofenac Sodium	3.01	100mg	Tablet	10s strip	Fensaide	Nicholas	12	Fensaide	Nicholas	12
Antimalarials	Chloroquine Phosphate	3.65	250mg	Tablet	10s strip	Match-Q	Lifestar	6.5	Laquin	Stadmed	3.29
Antiprotozolas/Treats bacterial infections of the vagina, stomach, skin, joints, and respiratory tract	Metronidazole	2.34	200mg	Tablet	10s strip	Metrogyl	J.B Chemical	4.1	Flagyl	Nicholas	3.58
Tuberculostatic	Pyrazinamide	9.27	500mg			Pyzina	Lupin	44.6	Montozin	Shreya	17.12
Tuberculostatic	Rifampicin	12.47	150mg	Capsule		Rcin	Lupin	20.27	Rifatis	Sitrocs Zenetica	16.3
Tuberculostatic	Streptomycin	5.2	.75gm	Injection	1 vial	Ambistryn-s	Nicholas piramal	7.86	Ambistryn-s	Nicholas piramal	7.86

Source: Comparative Analysis of Jan Aushadhi & Average Branded Market Price, Dept. of Pharmaceuticals, GOI

Table A.3: Some Drugs of Relevance for Indian Women and Maximum and Minimum Prices of Selected Branded Products

Therapeutic Group/ Indications	Generic Name	Strenth	Type	Packsize	Brand Name (Max.)	Manufactur er (Max.)	Max.MRP, (Rs.)	Brand Name (Min.)	Manufactur er (Min.)	Min.MRP (Rs.)
Post Partum and post abortal haemorrhage, other treatment of uterus	Methylergometrine Maleate	0.125 mg	Tablet	10s strips	Methergin	Novartis	100	Ingagen-M	Inga	30
Breast cancer	Letrozole 2.5mg	2.5mg	Tablet	10s strip	Femara	Novartis	1815	Oncolet	Biochem	99
Skin Cancer	Rituximab	100mg	Vial	1 vial	Mabthera	Roche	20000	Reditux	Reddy's	10000
Breast Cancer	Tamoxifen	10mg	Tablet	1 Tablet	Nolvadex	ICI	19	Tamodex	Biochem	2.7
Skeletal Fractures in Cancer patients	Zoledronic acid	4mg	Vial	1 vial	zometa	Novartis	13900	Zoldria	Cipla	2800
Rheumatoid arthritis	Leflunomide	10mg	Tablet	10s strip	Arava	Aventis	440	Rumalef	Zydus	80
Viral infections including HIV/AIDS	Zidovudine	100mg	Capsule	10s strip	Retrovir	GSK	20.4	Zidovir	Cipla	7.7
Worm infestation	Albendazole	400mg	Tablet	1s strip	Zentel	GSK	17	Milibend	Glenmark	6
Depressive disorder	Escitalopram	10mg	Tablet	1s strip	Cipralex	Lundbeck	14	Stalopam	Lupin	6
Peripheral vascular disease	Flunarizine	10mg	Tablet	10s strip	Sibelium	J & J	52	Slurin	FDC	25
Neurological disorder	Gabapentin	300mg	Tablet	10s strip	Neurontin	Pfizer	313	Gabapin	Intas	98
Nausea & vomiting	Metoclopramide	10mg	Tablet	10s strip	Perinorm	IPCA	15	Vominorm	Cipla	8.4
Blood Pressure	Valsartan	80mg	Tablet	10s strip	Diovan	Novartis	410	Starval	Ranbaxy	69
Genito-Urinary Infections	Ofloxacin	200mg	Tablet	1 Tablet	Tarivid	Aventis	31	Zo	FDC	3.2
Bacteria infections incl. urinary tract	Levofloxacin	500mg	Tablet	1 Tablet	Tavanic	Aventis	95	Levoflox	Cipla	6.82
Bacteria infections incl. urinary tract	Ciprofloxacin	500mg	Tablet	1 Tablet	Cifran	Ranbaxy	9.8	zoxan	FDC	3.9
Bacteria Infections	Azithromycin	250mg			Vicon	Pfizer	39.14	Zathrin	FDC	8.5

Source:MIMS, Sept 2009, AIDAN (2009)

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