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At any price?

Examination of the business behavior of Boehringer Ingelheim, Bayer and Baxter in India

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Content

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Roughly one third of the Indian population are children. *Photo: Andrea Czekanski*

I India: In between five-star medical care and insufficient health care

1. The health care system in India

"We should no longer be guilty of the neglect of the health of our people." This is what Mahatma Gandhi demanded in 1940[2]. Since then, Indian health policy has achieved considerable success. Life expectancy has almost doubled, infant mortality has fallen and infectious diseases, such as leprosy or polio have been driven back. However, inequality and poverty characterize India even today.[3]

Health in figures[1]

Total population (2008)		1,181,412
under 15 (2008)		32,0%
Population living in rural areas (2008)		71,0%
Life expectancy at birth (both sexes, 2008)		64
Under-5 mortality rate per 1,000 live births (2004)		85
Maternal mortality ratio per 100,000 live births (2001-2003)		301
Total expenditure on health as % of GDP (2008)		4.0%
General government expenditure on health as % of general government expenditure (2008)		4.1%
Population living below national poverty line (1999-2000)		26.1%
Adult (15+) literacy rate (2000-2004)		61.0%
Adult male literacy rate (2000-2004)		73.4%
Adult female literacy rate (2000-2004)		47.8%
population with access to improved drinking water supply (2008)		88.0%
population with sustainable access to improved sanitation (2008)		31.0%

Laxmi was treated against tuberculosis for months and cured. She was infected by her husband who likewise received therapy. Now they can both look after their children again. *Photo: WHO, P. Virot*

Characterized by inequality and poverty

The federal state of Kerala in the south of India has, for example, a very well developed public health care system and a literacy rate of almost 100 percent. In contrast, the health care system of the north-eastern federal state of Arunachal Pradesh is only rudimentary and the illiteracy rate is more than 50 percent.

An estimated 1.2 billion people live in India, more than half of them are considered poor according to the standards of the current Human Development Report, which covers health, education and standard of living. Almost 42 percent of the population live on less than 1.25 dollars per day[4]. Almost one million Indians still die each year as a result of insufficient health care. 700 million people do not have access to adequate treatment by specialist care as 80 percent of the medical specialists live in cities[5] whereas 70 percent of the Indian population live in rural areas.[6]

Polio still has not been exterminated in India. Many children suffer from the consequences of this severe disease.

Photo: WHO, P. Virot

For many families, the income is only enough for basics. Insufficient public health care is a result of a large number of facts. In addition to cultural differences and different languages – there are 22 official (and about 100 inofficial) languages in India – adequate treatment is further impeded by poor infrastructure (such as large distances to the next hospital), a lack of social security systems or even the stigmatization of certain patient groups (in case of tuberculosis or Aids). Although the treatment of tuberculosis or Aids is free of charge, many patients do not or only belatedly go to the respective therapy centres since they have to fear social stigma.

At the same time, tuberculosis and HIV are a grave problem. Out of 100,000 Indians, 190 suffer from TB (in Germany only 2) and roughly 2.5 million people are HIV positive. In many places, prevention is hardly possible. For example, the federal state of Karnataka prohibits sex education in school. Thus, people do not know much about Aids and the paths of infection. Accordingly, two thirds of the women and half of the men think that HIV is transmitted by insects.

Health in India and in Germany – a comparison[7]

Population 2008	India	Germany
Inhabitants (Mio.)	1,181	82
Population growth (1998-2008)	1.6	0.0 %
Life expectancy (years)	64	80
Under-5 mortality rate /1,000 live births	69	4
Population living in urban areas	29.0 %	74.0 %

Tuberculosis and Aids 2008	India	Germany
Tuberculosis (prevalence/100,000)	190	2
Prevalence of HIV among adults aged 15-49	0.3 %	0.1 %

Reported cases	India	Germany
Cholera (2008)	2,680	0
Diphtheria (2008)	6,081	0
Leprosy (2008)	134,184	0
Measles (2008)	48,181	917
Polio (2009)	723	0

State of nutrition 2000-2009	India	Germany
Underweight infants %	43.5	1.1
Overweight infants %	1.9	3.5

Right of protection

According to the constitution of 1947, the Indian population has the right of public social protection. A two-tier system of a state insurance of employees and free-of-charge health services for low-income citizens is meant to provide such protection. Thus, the health care system and the health insurance system are closely connected.[8] However, the financial basis of the health care system is weak: merely 4 percent of the Indian gross national product are spent on health (2008).[9] This amount lies far below the level of international recommendations and also below the average of what other countries of this region spend on their health care systems.[10] Moreover three quarters of the expenditure on health, go into the private health sector (including NGOs) and only one quarter is spent in the public health sector. It is only a small proportion of the total expenditure on health that is borne by the state. Health economists have calculated that the government only paid 15 % of the 1,500 billion Rupees that were spent in the health sector. Four percent originate from the public social insurance and one percent from private insurance companies. 80 percent were paid by the patients themselves, e.g. at the purchase of medication, or therapies. But most patients are poor. Of the poorest 20 percent of the population, more than half take on debts or sell their property to be able to pay for health services.[11]

Well cared for by the state?

As in Germany, the state insurance is a solidarity-based, contributory insurance of employees: accordingly, employees contribute 2.25 % and employers 5 % of the gross income to the public health insurance. In addition, the state grants a subsidy of 12.5 % of all medical costs incurred. The basis of the insurance is the „Employees' State Insurance Act" (ESI). It covers the risk of illness, maternity, occupational accidents, funeral costs and the survivors' benefits. Nevertheless, there is no comprehensive and effective protection for the population in India since a large proportion of the population is excluded from this state insurance. Among them are, for example, seasonal workers,

Treatment in the sub-centre: health workers treat minor injuries, disorders such as diarrhoea or bronchitis and carry out preventive medical check-ups of pregnant women.

Photo: Andrea Czekanski

For many families, the income is only enoug for basics.

Photo: WHO, SEARO

agricultural workers and people with a monthly income of more than 6,500 Rupees. As a result, increasing wages cause more and more people to be ineligible for the state insurance whereas they still cannot afford private insurance. In the city of Bangalore, a monthly income of 6,500 Rupees is hardly sufficient to support a family.
The state insurance is restricted to the formal sector, although a large proportion of employees work in the informal sector (which generates about 60 % of the Indian gross domestic product). Only about 8 % of the Indian population receive the benefits of continuation of payment in case of illness and the right to social security. Unemployed people are generally not covered by social security.[12] In total, about 10 percent of all Indians are insured, whereas 50 percent of the upper and middle classes are insured.[13]

An insurance for the poor

In 2004, the government placed an obligation on all health insurance companies to introduce the so-called Universal Health Insurance (UHI). This was aimed at reaching the people below the poverty line. This so-called "Rupee-a-Day" insurance (the annual contribution is 365 Rupees per person) is, however, not very popular. On the one hand, it means a financial loss for the insurance company and is therefore hardly advertised. On the other hand, the annual contribution has to be paid in one sum, which families – and especially those with several children – often cannot afford..[14]

Public health care system

On the national level, the Ministry of Health and Family Welfare is the highest authority of the health care system. It is divided into two departments: the Department of Health and Family Welfare and the Department of Ayurvedic, Unani, Siddha and Homeopathic Medicines (AYUSH). The latter reflects the importance of traditional medical methods within the Indian health system and regulates, for example, any advertising for talismans and other magical products. The governments of the respective federal states are responsible for public health, for the sewage and waste disposal systems and for public hospitals. Medical training lies within the responsibilities of the central government in Delhi.[15]
Primary health care for all is the aim of the public health care system. Different public institutions are meant to ensure basic medical care. The first places to go for patients are generally the sub-centres (SC). These health centres are staffed by a male and a female health worker. They offer basic medical services and treat e.g. bronchitis, diarrhoea or injuries. They also examine pregnant women and babies

The majority of the Indians are poor. Hardly any can afford a private insurance. Frequently persons who fall seriously ill will have to highly indebt themselves to be able to compensate loss of income, visits to the doctor and necessary medication.

Photo: Andrea Czekanski

Examination of a pregnant woman in India – in the public health care system it is free of charge. *Photo WHO, P. Virot*

and counsel families in nutritional issues. Patients with severe illnesses are sent to the next Primary Health Centre (PHC) or directly to hospital. One sub-centre is provided for each 5,000 inhabitants.

For about 30,000 inhabitants there is one PHC. These centres are intended to ensure health care in rural areas. Each PHC has a medical head (doctor), two health care assistants, health workers and additional personnel. On the next level are the Community Health Centres (CHC) which provide health care for 80,000 to 120,000 inhabitants. In addition to the basic medical care, they also offer specialized care in general medicine, pediatrics, surgery, obstetrics and gynecology. These centres were set up in smaller hospitals or in health centres or even built anew. For further specialized examinations and treatments, the patients have to go to the district hospital (secondary sector). These hospitals provide for a population of 1 – 1,5 million people. In addition to these facilities, there are so-called dispensaries (state-funded pharmacies) and specialized clinics (tertiary sector).[16]

Long distances and not enough personnel

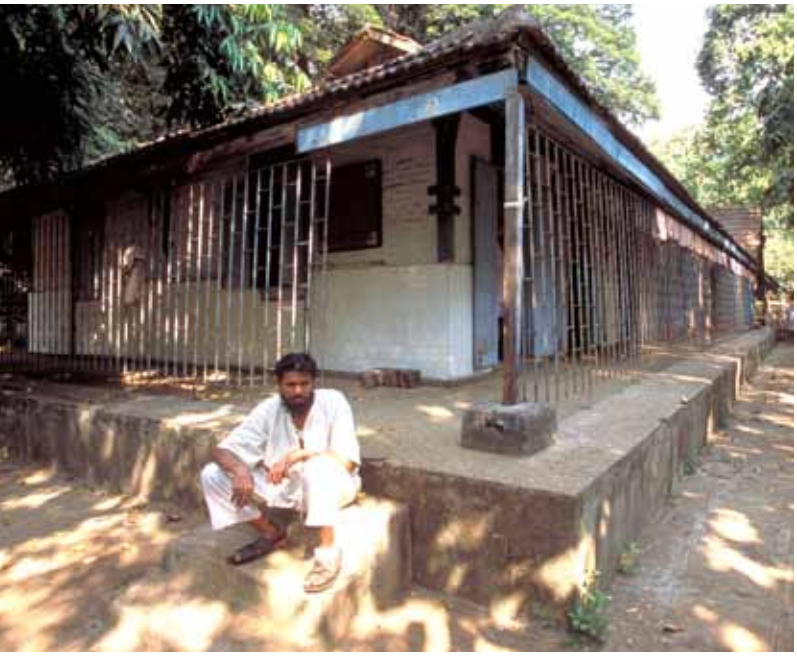
Although, the public health system has continually been improved since the 1950ies, there is still a lack of medical personnel in particular in rural areas. Even if they originally came from rural areas, qualified young Indians stay in cities, which are more attractive for them, or work in private institutions which pay higher wages. Whereas doctors earn about 20,000 Rupees per month in a public institution, private clinics pay up to 100,000 Rupees. Moreover, there is blatant lack of hospital beds . As a result of the long distances and the bad traffic connections, up to 25 percent of the population in Madhya Pradesh and Orisa do not have access to health care institutions.[18]

Luxury hospitals and self-appointed doctors

The public medical institutions are free-of-charge for the needy except for a small

Rural health care system in India[17]	
District Hospital	with many beds, doctors, specialists
Rural Community Health Centres for about 100,000 people;	30 beds each, 4 medical specialists
Rural Primary Health Centres for about 30,000 people;	one doctor, one male and one female health assistant each
Sub-Centres	for 5,000 people; one male and one female health worker each.

administrative fee of 5 Rupees which is charged in some federal states. In addition, there are private medical practices and hospitals and even luxurious private hospitals, but also numerous health care institutions and hospitals run by non-governmental organizations (NGOs) as well as by charity and church organizations. NGOs play an important role in health care for the poor: more than 7000 NGOs run a health care institutions and programs in India, many of them are of charitable character.[19] Christian institutions are often rooted in India's colonial past and were a part of missionary activities. Today, many of the Christian hospitals enjoy an excellent medical reputation and primarily provide services for the affluent middle classes. In contrast to the purely private institutions, they often also treat a certain number of poor patients free-of-charge or at a low fee.



A government-run leprosy hospital in Mumbai/India. Photo: WHO, P. Virot

Predominantly in cities many unregistered medical practitioners and healers offer their services. They practice various treatment methods from Ayurveda via homeopathy or Unani to mainstream medicine, but part of them do not have any medical training. For most poor patients, these unregistered practitioners are the first place to go. They are close by and cheap.

Each visit to the doctor has to be paid

Patients have to pay for each consultation of a doctor out of their own pockets. The government-funded primary health care does not cover ambulatory treatment by registered practitioners. The number of well-equipped registered medical practices is therefore low, however, it is steadily increasing as a result of a growing middle class and private health insurances which cover these services.

Poor accessibility, but above all the bad quality of the services provided in government-run institutions is an essential reason for many patients to avoid the public health care system. The majority of the rural and urban population prefer the health services of the private sector despite higher prices.[20] The National Family Health Survey (NFHS)[21] states exact figures: almost two thirds of all Indian households make use of the private health services and merely one third use public services. 46 percent of urban households and 36 percent of rural ones stated that they would seek out a private practice or a private hospital if they were seriously ill.[22]

This tendency has its price: to be able to pay for the high costs, about 40 percent of all Indians admitted as in-patients have to sell property or go in heavy debts.[23] Aditi Iyer, Research Consultant des Indian Institute of Management Bangalore, summarizes the results of research carried out in India in 2005: „[household] health expenses were the main reason for their economic decline."[24]

Private sector suppliers dominate

Private sector suppliers dominate health infrastructure in India. More than 80 percent of the ambulatory health services (without unregistered practitioners) and a somewhat lower proportion of the in–patient treatments are provided in private institutions.[25] The level of privately run hospitals (corporate hospitals) often equals the standard in industrial countries. Their range of services, however, is mostly focused on well-to-do city dwellers and, last but not least, on medical tourists who like to

A private hospital in Bangalore/India

Photo: Manipal at night. Wikimedia

go to ayurvedic luxury hospitals such as those in Kerala.

Many companies have their own health service institution which is reserved for their own employees and which also belong to the private sector. In addition there are special medical institutions for some professional groups of the public sector: e.g. the state-run railway has its own network of hospitals and pharmacies or the employees of the central government are eligible to the „Central Government Health Service Scheme". These institutions are run by the state but reserved for only these professional groups.

Thus India's health care finds itself in a dilemma today: on the one hand top health care is provided by highly qualified doctors, who are among the world's best. On the other hand, this is of little use to many patients since they cannot pay for it.

ASHWINI - an alternative insurance

A positive example for comprehensive and socially just health care is the Association for Health Welfare in the Nilgiris (ASHWINI). The story of ASHWINI began in 1986 with the foundation of ACCORD, an NGO which campaigns for the rights of the Adivasi, India's indigenous population. The Adivasi were driven into poverty mainly by land confiscation. In 1987 ACCORD initiated a village health program and founded ASHWINI. Today the project runs the self-managed Gudalur Adivasi hospital with 80 beds and eight sub-centres each with one barefoot doctor trained by them. In the villages, additional health care workers are engaged in health education, examine pregnant women and children, treat minor illnesses and transfer seriously ill patients to the next health centre or the hospital. ASHWINI's health institutions enjoy a good reputation as a result of their high quality standard and are therefore also consulted by non-Adivasi. The treatment in those health institutions costs less than in most private hospitals. It is not free of charge, but it doesn´t aim to make profits. In order for the project to be self-supporting and available to all Adivasi, ASHWINI arranged a group insurance with the New India Assurance. ASHWINI transfers the insurance contribution. The Adivasi pay a small annual fee for the family and can make use of all health care services free of charge. Families which do not pay the contribution are also treated free of charge, however, they have to pay for any medication themselves. Since ASHWINI receives all medication from the non-profit company LOCOST and only essential medicines are used, the prices are low.

This contributory insurance allows uncomplicated and effective help for the Adivasi in case of an illness and sustains the self-managed health institution. Furthermore, it is directed at the special needs of the Adivasi: anaemia, infectious diseases, tuberculosis, malnourishment, maternal care and the medical treatment of children. The AHSWINI concept guarantees excellent basic health care for poor people. Although it cannot be compared to the comprehensive services which are financed by our health insurances in Germany, it is an important step on the way to better health.[26]

The pharmaceutical market in India

Two ministries regulate the pharmaceutical market in India: the Ministry of Chemicals and Fertilizers (MCF) is responsible for pharmaceutical policies, regulating the industry and price control. Quality standards and control as well the licensing of new drugs lie within the responsibilities of the Ministry of Health and Family Welfare (MoHFW).

The Central Drugs Standard Control Organization (CDSCO) in New Delhi is responsible for the regulation of the pharmaceutical market, which reports to the Ministry of Health. The Drug Controller General of India (DCGI) works under its umbrella. This authority controls the pharmaceutical market and clinical trials, prepares quality standards and directives and is also responsible for drug approval.

Production of generics at the Indian manufacturer Cipla.
Photo: Christiane Fischer

Pharmacy for the world's poor: Indian generics

Up until the 1970ies, India was in effect dependent on the import of finished pharmaceutical products from multinational companies. This changed rapidly when the government introduced a process only patent law in 1974. From then on, Indian manufacturers were allowed to produce drugs which were protected by a product patent elsewhere. The company only had to use a different production process. A patent could then be granted on the production process. This legal situation and tax incentives and state subsidies resulted in an unprecedented growth of the pharmaceutical industry. Today there are about 17,000 pharmaceutical companies producing more than 40,000 drugs.

The most important line of business is the production of generics, i.e. the legal copying of branded products. India holds a share of about 20 percent in the worldwide production of generics. Indian manufacturers offer therapies against HIV/Aids, tuberculosis and malaria at revolutionarily low prices. That makes India the most important supplier for so-called developing countries. Large relieve organizations such as Médecins sans Frontières (MSF) are reliant on on Indian generics. Thus, 80 percent of the Aids drugs used by MSF worldwide originate from Indian production.[27]

Only real innovations are patented

In 2005, the legal situation changed. When entering the World Trade Organization (WTO) in 1994, India had to acknowledge the TRIPS agreement. It demands product patent protection of at least twenty years in all member states. India was granted a transitional period until 2005 in order to adapt its patent laws. Since then, product patents are anchored in law. However, not every new drug can be patented in India. Small changes in already existing products, so-called marginal innovations, are excluded from patentability according to Section 3d of the Indian patent law, unless they imply a therapeutic improvement.[28] As a result, many important Aids drugs, such as TDF or Lopinavir, are not protected by patents in India.

An interesting field of research: India offers an almost inexhaustible reservoir of test subjects. Many acute and chronic diseases are widely spread and many of the patients have never been treated with medication. *Photo: Andrea Czekanski*

Approval is not coupled with patent protection

Cipla is one of the largest pharmaceutical companies in India and the most important producer of low-cost Aids drugs. The name Cipla was reported in the German newspapers in connection with a law suit of the Bayer Corporation. The German corporation wanted to prevent the approval of a product imitating their cancer drug Nexavar® (Sorafenib). The Indian authorities (DCGI) had handled an application for approval by Cipla 11 years prior to the expiry of the patent protection. Different than in Europe and the USA, no data protection exists in India for the approval documents of patented preparations. Furthermore, the approval of a drug is not coupled to patent protection (patent linkage). Thus, Indian manufacturers of generics are allowed to imitate and produce patented products and export them to countries without the necessary patent protection. However, they are not allowed to sell such generics in India. The suit filed by Bayer against the approval of Cipla's Sorafenib was rejected in several instances. The Indian Supreme Court confirmed that there was no patent linkage in India.

Research is booming

Pharmaceutical research is likewise booming in India: in October 2008, 582 clinical trials were registered at the DCGI in India, 72 percent were carried out by pharmaceutical companies. The number of Contract Research Organizations (CRO), which handle the organization of clinical research, has doubled to 150 companies within a few years.[29] India is an advantageous field for international pharmaceutical companies in India. Carrying out a clinical study in India is about 50 percent cheaper than in Western industrialized countries. Moreover, the country offers well-equipped clinics, highly-qualified personnel and a large population in which many acute and also chronic diseases are widely spread.[30]

The Indian government massively supported this growth trend: in 2005 the drugs and cosmetics directive was supplemented in order to allow clinical trials of foreign sponsors. Since then, active agents can be tested in India, which were developed abroad (phase-2-studies). However, studies relating to the safety and tolerance of the active agent (phase 1) must already exist.

In addition to existing research results, the sponsor also has to supply documents relating to informed consent of the tested persons.

Legislation is lagging behind

Furthermore, pharmaceutical companies get tax advantages and may hope for a more speedy process of approval by national ethics committees in the future. The examination of the study design by an ethics committee was prescribed in 2005. However, these committees do not work satisfactorily.[31] They are not registered, do not work according to the same standards and their employees are not sufficiently trained. A new law prescribing the registration of the ethics committee and their examination by the drug approval authority DCGI, is to be passed in the near future. This would also penalize offences against ethical principles. In November 2010, the controlling authority DSCO furthermore introduced a control program for clinical trials and phrased new examination standards. Inspectors of this authority were trained by the US-American supervisory authority FDA.[32]

Ethical standards at the test

Clinical trials have to be viewed critically in the context of poverty and a lack of health care services. A participation in clinical trials offers the chance for a therapy for many poor people who would otherwise not be able to afford such without selling their property or taking on a credit. Sandhya Srinivasan, editor in chief of the Indian Journal of Medical Ethics, says: "In a country where 26 percent of participants are enrolling for clinical trials just so that they get free or quality healthcare, it is dangerous to allow contract research organizations easy access to patient databases and to offer medicos payment for recruiting patients in trials."[33]

An Indian survey on the informed consent of participants provides information on the problem: 76 percent of the patients recruited for the clinical study stated that their local physicians carried out the trial and 97 percent participated in the trial on their advice. If the physician in charge is also the principal investigator, there exists a conflict of interests.[34] Contract research organizations which are specialized in the recruitment of participants moreover set up databases with potential participants while making use of public or private databases or place advertisements in the media.

The number of fatalities in clinical trials, however, has continually increased in recent years. According to the information provided by the ministry of health, 462 people died in the first half of 2010. In 2007 there were 132 fatalities, in 2008 there were 288 and in 2009 637 people died.[35]

As early as 2006, the Dutch organizations WEMOS and SOMO published a compilation of 22 clinical trials ignoring ethical directives in poor countries. Eight of them had been carried out in India, among them trials of international corporations such as Johnson & Johnson and Pfizer and likewise the US-American John Hopkins University.[36]

Quality drugs at a low price

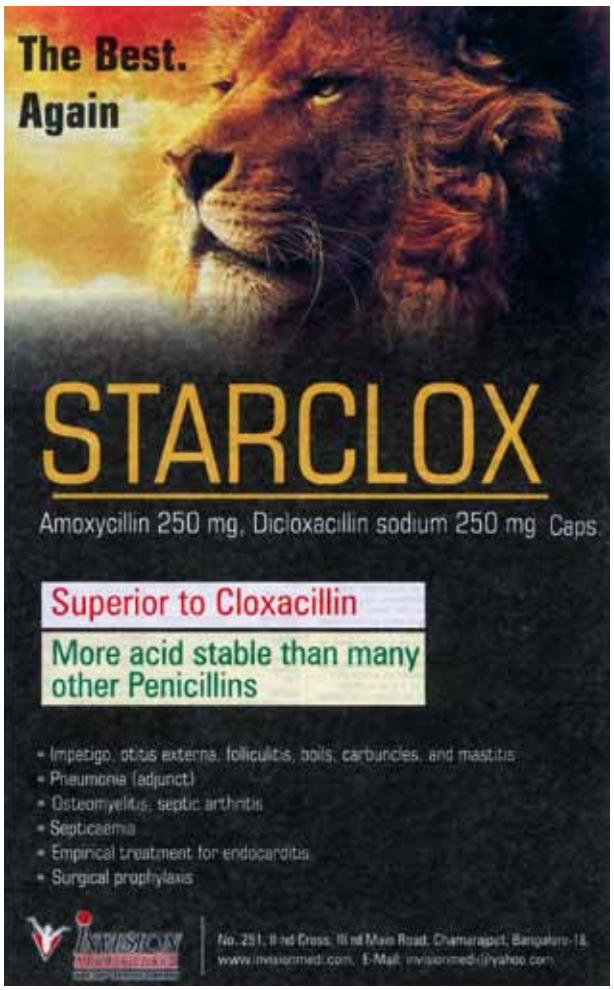
Low Cost Standard Therapeutics (LOCOST) is a positive example for the fact that drugs can also be produced without profit.[37]

The small non-profit company manufactures more than 60 essential drugs. LOCOST drugs only cost one fifth of the Indian prices and some even less. Their customers are mainly NGOs. LOCOST is also engaged in educational programs for end-users relating to health, disease and the rational use of medicines, and also in further training on the rational use of medicines in therapies for doctors.

The ASHWINI hospital described above also obtains its medicines from LOCOST.

Pharmaceutical advertizing

Pharmaceutical advertizing directed at laypersons is strictly regulated in India and forbidden with few exceptions. The Indian Law (Drugs and Cosmetics Act of 1940[38]) divides drugs into different groups. Only those drugs



Dubicus information directed at doctors: an Indian company promotes the antibiotic Amoxycillin in the Indian Compendium of Medicines CIMS.

falling under the so-called "schedule K" may be advertized in public. These include the typical medicines of any families' medicine cabinet, such as Paracetamol or ASS. Ayurveda, Unani and Siddha medicines and homeopathic products may also be advertised as a rule. The Drugs and Magic Remedies Advertisement Act of 1954[39], however, lists diseases and incidents (e.g. appendicitis, epilepsies, fever, high blood pressure, Aids, miscarriages) for which advertising is principally not admissible. Campaigns for health care education for example in the field of family planning, hygiene or pain is permitted provided the name of the medical drug is not mentioned. [40]

Doctors open to bribery

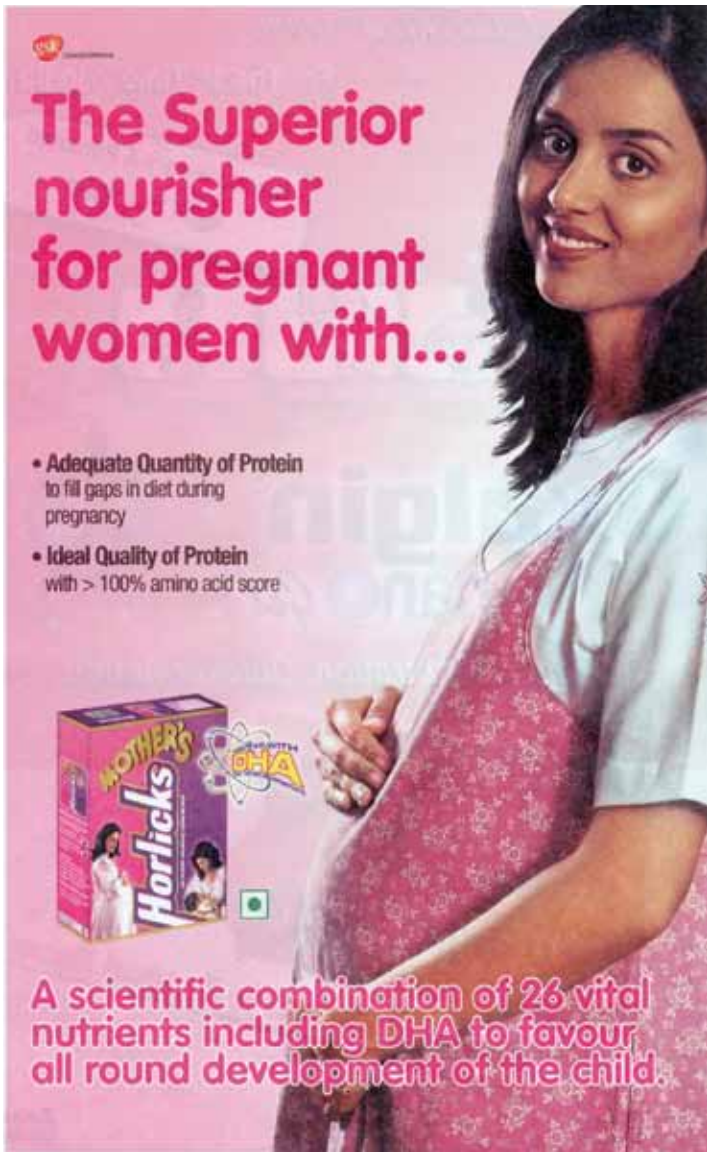
Since public pharmaceutical advertizing is largely prohibited in India, the companies are particulary dependent on the prescription practice of doctors. The companies employ a large number of medical representatives who visit doctors' surgeries and clinics. To work as a medical representative is a desirable position in India, says Dr. Roopa Devadasan of the Institute of Public Health (IPH) in Bangalore: "Medical representatives meet important people, they are well-dressed and carry black briefcases – all of which is seen as status symbols in India."[41] The favor of medical practitioners is not rarely bought with presents, invitations or some days spent at a hotel.[42]

Chandra M. Gulhati of the Monthly Index of Medical Specialty India (MIMS) speaks about such forms of corruption in an open manner: "The commercial needs of innumerable, fiercely competing pharmaceutical companies has led them to depend on the tried and tested 3Cs: convince, if possible, confuse, if necessary, and corrupt, if nothing else works.[43]

The company GlaxoSmithKline promotes a superfluous nutrional supplement for pregnant women. Advertisement in the Indian Compendium of Medicines CIMS.

In India there is no legally binding regulation controlling promotion directed at doctors. The Medical Council of India (MCI), the professional representation of the medical profession, had indeed prepared a code of ethics; however, it was considered largely ineffective. In March 2010, leading member of the MCI were arrested as a result of accusations of corruption, in

Videos by the National Rural Health Mission vehemently propagate the pill for family planning.



GlaxoSmith Kline advertizes a useless nutritional supplement for pregnant women in the Indian drug list CIMS.

May the organization was dissolved by the government. The strict code rather served as an ethical fig leaf to prevent the dissolution of the MCI, speculated the Indian Journal of Medical Ethics in an editorial.[44]

Modest presents

The lobby of the pharmaceutical industry (Organization of Pharmaceutical Producers of India/OPPI) likewise imposed a self-commitment which is not legally binding. It promises therein not to pay for extensive travels including families, shopping trips or similar pleasures; but to keep promotional gifts "modest in value". A vague phrase which leaves ample room.[45]
As is the case in the European Union, the lobby of the Indian pharmaceutical industry tries very hard to achieve a relaxation in the ban on advertising.[46] In future, they intend to promote prescription drugs not only among doctors but also among laymen. This is based on the model of the liberal pharmaceutical markets of New Zealand and the USA. The industry argues that advertising directed at laypersons supports patient information. "DTC prescription drug advertisement will create a new generation of informed patients. Hence DTC advertising (...) will create a healthier India."[47]
The argument that pharmaceutical advertising benefits health care in India may be doubted. Quality health care information and advertising are rather different things.

The companies examined

Bayer HealthCare

The company Bayer AG, together with its group Bayer HealthCare, counts among the big fish in the pharmaceutical pond. The company markets its pharmaceutical products in more than 100 countries and achieved a turnover of roughly 10.5 billion Euros in 2009.[48]

About 15-17 percent thereof are invested in research and development.[49] Science for a better life – that is the corporation's motto.

In India, Bayer HealthCare is active in Bayer Schering Pharma, Diabetes Health Care and Animal Health. The latter field of business was not examined.

Bayer wishes to significantly expand its business in the growing market of India. The corporation expects a turnover or roughly one billion Euros by 2015; which so far has been 400 million. However, only five percent of the company's turnover in India originate from the pharmaceutical field of business. As a result, Bayer counts on acquisition of and cooperation with other companies in future. [50]

Likewise, the most recent spin-off of a new marketing and sales company as a joint venture with the Indian company Zydus Cadila is directed at strengthening Bayer's presence in India.[51]

Bayer's contraceptive pills Yazâ, Yasminâ and Yasminelleâ (drospirenone and ethinylestradiol) are the company's blockbusters with a turnover of 1.2 billion Euros (2008) worldwide. Yasminâ is also sold in India. In the third place of their bestsellers is the cardiac preparation Adalatâ (nifedipine) (626 million Euro) and in the tenth place is the preparation for lowering the blood sugar level Glucobayâ (Acarbose) (304 million Euros), which are both sold in India as well.[52]

Boehringer Ingelheim

The German family business Boehringer Ingelheim researches and produces human and animal pharmaceuticals. In 2009 the company generated a turnover of 12,721 billion Euros worldwide. Of this, 17.4 percent were re-invested into research and development. The company wants to focus on the development of advanced pharmaceuticals which allow a better medical care for patients. "Value through innovation" – that is the company's motto.[53]

The proportion of their turnover that Boehringer Ingelheim generates in the field of prescription drugs, is larger by far. Among them are various drugs against cardio-vascular diseases such as Micardisâ (telmisartan), which is i.a. also sold in India, but also drugs against high blood pressure or HIV/Aids. The drug Micardisâ for the treatment of essential high blood pressure generated proceeds of 1,123 million Euros and a growth of about 23 percent in local currency in the year 2007. Aggrenoxâ (dipyridamole/ASS), a drug for the secondary prevention of apoplexies, which is likewise sold in India, generated proceeds of 278 million Euros.[54]

Boehringer Ingelheim also plan to expand their activities in India. Thus, the company presently supports their Indian sub-contractor Kemwell in constructing a biopharmaceutical production site in Bangalore, India, by providing them with bio-technological know-how.[55]

Boehringer Ingelheim only has about 20 employees in India. Compared to US-corporations such as Pfizer or GlaxoSmithKline, who employ 2,000 or 3,500 Indians, respectively, this is precious little. "We started off too late", summarize the company's representatives to the Pharma-Kampagne.[56] As late as 2005, Boehringer Ingelheim founded an Indian subsidy in Mumbai. "We have created a small, but adequate marketing and supply chain network", says Jürgen Beck, Boehringer Ingelheim's manager in India. The cooperation with the local partner Zydus Cadila in the fields of marketing and sales should furthermore allow the complete portfolio of the German company to be offered in India. [57]

Baxter

Baxter International Inc. develops, produces and markets bio-technologically produced drugs and vaccines which are obtained from blood plasma. The company's portfolio comprises in particular drugs for the treatment of hemophilia, immune-deficiencies, infectious diseases, cancer and renal damage. Moreover, Baxter is the world´s largest manufacturer of infusion solutions and systems for intravenous administrations. Baxter's products for artificial nutrition and infusion systems were not considered in this study.

The company offers its products in more than 100 countries. Baxter produces in 27 countries and operates three production sites in India, one in Manesar, Haryana, one in Waluj, Maharashtra and another one in Alathur, Tamil Nadu with altogether about 700 employees. The plants produce for the Indian market as well as for export. [58]

Baxter's global turnover amounted to roughly 12.6 billion US-Dollars in 2009. According to their own information, the company invested 917 million US-Dollars in research and development in 2009, that corresponds to 7.3 percent of the net turnover.[59]

The best-selling product is Advate®, a blood substitute produced by recombinant technology for the treatment of hemophilia, which generated sales proceeds worldwide of more than 1.7 billion US-Dollars in 2009. The drug is also sold in India under the name Recombinate®.[60]

According to Baxter, the company accepts social responsibility through the Baxter International Foundation and a sustainable business ethics upon which their employees act worldwide.[61]

Endnotes

1 WHO (2008) World Health Statistics. http://www.who.int/countries/ind/en/ (1.3.2011)
WHO (2010) National Health Accounts (NHA). India: National Expenditure on Health. http://www.who.int/nha/country/ind/en/ (15.9.2010)
WHO (2006) Country Cooperation Strategy at a glance. http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_ind_en.pdf (1.3.2011)
2 Gandhi MK (2008) The Essential Writings. Oxford: University Press
3 Ram Murthy S, HA, June 2006, 8 Health Care Today, p 61
4 UNDP (2010) Human Development Report; http://hdr.undp.org/en/ (am 4.3.11)
5 Lacking healthcare, a million Indians die every year. http://economictimes.indiatimes.com/Healthcare/Lacking_healthcare_a_million_Indians_die_every_year_Oxford_University/articleshow/4066183.cms (4.10.2010)
6 WHO (2010) National Health Accounts (NHA). India: National Expenditure on Health. http://www.who.int/nha/country/ind/en/ (15.9.2010)
7 National Family Health Survey (2006). http://www.nfhsindia.org/nfhs3.html (24.9.2010)
WHO (2010) World Health Statistics. http://www.who.int/whosis/whostat/2010/en/index.html (24.9.2010)
8 Grosse-Tebbe, Deshpande (2002) Indien. Private Dienstleister als Stütze des Gesundheitssystems. In: Andersen, DEG, F.A.Z.-Institut, GTZ, manager magazin (Hrsg) Gesundheitswesen – Perspektiven für private Unternehmen. Frankfurt
9 WHO (2010) National Health Accounts (NHA). India: National Expenditure on Health. http://www.who.int/nha/country/ind/en/ (15.9.2010)
10 Boston Analytics (2009) Health Care in India. Report Highlights, Boston Massachusetts/USA
11 Duggal R (2005) The out-of-pocket burden of healthcare. Agenda: access to public health. Pune, India: Centre for Communication and Development Studies, p 20-25
12 Grosse-Tebbe, Deshpande (2002) Indien. Private Dienstleister als Stütze des Gesundheitssystems. In: Andersen, DEG, F.A.Z.-Institut, GTZ, manager magazin (Hrsg) Gesundheitswesen – Perspektiven für private Unternehmen. Frankfurt
13 Boston Analytics (2009) Health Care in India. Report Highlights. Boston Massachusetts/USA
14 Bearing Point, Inc. (2008) Private Health Insurance in India. Promise and Reality. Hrsg. im Auftrag der United States Agency for International Development
15 WHO/SEARO (2007) Country Health System Profile India, http://www.searo.who.int/en/Section313/Section1519.htm (6.3.11)
16 Grosse-Tebbe, Deshpande (2002) Indien. Private Dienstleister als Stütze des Gesundheitssystems. In: Andersen, DEG, F.A.Z.-Institut, GTZ, manager magazin (Hrsg) Gesundheitswesen – Perspektiven für private Unternehmen. Frankfurt
17 WHO/SEARO (2007) Country Health System Profile India http://www.searo.who.int/en/Section313/Section1519.htm (6.3.11)
18 WHO/SEARO (2007) Country Health System Profile India http://www.searo.who.int/en/Section313/Section1519.htm (6.3.11)
19 Boston Analytics (2009) Health Care in India. Report Highlights, Boston Massachusetts/USA
20 Bearing Point, Inc. (2008) Private Health Insurance in India. Promise and Reality. Hrsg. im Auftrag der United States Agency for International Development;
WHO/SEARO (2007) Country Health System Profile India http://www.searo.who.int/en/Section313/Section1519.htm (6.3.11)
21 The National Family Health Survey (NFHS) is published by the Ministry of Health and Family Welfare (MoHFW). The study presents data on national health indicators in rural and urban areas, e.g. information on fertility, mortality, mother and child health risk behavior, HIV prevalence.
22 International Institute for Population Sciences (IIPS) and Macro International (2007) National Family Health Survey (NFHS-3). India: Volume I. Mumbai: IIPS
23 WHO/SEARO (2007) Country Health System Profile India http://www.searo.who.int/en/Section313/Section1519.htm (6.3.11)
24 Iyer A (2005) Ill and impoverished. The medical poverty trap. http://infochangeindia.org/20050614404/Agenda/Access-Denied/Ill-and-impoverished-The-medical-poverty-trap.html (20.9.2010)
25 Srinivasan S (o.J.) Health: Background and Perspective. http://infochangeindia.org/200210045930/Health/Backgrounder/Health-Background-Perspective.html (21.9.2010)
26 http://www.ashwini.org/ (1.3.2011)
http://www.adivasi.net/ (1.3.2011)
27 MSF Letter to EC Trade Commissioner on EU-India FTA, 6.4.10
28 The Patents (Amendment) Act. http://www.ipindia.nic.in/ipr/patent/patent_2005.pdf (1.3.2011)
29 Srinivasan S (2009) Trial by fire. http://infochangeindia.org/200909177947/Health/Analysis/Trial-by-fire.html (1.3.2011)
30 SOMO (Hrsg) (2011) Putting Contract Research Organisations on the Radar. An exploratory study on outsourcing of clinical trials by pharmaceutical companies to contract research organizations, p 49
http://somo.nl/publications-en/Publication_3615/view (6.3.11)
31 Sengupta A (2009) Fatal Trials. clinical trials are killing people. Indian J Med Ethics; Vol. 6, No. 3
32 SOMO (Hrsg) (2011) Putting Contract Research Organisations on the Radar. An exploratory study on outsourcing of clinical trials by pharmaceutical companies to contract research organizations, p 53
http://somo.nl/publications-en/Publication_3615/view (3.6.11)
33 Srinivasan S (2009) Trial by fire. http://infochangeindia.org/200909177947/Health/Analysis/Trial-by-fire.html (1.3.2011)
Srinivasan S (2009) Ethical concerns in clinical trials in India. An investigation. Mumbai: Centre for Studies in Ethics and Rights
SOMO (Hrsg) (2011) Putting Contract Research Organisations on the Radar. An exploratory study on outsourcing of clinical trials by pharmaceutical companies to contract research organizations, p.50
http://somo.nl/publications-en/Publication_3615/view (6.3.11)
34 Srinivasan S (2009) Trial by fire. http://infochangeindia.org/200909177947/Health/Analysis/Trial-by-fire.html (1.3.2011)
35 462 deaths related to testing of experimental drugs on patients in India till mid-2010 alone show health ministry figures. http://www.dancewithshadows.com/pillscribe/462-deaths-related-to-testing-of-experimental-drugs-on-patients-in-india-till-mid-2010-alone-show-health-ministry-figures/ (1.3.2011)
36 SOMO (2006) Briefing paper on ehtics in clinical trials. Examples of unethical trials. http://www.wemos.nl/Eng/publications_2006_examples_of_unethical_trials_2006.htm (1.3.2011)
37 http://www.locostindia.com/ (1.3.2011)
38 Drugs and Cosmetics Act. http://www.medindia.net/indian_health_act/drugs_and_cosmetics_act_1940/list-of-acts.htm (1.3.2011)
39 The Drugs and Magic Remedies (Objectionable Advertisements) Act. http://www.medindia.net/indian_health_act/the-drugs-and-magic-remedies-act-1955.htm (1.3.2011)
40 Mack J: High time to permit Pharma DTC in India? 18.4.2007 In: Pharma Marketing Network Forums
http://www.forums.pharma-mkting.com/showthread.php?t=380
41 Conversation in december 2010
42 Mahajan V (2010) White coated corruption. Indian J Med Ethics; Vol. 7, No. 1
43 Gulhati C (2004) Marketing of medicines in India. BMJ; 328 (7443), p778-9
44 Thomas G (2010) Gifts to doctors, scientific information and the credibility gap in the medical council of India. Indian J Med Ethics; Vol. 7, No. 2
45 Chiplunkar S (2009) DTC advertising prescription drugs. http://www.pharmabiz.com/article/detnews.asp?articleid=48300&sectionid=46 (1.3.2011)
46 EU-Kommission will Werbeverbot für rezeptpflichtige Medikamente lockern. http://www.aerztezeitung.de/politik_gesellschaft/arzneimittelpolitik/article/525903/eu-kommission-will-werbeverbot-rezeptpflichtige-medikamente-lockern.html (1.3.2011)
Direct to Consumer (DTC) Advertising in Pharmaceuticals – Current and Future Market Outlook. http://www.indiaprline.com/2009/12/05/direct-to-consumer-dtc-advertising-in-pharmaceuticals-current-and-future-market-outlook/ (1.3.2011)
47 Chiplunkar S (2009) DTC advertising prescription drugs. http://www.pharmabiz.com/article/detnews.asp?articleid=48300&sectionid=46 (1.3.2011)
48 http://www.bayerscheringpharma.de/de/unternehmen/ueber_uns/unternehmensprofil/index.php (1.3.2011)
49 Wild H (2008) Bayer Schering Pharma´s Approach to R&D. Internal and external sourcing of innovation. Bayer Schering Pharma. Vortrag beim India Pharma Summit 2009, Mumbai
50 Bayer peilt Milliardenumsatz in Indien an. In: CHEManager-online.com,24.1.2011 http://www.chemanager-online.com/ (24.1.2011)
Knop C, Koch B: In Schwellenländern gibt es Verbesserungsbedarf. Im Gespräch: Bayer Chef Marijn Dekkers. In: Faz.net, 26.1.2011
http://www.faz.net/s/homepage.html (26.1.2011)
51 Bayer stärkt Pharmageschäft in Indien durch Joint Venture mit Zydus Cadila. http://www.investor.bayer.de/news/investor-news/investor-news/showNewsItem/1250/1296576540/3df703b226/ (28.1.2011)
52 Wild H (2008) Bayer Schering Pharma´s Approach to R&D. Internal and external sourcing of innovation. Bayer Schering Pharma, Vortrag beim India Pharma Summit 2009, Mumbai
53 http://www.boehringer-ingelheim.de/unternehmensprofil.html (1.3.2011)
54 Boehringer Ingelheim wächst 2007 wieder schneller als der Markt. Spiriva®, Micardis® und Flomax® die größten Produkte. http://derstandard.at/3293993 (1.3.2011)
55 http://www.kemwellpharma.com/ (1.3.2011)
56 Gespräch in Ingelheim im Dezember 2010
57 Boehringer Ingelheim Finally Increases Presence. http://www.pharmaceuticals-insight.com/file/68790/boehringer-ingelheim-finally-increases-presence.html (1.3.2011)
58 http://www.baxter.in (1.3.2011)
59 Business report of Baxter International Inc. http://www.baxter.com/investors/reports_and_financials/annual_report.html (1.3.2011)
60 Vectura: Annual Reports and Accounts 2009/10. http://ar10.vectura.com/business_review/products/ (1.3.2011)
Baxter Achieves Record Sales, Earnings and Cash Flow for Full-year 2009. Presseerklärung 28.1.2010 http://www.baxter.com/press_room/press_releases/2010/01_28_10-yearendearnings.html (28.2.2011)
61 http://www.baxter.de/ueber_baxter/unternehmen/gesell_verantwortung/index.html (28.2.2011)

II Methods of the trial

The present study evaluates the business behavior of the pharmaceutical companies Boehringer Ingelheim, Bayer HealthCare and Baxter in India. All three companies do not only possess large market shares in Germany, they also show considerable business activities in India. Moreover, with Bayer and Boehringer Ingelheim, two German companies were selected.

The evaluation of the business practices was based on the Declaration of Human Rights of the United Nations, the Helsinki Declaration of the World Medical Association as well as the companies' own Corporate Social Responsibility Codices. All data were collected by the Institute of Public Health (IPH) in Bangalore in India. The institute is a tantamount project partner and was included in the development of the study design as well as in the processing and distribution of the results.

Why India?

India is the main exporter of low-priced generics into poor countries. Thus, the country holds a particular significance in the global supply of medicines. Aspiring Indian companies increasingly produce for a global market whereas international pharmaceutical corporations often outsource their research activities and production sites to India. Whether Indian patients profit from this globalization process is an open question a first answer to which is given by this study. It examines the effects of the business behavior of international pharmaceutical companies on Indian patients. Which effects do the business practices and also research efforts of Bayer HealthCare, Baxter and Boehringer Ingelheim have on the access to and availability of essential drugs?

Roughly 80 percent of the drugs used in Africa for the treatment of Aids are Indian generics. *Photo: WHO, Eric Miller*

Methods

The study presents results from quantitative and qualitative methods and this increases their validity and reliability. The quantitative surveys (direct data collection and literature research) provide figures and facts on the amount of the branded medicines available, the proportion of rational and irrational products in the company's portfolio, the price of the pharmaceuticals offered and as regards clinical trials of relevant manufacturers. Semi-structured interviews were used as a qualitative method for determining personal consequences of the business behavior for doctors, pharmacists and patients.

The data were predominantly collected in India and compared to the companies' own information. In addition, internet databases, such as MIMS India[1] or also the official US-register of clinical trials[2] were used. All three companies had been informed of the study beforehand and asked for statements as well as for relevant documents.

Aims and background of the semi-structured interviews

In order to gain a deeper understanding of the matter beyond figures and facts, semi-structured interviews were held in the federal states of Karnataka and Tamil Nadu. An open questionnaire served as a conversation guide.
6 doctors, 6 pharmacists and 6 patients (3 poor and 3 well-to-do) from the public, private and NGO sectors were interviewed, and in addition one representative of a company. Strict confidentiality was guaranteed and the interviews were recorded directly afterwards from memory. This method made it possible to record relevant information in condensed form. At the same time, the fact that no sound storage medium was used represented an important prerequisite to gain the interviewees' trust and to guarantee their anonymity. In addition to English, the interviewer also spoke Kannada and Tamil so that no information was lost in translation. The patients were interviewed at their homes since their living conditions also supplied important background information on their economic situation.
The condensed statements of the interviews were interpreted with a thematic text analysis. Important topics were worked out and included in the discussion of the quantitative results of the study. Here, they served as supplementary information but do not claim to be generally valid.

Limitations

The collection of data only refers to medicinal drugs which are available in India and to clinical trials carried out by Bayer Schering, Baxter or Boehringer Ingelheim in India now or at the time of data collection, and which were listed in freely accessible databases and/or in information provided by the company. The data collection took place from January to November 2010, some interviews, however, were carried out as late as January 2011.

The collection of data

All data questionnaires and interview guidelines, relating to the study can be inspected at the BUKO Pharma-Kampagne.

1. Which of the companies' own drugs were on the market in January 2010?

In India, there are two important pharmaceutical compendia: Monthly Index of Medical Specialties India (MIMS) is only available in book form, whereas the Current Index of Medical Specialties (CIMS) is available as a print and as an online version[4].
All three are not identical, not even the CIMS print and its online version. In addition, there are many medical drugs on the market which are listed in none of these reference books. For this reason, we carried out research in Indian pharmacies (hospital pharmacies and free pharmacies) in order to supplement or confirm our data, respectively. To obtain a picture as complete as possible, all companies were asked to check our lists of products. Only Baxter denied any information and comments.

The following information was collected in an access database:

- Name of the manufacturer
- Dosage, type of application, packaging size, generic name, brand-name
- Is the drug essential (comparison with the WHO list)? We discarded the national Indian list because it was too old and experts deemed it to be of inferior quality so that the definition is mostly taken from the WHO list.
- Is the drug rational or irrational?
- Price in Indian Rupees
- Availability via the public health system in Tamil Nadu and Karnataka
- Patent status of the drug in India
- Is it an innovation (later than 1995 on the Indian market)?
- Is the drug declared to be an essential innovation?

Do the poor in India have access to the preparations of Boehringer Ingelheim, Bayer and Baxter? *Photo: Andrea Czekanski*

2. Which drugs are essential?

To research this, the Model list of essential medicines of the WHO of 2010 was used.[65] The list contains about 350 active agents which are essential for health care. The drugs are listed under their international non-proprietary name (INN). We have marked each drug present on the WHO list as essential (e).

3. How good is the portfolio of the companies?

Medicinal drugs which are not essential may still be safe, harmless and of medicinal use. In order to be able to evaluate the respective company portfolio in regard to its quality, i.e. the efficacy and safety as well as the medicinal use, each pharmaceutical was evaluated by pharmacologists. All drugs underwent a uniform evaluation process and were examined on the basis of clinical-pharmacological criteria. Pharmaceuticals which are effective and harmless according to current scientific knowledge, were graded as rational (r), the rest as irrational (i).

Our evaluation used the scientific criteria for rational drug therapy, which are based on clinical evidence. The pharmaceutical industry claims that their products suffice these criteria. In the evaluation process, the drugs were divided into two main groups and several sub-groups. The two main groups separate positive (r) from negative (i) drugs. The respective sub-groups state the most important reason for the classification (see illustration below).

We have tried to make each decision on the basis of the acknowledged international specialist literature that provides reliable information on the current state of the international scientific discussion. However, we are conscious of the fact that both objective facts as well as subjective values enter into the evaluation. Nevertheless, on the basis of the clearly defined evaluation criteria of the study, a good insight into the quality of the examined drugs can be achieved.

The evaluation process which eventually resulted in the classification into positive and negative drugs is documented by the following "decision diagram". Each drug was subjected to each of the individual evaluation issues in turn. If the examination relating to one criterion resulted in a negative evaluation, the drug was sorted into the corresponding evaluation group and no further criteria were examined.

Classification of the drugs in accordance to the grounds for evaluation

Positive	**Drug of first choice**	Drugs of proven efficacy and an adequate risk-benefit-ratio, which represent the best treatment for most patients in specific fields of application.
	Drug of other choice	Products for a smaller number of patients not profiting from a first-choice medicinal product. The risk-benefit-ratio is often more unfavorable than for the drugs of first choice.
	Drugs for specialists	Drugs the use of which necessitates particular prerequisites, e.g. a special diagnostic, apparatus or special therapeutic experience. If they are used without control, they bear a high potential risk (e.g. anti-cancer drugs).
Negative	**Irrational combination**	Combinations of different active agents are principally problematic since the interaction of the single substances and desirable and undesirable effects cannot be calculated. Different substances moreover have different profiles as regards bio-availability and pharmacokinetics: one substance is often more rapidly reabsorbed or decomposed than the other. In addition, the dosage of one of the active agents cannot be individually adapted without changing the dosage of all other substances as well. It is not only the desired effects of the medicinal agents, which are combined, but also their side effects and risks. Combination preparations are evaluated as irrational if they contain more than three active agents, if they contain an ineffective or incorrectly dosed active agent, or if the active agents have mutually exclusive efficacy profiles.
	Ineffective drugs	Drugs the efficacy of which could not be proven although several trials have been carried out.
	Controversial effectiveness	Controversial information has been given on these drugs. As long as no unequivocal data are provided, these drugs should not be used but be replaced with a reliable drug.
	Insufficient testing	This drug has not been tested sufficiently and should be replaced by a better tried and proven drug.
	Alternative with fewer risks available	Although these drugs are effective, they also include a higher risk than others and thus a worse risk-benefit ratio than alternative products.
	More effective alternative available	It is not justified to use drugs which are less effective than alternative products. Patients have the right to receive the most effective medicine.
	Wrong amount of active agent	These medicinal products contain active agents in an amount that is either too large or too small. They should therefore not be used.
	Wrong form of dosage	Medical drugs must be applied in a suitable form of dosage to be effective and harmless. There are substances which are more dangerous as an injection than in tablet form. E.g. if a drug has to be taken at varying intervals, a time-release capsule is not a suitable form of dosage.

4. Price and availability

Prices and availability were determined on the basis of the established WHO/HAI methodology.[5] A selection of 63 medical drugs was examined in 5 institutions of the public, private and NGO sectors each in both federal states (together 30 institutions). The prices were recorded in Indian Rupees, but they can be converted into international Dollars (Purchasing Power Parity, PPP) in order to allow comparisons between countries.

Moreover, we examined whether essential drugs were listed in the medicine list of the federal states of Karnataka and Tamil Nadu and whether their prices were affordable for the poor.

5. Which of the companies' innovations are on the market?

Which innovative medical drugs of Bayer Schering, Baxter and Boehringer Ingelheim have entered the Indian market since 1995? (Medical drugs which had already been on the Indian market before 1995 cannot be patented.)
Information was provided by the companies' websites, correspondence with the companies and with the Lawyers Collective in Bangalore. All medical drugs listed on the WHO model list were classified as vital innovations.
Information on the patent status was obtained from the following sources:

http://india.bigpatents.org
https://www.ipindiaonline.gov.in/patentpublishedSearch/(S(v43jii55g01iz55r01541eh))/patentwebSearch.aspx (database relating to patent applications)
http://ipindia.nic.in/patsea.htm (database relating to granted patents)

6. How good is the health care of the poor?

Interviews with doctors (public, private, NGO sectors) and poor patients are to give information whether sick people without means have access to necessary therapies. Are the prescription patterns of doctors different in case of poor or rich patients? Those persons were considered poor, who saw themselves as poor and who were considered poor by the interviewer. So-called proxy indicators (gas instead of kerosene, television set) were additionally consulted.

7. Which research projects are pursued by the companies in India?

We have determined the research activities of the companies by public databases[6] as well as by correspondence with the companies, their websites and by correspondence with the Indian ministry of research. Our particular interest was focused on the question whether neglected diseases such as TB, malaria, chikungunya or dengue fever, or other diseases common in India, such as pneumonia, bronchitis, diarrhoea and HIV, were part of the research portfolio of those companies. And if so, how large is their proportion in the overall research spectrum?

8. General business behavior of the three companies

The marketing behavior of Bayer, Baxter and Boehringer Ingelheim was determined in three areas:

Advertisement
Promotional practices were determined by actual examples of product advertizing. The sources of information were educational, promotional and information material for doctors and students, moreover press articles as well as written correspondence and interviews with companies, doctors and ministries.

Partnerships
Furthermore, so-called partnership projects of the companies (e.g. with the Indian government or Indian patient groups) as well as donation and health programs were examined. Sources of information were correspondence and interviews with companies, doctors and government authorities, which are responsible for possible programs and, in addition, company websites and literature research.

Disease awareness
Other important marketing strategies were also examined, such as disease awareness campaigns or the sponsoring of public events and of patient groups. As sources of information we used semi-structured interviews with doctors (public, private and NGO sectors), companies and health ministries as well as the companies' websites and correspondence with the companies.

Endnotes

1 *Clinical Trials Registry India - National Institute of Medical Statistics. http://www.ctri.in/Clinicaltrials/index.jsp (1.3.2011)*
2 *Clinical Trials - U.S. National Institutes of Health. http://clinicaltrials.gov/ (1.3.2011)*
3 *Current Index of Medical Specialities. http://www.cimsasia.com/ (1.3.2011)*
4 *WHO: Essential medicines. http://www.who.int/topics/essential_medicines/en/index.html (1.3.2011)*
5 *HAI: Medicine Prices, Availability, Affordability and Price Components. http://www.haiweb.org/medicineprices/manual/documents.html (1.3.2011)*
6 *Indisches Verzeichnis http://www.ctri.in/Clinicaltrials/index.jsp, US-Verzeichnis http://clinicaltrials.gov/*

III Study results

1. The product portfolio of the companies

Together Bayer Schering Pharma, Baxter and Boehringer Ingelheim sell 90 active agents in 184 different pharmaceutical dosage forms. For historical reasons, the companies market part of their products through the company Zydus Cadila/German Remedies. Prior to 1995, foreign manufacturers were only allowed to offer drugs to a restricted extent. Thus, a number of German companies founded German Remedies as an Indian subcontractor, who has partially marketed their products until today.

Boehringer Ingelheim

The product portfolio:
13 different preparations in 27 different forms of dosage and formulations. None of these drugs are essential, 8 (30%) are rational and 19 (70%) are irrational.

Rational and irrational drugs:
Three of the products which were evaluated as **rational** are low-priced, long-standing preparations: bisacodyl (Dulcolax®) is a medication against constipation, clonidine (Catapres®) is used against high blood pressure which cannot be controlled otherwise. Hyoscine butylbromide (Buscopan®) acts against abdominal cramps and also in case of colics; however, it has only been verified as active in ampoules.
Alteplase (Actilyse®) is likewise rational but costly and is verified to be active in case of an acute cardiac attack. However, 1 ampoule of 50 mg costs 37,500 Rs and would thus even blow the budget of the middle classes. The price exceeds the average monthly income of most Indians. In comparison: a teacher earns between 10,000 and 20,000 Rs per month, a domestic about 3,000 – 10,000 Rs.

Irrational: Some irrational formulations of rational products were evaluated, such as **hyoscine butylbromide** (Buscopan®) in the form of tablets or **hyoscine butylbromide** in combination with paracetamole (Buscopan plus®). Likewise the combination of clonidine and chlorothalidone (Catapres DIU®) had to be devalued as irrational. Persantine®, Alupent® und Metalyse® are also irrational, but low-priced.
Dipyridamole (Persantin®) is no longer admitted in Germany as a mono-preparation, but only in combination with the blood dilutor aspirin (Aggrenox®) for the treatment of strokes. However, Aggrenox® is expensive in India.
Orciprenaline sulphate (Alupent®) is a medication for asthma which is considered out of date.
The cardiac mexiletine hydrochloride (Mexitil®) is no longer on the market in Germany. According to Boehringer Ingelheim, they do not intend to offer the drug in India any longer.[1] At present, however, stocks are still being sold out in Indian pharmacies.
The bestseller telmisartane (Micardis®) was also devalued. According to the professional journal „arznei-telegramm“ *(drug telegram)*, the drug does not prevent cardiovascular events any better than a placebo, irrespective of its clear hypotensive effect.[2] The drug is furthermore considerably more expensive than comparable therapies.
Tenecteplase (Metalyse®) is used in case of a heart attack like alteplase (Actilyse®). With its 28,000 Rs per ampoul, it costs twice as much without offering a therapeutic advantage.
With only 27 different forms of dosage and formulation, Boehringer Ingelheim has about a quarter as many drugs on the market as in Germany (G: 110). The older drugs are marketed via Zydus Cadila/German Remedies. Boehringer Ingelheim intends to expand its distribution chain in India. Dipyridamole and ASS (Aggrenox®), telmisartan Micardis® (plus®) and alteplase (Actilyse®) is already being marketed directly by Boehringer Ingelheim. In addition to a largely irrational product portfolio, five of the 13 drugs sold (38%) are high priced.

Poorly served in matters of contraception: The Bayer pills Diane 35® and Yasmin® pose an increased risk potential and are expensive.
Bild: © Anna C., Fotolia.com

The company does not offer any drug against neglected diseases.

Result: Among the companies in our study, Boehringer Ingelheim has the worst product portfolio on the Indian market. Moreover, many of the irrational products are very expensive and clearly intended for the solvent middle classes.

Bayer Schering Pharma

The product portfolio: 39 different preparations in a total of 77 forms of dosage and formulation were evaluated.
9 drugs (12%) are essential, 40 (52%) are rational and 28 (36%) are irrational.

Essential drugs: The essential drugs are mostly old preparations such as nifedipine (Adalat®) or chloroquine (Resochin®), which are only of limited use in the treatment of high blood pressure and malaria. Bayer Schering Pharma have no essential innovations in their portfolio. The old antimalarial chloroquine (Resochin®) can only be used to a limited extent as a result of frequently occurring resistances. For want of alternatives, it is still frequently being used in India, particularly by the poor.

Rational and irrational drugs: Rational preparations are the long-standing drugs such as phenobarbital (Luminal®, Luminalettes®) or clotrimoxazole (Canesten®), but also new products such as the X-ray contrast agent iopromide (Ultravist®) and gadopentetate dimeglumine (Magnevist®) or the anti-cancer drug sorafenib (Nexavar®).
Several of the rational Bayer drugs blow the budgets of the majority of the Indian population: the x-ray contrast agent Ultravist® costs 2,667 Rs for 20 ml and the multiple sclerosis drug interferon beta 116,300 Rs for 15 pre-filled syringes. Bayer's anti-cancer drugs are likewise unaffordable: sorafenib tosylate (Nexavar®) with 280,430 Rs for 120 tablets à 200 mg and the anti-leukemia drug fludarabine phosphate (Fludara®) with 33,315 Rs for 20 tablets. The preparation was moreover evaluated as irrational in tablet form. A total of 10 (13%) products were classified as costly.

Risky contraceptive pills
Particularly crucial is the marketing of the disputed and irrational contraceptives Diane 35® and Yasmin®. Interviews with Indian doctors confirmed that medical sales representative promoted Bayer's contraceptive pills particularly

intensively in private hospitals. The combination of cyproterone acetate and ethinylestradiole (Diane 35®) is no longer approved as a contraceptive pill in Germany since the suspicion of liver tumors arose at the Federal Institute for pharmaceuticals and medical drugs in 1994. Since then, the indications of this agent have been severely restricted. The drug is only approved as a substitute in case of androgen-induced disorders of women as well as for the treatment of severe acne.[3] The active agents further bear an increased risk of thrombosis.[4] In contrast, the Indian Compendium of Medicines CIMS India clearly lists DIANE 35® as a contraceptive.[5]

The combination of drospirenone and ethinyl estradiol (Yasmin®) is in fact approved as a contraceptive pill in Germany as well and is becoming more and more popular among young women and girls. However, the professional magazine arznei-telegramm (drug telegram) advises against the use of the pill. In comparison with other contraceptives, the risk of thrombosis is significantly higher.[6]

Indian women who take Bayer's Yasmin® and Diane 35® are deceived twice since the contraceptive pills cannot only damage their health, they are moreover expensive. The preparations cost 231 or 360 Rs per menstrual cycle and take money out of the women's pockets unnecessarily. The contraceptive pills levonorgestrel & ethinyl estradiol with significantly fewer side effects can be obtained free-of-charge in the public health system as Mala N®. Under the name Mala D®, the preparation is made available by NGOs and other organizations for 0.25 Rs per menstrual cycle in the family welfare program. Both preparations are produced by Indian companies.[7]

Useless mixtures of vitamins

Vitamin mixtures from Bayer, such as Bayer's Tonic®, Edinol® or Supradyn® are highly problematic. Although these products are relatively cheap, they do not have a proven advantage for the patients. It is above all poor people, mostly women and children, who take these tonics, as our Indian partners confirmed. Albeit Bayer's Tonic® is not approved for the treatment of children in India, Indian pharmacists still recommend it as a tonic for children since the preparation has been recommended for decades by the German manufacturer as a restorative tonic and appetite stimulant for the little ones. In addition to liver extracts, yeast and sugar, Bayer's Tonic® also contains much alcohol (10%). It is above all malnourished children who are in danger of developing fatal liver cirrhoses if they take the tonic on a regular basis. If those 85.65 Rs which this useless and harmful preparation cost in 2010 were used otherwise, a larger family could be fed with healthy food for at least one day.

For the price of one bottle of Bayer´s Tonic, this much healthy food could be bought. *Foto: T. Jayashree*

Most Indians can't afford the drugs of Bayer Schering Pharma, Baxter and Boehringer Ingelheim. *Photo: WHO/P. Virot*

Irrational diabetic preparations

Irrational diabetic preparations such as acarbose (Glucobay®) or the irrational combination glimepiride and metformine (Gimibay ®) are also questionable. Diabetes is an increasing problem in India – about 40 million people are affected. In urban areas, the prevalence has meanwhile reached 9%. The availability of affordable rational preparations is essential.

Bayer tried to prove the benefits of acarbose (Glucobay®) in its comprehensive STOP-NIDDM survey. However, this was not successful. Bayer employees participated in the performance of the survey, which resulted in conflicts of interests and contradictory data in the professional magazines Lancet and JAMA. The professional magazine arznei-telegramm (drug telegram) arrives at the conclusion that "It has not been proven that acarbose (Glucobay®) is beneficial for lowering the risk of cardiovascular diseases in patients with an increased blood sugar level. The alleged published proof of benefits by the STOP-NIDDM study is based on a data manipulation to the advantage of acarbose."[8]

Conclusions: The product portfolio of Bayer Schering Pharma with 52% of rational and 12% of essential drugs is better than the portfolio of Boehringer Ingelheim. However, Bayer has far more problematic drugs on the Indian market.

Baxter

The product portfolio: Baxter sells 38 different preparations in India with a total of 80 forms of dosage and formulation. 35 preparations (43.75%) were graded as essential and rational and 10 (12.5%) as irrational.

Essential preparations: Baxter sells numerous essential drugs in India, among them important antibiotics, anti-cancer drugs and infusion solutions such as dextrose.

Rational und irrational products: As in other countries, Baxter primarily focuses on infusion solutions. On the one hand, they sell dextrose, Ringer and similar solutions, on the other hand antibiotics and anti-cancer drugs. The anti-cancer drugs are marketed via Zydus Cadila/ German Remedies, the rest are mostly marketed by Baxter themselves. A larger proportion of the drugs is to be graded as **rational** and also relevant. Irrational products are irrational combinations of antibiotics or irrational products like the muscle relaxant atracurium besylate (AcuBax®), which is not a product of choice any more, because there are better alternatives available.

With the exception of some products such as desflurane (Suprane®) isoflurance (Aerane®) or

human albumin (Buminat®, Humanalbumin®), which are costly, all Baxter drugs lie within the medium price range. There are few cheaper alternatives available to many infusion solutions in the field of anti-cancer or antibiotics therapy. However, in particular in the case of antibiotics, tablets could often be used instead, which are generally produced as generics and thus offered at a lower price. In India, infusions are seen as the more potent medicine in particular among the poor majority of the population. This culture-based assumption was also confirmed in interviews with Indian patients and doctors. Simple infusion solutions such as 5% dextrose, which Baxter sells for a price ranging from 69 Rs to 82 Rs per 500 ml, are offered by generic companies for 17 Rs. Ringer lactate offered by Baxter for 68-77 Rs per 500 ml can be obtained as a generic for a price as low as 17.90 Rs.[9]
With 77 different forms of dosage and formulation, Baxter offers half as many preparations as in Germany (with 186).

Conclusions: The product portfolio is good, comprising few irrational and many essential products. The pricing allows the conclusion that Baxter (as Bayer Schering Pharma and Boehringer Ingelheim) are focused on the private sector and thus on the Indian middle classes. Many of the products have no generic alternative, e.g. an antibiotic infusion solution, so that the pricing is largely left to the company. This excludes the poor from access to important drugs.

Patients in front of a public clinic in Delhi. It would be in vain to search for brand-name pharmaceuticals by Bayer, Baxter and Boehringer Ingelheim here – the pharmaceuticals are too expensive. *Photo: WHO, P. Virot*

2. Access to pharmaceutical drugs

Price and availability

Only the price for one substance of the company Bayer Schering Pharma (chloroquine) is regulated and Resorchin® of Bayer Schering Pharma complies with the regulation. In addition there are price regulations for irrational multi-vitamin mixtures, but it is not possible and practical to compare them with the Bayer products. In case of ciprofloxacine there is no price regulation for the tablets Ciprobay® sold by Bayer Schering Pharma. Of the Baxter preparations, only the lactate Ringer was regulated. It was restricted to 46.20 Rs for a 500 ml infusion solution and was exceeded by Baxter with 68 Rs. There was a price regulation for metronidazole in tablet form, but not for the infusion sold by Baxter. None of the substances sold by Boehringer Ingelheim are governed by a price regulation. Although India is entitled to regulate pharmaceutical prices, the Indian law does not, in fact, allow a price regulation for new substances[10] which often results in a rise in prices for the patients.

The public sector

None of the drugs of the three companies were used in any of the public hospitals, which confirms the quantitative survey as well as the qualitative interviews. All interviewed doctors had treated a similar scope of incidents: disorders, above all high blood pressure, malaria, pneumonia, dehydration after diarrhoea, fungal infection or amoebic dysentery. However in the public sector, the treatment comprised only of the cheaper Indian generics. The doctors interviewed stated that they always prescribed the generic which was then handed out by the pharmacist from a list of available drugs. This principle was also confirmed by the pharmacists interviewed. Neither the doctors nor the pharmacists are familiar with brand-name products and company names. The list of available drugs is determined in a tender by the federal state. The available drugs are free of charge, sometimes the patient has to pay a small processing fee of 5.0 Rs.

In the public sector, new and improved drugs of the second therapy line are often not available. Grave problems may follow for the patient. It is often the case that e.g. chloroquine is not effective in a case of malaria. An Indian doctor working in a public hospital reported: "Two weeks ago I was treating a patient suffering from malaria with chloroquine. Thank God it worked since other drugs are hardly available!"

Patients with severe disorders, e.g. a cervix carcinoma, are transferred to the next specialist hospital (secondary or tertiary sector).

Baxter is the only one of the three companies in the survey, which is mentioned in the new tender in Tamil Nadu[11]. The drugs included are desflurane (Suprane®) which is sold to the public clinics at a price of 6,100 Rs per 240 ml bottle instead of the 7,950 Rs of the private sector. Human albumin 20% is available in the public sector at 2,740 Rs instead of 5,600 Rs (prices in the private sector).[12] Thus the Baxter drugs are the most expensive ones that the public institutions in Tamil Nadu can order. However, in the public hospitals included in our survey, these drugs were not on stock.

NGO-Sector

Eight of the NGO hospitals included in our survey used 39 drugs of the three companies in a total of 82 forms of dosage and formulation. Two houses used 14 or 16 products, respectively, the other clinics 8-11. Two clinics offered a costly product with human albumin. One of the houses, a university clinic, also used sorafenib (Nexavar®) as well as alteplase (Actilyse®). Two NGO hospitals did not use any original preparations since they generally purchased their goods from the Indian non-profit company LOCOST[13] or cheap rational generics. In those interviews

Enjoys almost unlimited trust: Indian doctor in a public health centre. *Photo: Andrea Czekanski*

with doctors and pharmacists, it was confirmed that the doctors mostly used the generic name in their prescriptions. The patients received the corresponding drug from the pharmacist from the list of available pharmaceuticals. The list of available pharmaceuticals is determined by the respective clinic. Doctors working in the NGO sector often do not known the brand-name and manufacturer of the drugs, especially since the medical representatives mostly only visit the pharmacists.

Private sector

All hospitals used the drugs of the companies included in the survey. We found 37 drugs in 141 different forms of dosage and formulation. Among them was one costly preparation (human albumin 5%) and with vancomycine (Vancomate®) and cetirizine (Incid®), two preparation of the medium price range. One clinic used 33 products, another 22, four houses had 14 to 16 products of Bayer Schering Pharma, Baxter and Boehringer Ingelheim on offer. Four other private clinics used 5-9 products of the three companies. In interviews, the frequent use of the original preparations in our survey was confirmed. The doctors largely were aware of the brand-name and the doctors in part received the medical representative themselves. Depending on the hospital, the prescription states the name of the original preparation or the generic name. The patients then receive the corresponding medication from the list of available drugs at the clinic's pharmacy. The list of available drugs is determined by the hospital. In a large private hospital, this list contained e.g. two original preparations, as well as a multi-purpose generic. Since in the private sector 80 % of the patients have to pay for the drugs out of their purses, less affluent patients receive the generic and the more affluent ones receive the original preparation.

Summary assessment: Expensive drugs for the middle class

The selection of drugs and the sales strategies of the companies allow the conclusion that these companies focus their business strategies on the private and the NGO sectors. The drugs

offered by the companies in the survey are not used in the public sector. Only two of Baxter's products are listed in the tender for public clinics at all.

It is astonishing that many of the NGO clinics (church institutions as well as secular ones) only differ slightly from the private sector. The tendency towards original preparations exists in both sectors but it is even more pronounced in the private sector. High priced drugs are offered by clinics which run a small intensive care unit or by a university hospital.

In the private hospital which stocks 33 of the products in the survey, there is a diabetes centre. 14 Bayer products were found there and among them the diabetes preparation acarbose (Glucobay®) which was graded as irrational. It is above all private clinics which are in the focus of studies and training courses of these companies.

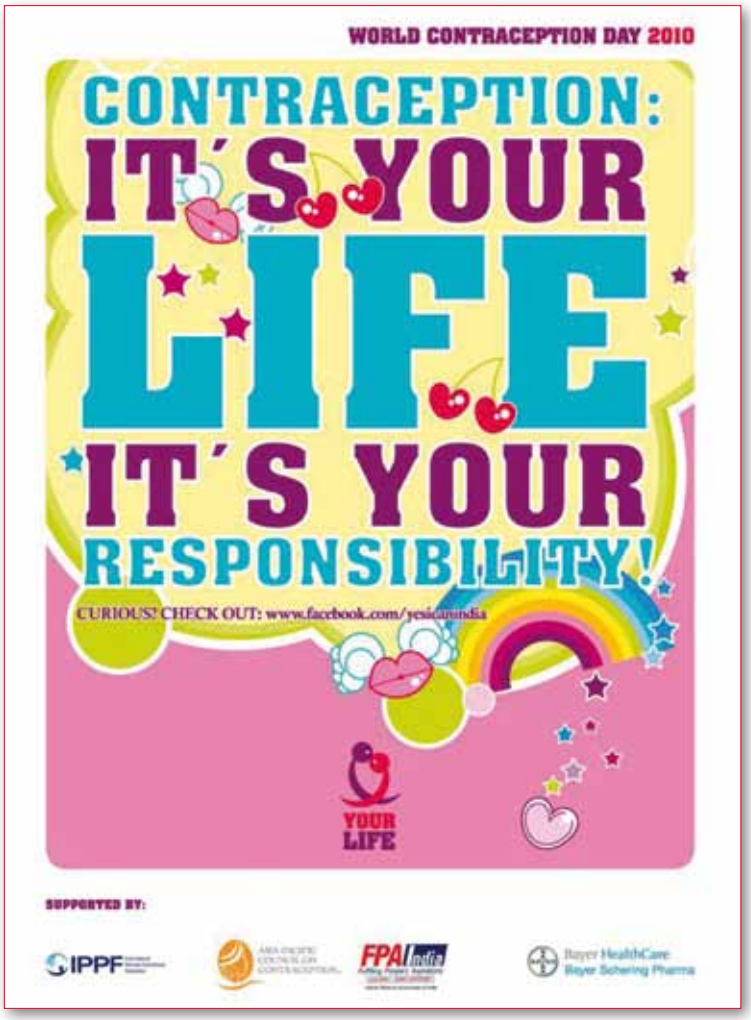
In the private as well as in the NGO sector, some prices differ considerably from the officially recommended prices – in both directions. In particular Baxter's infusion solutions are often offered at lower prices just as the telmisartan (Micardis®) preparation of Boehringer Ingelheim. This is an indication that the hospitals can get a price reduction. However, none of the companies confirmed this when we asked them. More than 80% of the products sold correspond to the maximum price allowed.

A lot of irrational products in the private sector

The selection of drugs found in the private and the NGO sector is largely identical. The main emphasis lies on the medium price range with many irrational products such as Bayer's Tonic® or hyoscine butylbromide (Buscopan®) as tablets. NGO clinics also distribute questionable oral contraceptives of the third generation such as Diane 35®. Private clinics additionally offer Yasmin®. Since Bayer sponsors various information campaigns on family planning and contraception, a connection has to be suspected. The World Contraception Day was carried out by Bayer Schering Pharma and the Family Planning Association of India (FPAI) on Sept. 26, 2010. A comprehensive website on this day, likewise sponsored by Bayer, offers information on the pill and all about contraception.[14]

Patients bear the costs

In the private and the NGO sectors, the patients usually have to pay for the costs for doctors, possible hospitalization, food and drugs themselves since less than 20 % of the population have a health insurance. In the public institutions, the drugs and the treatment are in fact free of charge, however, quite often high costs are incurred for the transport to the hospital. In addition, the patients lose their daily wages. If poor patients have to switch to NGO hospitals, the bill quickly exceeds their monthly wage, as one malaria patient explained: "I



Poster referring to the World Contraception Day in India which was sponsored by Bayer.

urgently need medical and financial help. When the public health service was not able to help me, I came here (note: into an NGO hospital)". In the course of his treatment, debts of 20,000 Rs had rapidly collected – at a monthly income of 6.000 Rs which is barely enough for him and his wife to live on.

Great confidence in doctors

Nevertheless all patients stated that they were more than satisfied with the treatment. All had a very high opinion of the doctors; one patient said: "They are my saviours!" This evaluation of very high patient satisfaction was shared by all persons interviewed.

Patients with little education and poor patients would often have preferred injections to tablets. Due to cultural reasons, this injections are seen as the stronger medicine than capsule or tablet. If a doctor did not comply with this wish, dissatisfaction was the result.

Mainly poor patients initially go to a non-registered practice in case of an illness. Only a part of non-registered medics, however, have a medical degree. They are favored by medical representatives. Dr. Roopa Devadasan explained in an interview with BUKO Pharma-Kampagne that these small medical practices followed the golden rule of receiving the first three medical representatives. Accordingly, when the practice opens, several representatives of pharmaceutical companies are already waiting in front of the surgery.[15] As our interviews confirmed, poor patients only made use of public (and sometimes NGO) institutions when they could not find help in the medical practice. Their relationship to physician in all sectors is characterized by great authority. The therapies prescribed are hardly questioned. As a rule, this relationship of confidence also exists in the case of the more affluent and better educated patients, who immediately go to a private or an NGO clinic in case of sickness.

Non-registered doctors are mostly the first place to go for patients. Their practices are favored by medical representatives.

Foto: Christiane Fischer

Innovations made by Bayer, Baxter and Boehringer Ingelheim do not close the gap in neglected diseases. The newer preparations hardly correspond to the need of the Indian population and very few offer a therapeutic advantage at all.

Foto: Andrea Czekanski

3. Access to innovative drugs

10 drugs of the companies in this survey were graded as innovative, i.e. these drugs were introduced in India after the year 1995. None of the preparations, however, can be considered essential. 6 preparations are even irrational, 4 are rational. Two of the innovative preparations (Lancibay®, Xirtam®) lie in the medium price range, all others are high priced (more than 500 Rs per package).

- Bayer Schering Pharma irrational: lansoprazole (Lancibay®), which is used for treating gastric ulcers, is significantly more expensive than the rational omeprazole. The effectiveness of high blood pressure preparation olmesartan medoxomil (Xirtam®) is disputed and does not offer a therapeutic advantage compared to the older preparations against high blood pressure
- Bayer Schering Pharma rational: The two X-ray contrasting agents gadopentetate dimeglumine (Magnevist®) and iopromide (Utravist®) and the anti-cancer agent sorafenib (Nexavar®)
- Boehringer Ingelheim irrational: aspirin and dipyridamole (Aggrenox®), tenecteplase (Metalyse®), telmisartan (Micardis®), telmisartan, hydrochlorothiacide (Micardis plus®)
- Boehringer Ingelheim rational: alteplase (Actilyse®)

Only one private and one NGO hospital had one of the innovative preparations on stock: Micardis plus®. However, the hospitals sell this preparation at a quarter of the company's prices. Private and NGO hospitals rarely use costly preparations.

Summary assessment: Nothing new for the poor

Newer, innovative pharmaceuticals are not available to the poor in India. Moreover, the innovative preparations produced by the companies in our survey do not correspond to the Indian need for pharmaceuticals for treating neglected diseases. In the case of malaria, this has a grave effect. If resistances develop in the treatment with chloroquine, newer and more effective preparations are not available for the poor. Likewise, tuberculosis and other diseases of the poor do not lie within the research interest of the companies.

Hardly useful innovations

Neither compulsory licenses nor non-obligatory licenses were granted on the existing innovations. None of the pharmaceuticals is included in the list of the drugs available in the

They are not in the focus of interest of the research: poor people in India. Photo: A. Czekanski

public sector. 6 of the 10 drugs, however, have to be graded as irrational. Rational products such as gadopentetate dimeglumine (Magnevist®) and iopromide (Utravist®) only have a small range of indication as X-ray contrasting agents; the same is true for alteplase (Actilyse®). The most relevant innovation is the anti-cancer drug sorafenib (Nexavar®). Bayer Schering Pharma owns the patent[16], but lost a patent suit against the company Cipla, in which the linkage of the patent to the production was on trial (patent linkage). The highest Indian Court denied a connection. Cipla is permitted to produce sorafenib as a generic, but not to sell it in India as a result of the patent protection existing there.[17] Cipla intends to produce sorafenib at a tenth of the Bayer Schering price. The market price of 280,000 Rs / 120 tablets is presently a massive obstacle to access.

4. Clinical trials in India

Boehringer Ingelheim: 38 clinical trials have reached varying phases.[18] None of the trials is related to neglected diseases. But 13 trials relate to the type II diabetes which is common in India. In addition, the company researches therapies against chronic lung diseases, cancer, blood dilution and Parkinson.

Bayer: 24 of Bayer's pharmaceutical trials have reached varying phases.[19] These include a large double-blind, multi-centre trial of moxifloxacine, an antibiotic which is tested for application in children suffering from a complicated intra-abdominal infection. The drug is also tested by the Tuberculosis Research Centre together with the National Institutes of Health (NIH) in tuberculosis therapy. Bayer do not finance this trial but emphasize in their sustainability report 2008 that they participate in the research for a new tuberculosis drug: „Bayer is working together worldwide with the Global Alliance for TB Drug Development, or TB Alliance for short, to develop a tuberculosis drug that significantly reduces the duration of treatment." [20]
The Bayer trials also mainly refer to chronic diseases: 9 trials relating to venous thrombosis, embolism and blood dilution, 4 to the cancer therapy with sorafenib.

Baxter: does not carry out any clinical trials in India.

Summary assessment

The research activities of the companies are strongly focused on the profitable areas and new areas of use of the bestselling products. None of the trials financed by the three companies of this survey is concerned with neglected diseases. Although the companies only offer a limited pharmaceutical portfolio, they use the market for numerous research projects relating to their blockbusters. In addition to a large reservoir of test persons and highly trained specialists, the country offers modern and well-equipped hospitals and comparatively low research costs. We could not find any direct violation of the requirements of the Helsinki declaration.

5. Patents

Boehringer Ingelheim has filed 519 patent applications in India, of which 99 have meanwhile been granted. For our survey, 14 applications and four patents are relevant. In addition, there is a product patent and an application for the important Aids drug nevirapine [21], the access to which has been guaranteed by the voluntary Non Assert Declaration of the company. In this case, they forego to enforce their patent rights. Boehringer Ingelheim applied for a patent on dipyridamole and aspirin (Aggrenox®).[22] A patent was granted on the company's telmisartan (Micardis®) on March 27, 2009[23], and a patent application was also filed for telmisartan and hydorchlorothiazide (Micardis plus®).[24]

Baxter has filed 248 patent applications, 48 of which were granted. Only one patent application refers to a drug contained in our survey.

The Bayer Group has filed 2314 patent applications (all business areas) in India, 363 of which have been granted. The majority, however, does not refer to the pharmaceutical area. Bayer has filed 7 patent applications on the drugs of this survey, 4 have been granted, 3 of them on moxifloxacin (Avalox®)[25], one on sorafenib (Nexavar®).[26] The patent on acarbose (Glucobay®) has expired.

Boehringer Ingelheim's Aids drugs are available in Africa at low prices – thanks to a company policy which does not insist on the assertion of their patent rights. *Photo: WHO, Eric Miller*

Summary assessment

Particularly the Bayer Group do everything to aggressively assert their patent rights, which is shown by the Nexavar® case.
Boehringer Ingelheim also assert their patent rights but, in the case of Aids, they were open to a Non Assert Declaration and thus to a fairer access to pharmaceuticals for their two HIV drugs nevirapine and tripanavir. In Africa and India, these important drugs may be produced as a generic without the company asserting their patent rights - an important step into the right direction.[27]
Baxter is following another route: the company produces numerous rational pharmaceuticals without any alternative treatment. They can determine the price for many products without competition.
None of the companies take alternatives to the existing patent system into consideration or are prepared to renounce the so-called TRIPS-plus regulations such as data exclusiveness which exist in Europe. The TRIPS-plus agreements, which are often enforced by industrialized countries in bilateral negotiations, exceed minimum standards valid worldwide, which is determined in the international agreement on the protection of intellectual property rights TRIPS. The European Union is also currently negotiating with India on a Free Trade Agreement (FTA) which contains such TRIPS-plus clauses. They would further tighten patent protection and thus block access to important drugs in many cases.

6. Marketing strategies

Direct advertizing

Since 1954, pharmaceutical advertizing has been prohibited in India, or only permitted in professional circles, respectively.[28] Information campaigns for family planning, health care and disease awareness are, in fact, permitted. The companies therefore focus their promotional activities on the sponsoring of campaigns or use social networks such as Facebook and Twitter, which attract in particular the young and solvent middle classes. Doctors and pharmacists are also intensively courted. A Bayer training film for medical representatives, which is available on the internet, impressively shows how doctors are encouraged to prescribe Glucobay®.[29] The page www.glucobay.com is linked to the Indian Bayer page. It contains scientifically unproven advertising statements for doctors: "Glucobay® delays the progression of diabetes and provides additional cardiovascular benefits". The link to the Indian web page cleverly evades the ban on advertising since one only has to click that one is a professional in order to see the advertisement.

A website sponsored by Bayer on the World Contraception Day in India cleverly introduces brand-names: One of the ambassador's name is Diana – similar to Bayer's pill.

Doctors courted

In an interview, a leading Indian medical representative of German Remedies explains: "Lay advertizing is largely without interest for us. We focus on doctors. As a rule-of-thumb: any doctor has to yield 10 times as much as we invest in them. We often put five million Rupees per year into a doctor and now you can calculate how much we earn through them."[30] In the interviews the doctors and pharmacists emphasized that the medical representatives primarily focus on the clinic pharmacists since they decided which drugs they handed out to the patients; however, in private hospitals, the promotion is also directed at the doctors. In addition, the confusing mass of unregistered doctors seems to be in the focus of the industry since they are the first place to go for majority of the patients.

Quality only from Germany?

Another strategy of the Bayer Schering Pharma is to discredit Indian companies by exposing them to the suspicion that they market counterfeit drugs or goods of a substandard quality; whereas Bayer's name is always equated with quality medicine.[31] Baxter also follows this strategy by praising their products as being of a particularly high quality.

Advertizing in the internet

As a freely accessible space which is difficult to control, the internet offers the possibility of directing customers to international websites, which are not subjected to the Indian regulations, and thus to draw their attention to branded products. Bayer subtly engage in product placement on their website relating to the World Contraception Day held in India. The ambassadors introduced on the start page are called Claire and Diana just like Bayer's contraceptive pills (Diane35®, Qlaira®).[32] Diane35® is also sold in India.

Social networks

Facebook is used by all companies for advertizing.[33] „Yes I can India“ is a page sponsored by Bayer, which has the intention of giving information on contraception for young people and which is promoted via Facebook.[34] Boehringer Ingelheim is in the lead at Twitter. In 2009, the company had 2,634 “followers”. But Baxter and Bayer have also discovered Twitter for their marketing.[35] It is possible for Indians to register via a special country code. Moreover, patients´ discussion forums such as e.g. the Cancer Compass are cleverly used. There, a friendly medical representative gives the information that the anti-cancer drug Nexavar® is available in India, naturally without stating the price.[36]

Partnership and disease awareness

Bayer strengthen their corporate image with numerous partnerships such as a partnership with the India Diabetes Educator Project. Consistent with their product portfolio comprising antidiabetics such as acarbose (Glucobay®), Bayer HealthCare trains diabetes health care professionals.[37] In addition, there are freely accessible films in which the name Bayer is mentioned and which pretend to provide education.[38] In the federal state of Karnataka, Biocon and Bayer HealthCare have undertaken a partnership to sharpen the awareness of diabetes and of Bayer products.[39] Moreover, the Bayer Schering Pharma sponsors various educational campaigns directed at family planning and contraceptives, a clever method to place themselves in a favorable light as the market leader in the contraceptive field. In 2010, the World Contraception Day was organized by the Bayer Schering Pharma and the Family Planning Association of India (FPAI) in India on 26 Sept. 2010.[40]

Baxter sponsored, together with health care institutions in Mumbai, Chennai, Kolkata, Lucknow, Delhi, Trivandrum and Jaipur the World Haemophilia Day on 17 April 2010 in correspondence with their product portfolio. The corresponding video was translated into Hindi, Begali and Tamil.[41] Baxter is the official partner of the patient support group Hemophilia Federation India.[42] Moreover, the company pride themselves to support the reputed Pulse Polio Program of the Indian government[43], in which every child under five is to be vaccinated annually (!) against polio no matter if it had already been vaccinated or not. Despite this vigorous vaccination campaign, the number of polio infections has risen. Moreover, the cost effectiveness of this vertical program is questionable.

The internet pages intended for the lay, www.bayerdiabetes.in, are anything else but neutral. They inform diabetes patients in detail on drug therapies and clearly show tablets with the Bayer logo in the adjacent picture.

Summary assessment

The WHO describe in their ethic criteria for pharmaceutical promotion: „In this context, ‚promotion’ refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.” In this sense, sponsoring of events or of patient support groups has to be interpreted as promotional measures and, even more so, a clever product placement, as in the case of Bayer’s contraceptive pills. Likewise, the partnerships entered into by the companies primarily seem to serve to cultivate the companies’ image.

7. Donation programs

In India, **Bayer** finance doctors and nurses in areas with tsunami victims, supports schools and children, environmental projects, projects against child labor and has an emergency fund.[44]

Baxter supports the disputed Pulse Polio Program of the Indian government. *Photo: WHO, P. Viro*

Similar donation programs are financed by **Baxter** via the Baxter International Foundation. The foundation supports the training of street children in India, maintains an emergency fund for Tsunami victims (in which infusion solutions are donated) and finances a project for Aids education as well as a house building project. Many of the Baxter initiatives are borne by their employees and it is not evident whether that was voluntary work.[45] These projects have to be evaluated as single measures which do help individuals, but which primarily are aimed at improving the company's image.

Boehringer Ingelheim supports an HIV and workplace project in India by supporting the corresponding labor union financially. In addition, India is included in the nevirapine donation program for reducing the mother-to-child transmission of Aids and meanwhile the company have distanced themselves from the controversial one-dosage recommendation. After Boehringer Ingelheim had long postulated the single treatment with nevirapine as an Aids prophylaxis, the company now fortunately recommends the implementation of the WHO treatment guidelines relating to mother-to-child transmission, in which nevirapine is only a part.[46] With the Non Assert Declaration, the company furthermore continues to permit all WHO prequalified producers in India and Africa to manufacture nevirapine and tripranavir as a generic.[114] The two latter aspects of the business policy have to be evaluated as primarily ethical and sustainable company decisions.

Summary assessment

The social projects of the companies have to be evaluated as single measures, which do in fact support specific individuals, but which are primarily suited to improve the companies' names and images. Although the nevirapine donation program of Boehringer Ingelheim also serves to improve their image, their Non Assert Declaration reaches far beyond the customary company commitment. It improves access to nevirapine and tripanavir in Africa. The access to medicine index therefore places Boehringer's patent policy at the second place in a list of 20 pharmaceutical companies examined, whereas Bayer is at place 14. Baxter was not examined.[48]

8. Communication behavior

At the beginning of this survey, we contacted all companies in writing. Moreover, interim results were presented for validation as well as individual questions were asked. In December 2010, we asked company representatives for an interview on the interim results and invited them to a public panel discussion in March 2010. Only Boehringer Ingelheim took part. The communication behavior of the three companies differed considerably.

Pharmacy or supermarket? Indian pharmacies mostly offer no advisory service to their customers. A better control of the drug market would be necessary to protect patients from risky products produced by national and international companies. *Photo: Christiane Fischer*

- **Boehringer Ingelheim** practiced an open and fair communication behavior and answered questions promptly and with a high-level content. They were immediately willing to take part in a direct dialogue. The company signalled a high willingness to engage in a dialogue.
- **Bayer** answered most questions after some hesitation and also provided us with a contact person. An appointment for a dialogue was also agreed upon. However, some questions were not answered, others only in part. The company did not give any information on their patent applications. Willingness to engage in dialogue exists.
- **Baxter** refused almost any kind of communication, did not answer letters or e-mails and declared on the phone that they would not engage in dialogue with NGOs. The only answer was an e-mail in December 2010, in which our offer for a dialogue was refused.

9. Conclusions

The companies Bayer, Baxter and Boehringer Ingelheim offer considerably fewer drugs in India as compared to Germany and exclusively aim at the Indian middle and upper classes with their price policy. Above all, Bayer and Boehringer Ingelheim distribute many expensive drugs with which patients are poorly served.

In the public health care system, not even one drug of the examined companies is being used. It is only private and NGO hospitals which use their products. Important drugs such as the cancer drug Nexavar® from Bayer are not available to poor patients. On the other hand, these companies take money out of the pockets of the poor for irrational vitamin mixtures such as Bayer's Tonic®.

Bayer and Boehringer Ingelheim carry out numerous research projects in India and profit from the fact that clinical trials cost only half in that poor country as compared to Europe. Despite that, this research is exclusively focused on profitable medical fields and at possible new applications of their blockbusters. Trials relating to neglected diseases are not financed by those companies.

Instead, it is above all Bayer who engages in subtle product placement to advance the sale of their products. Clever marketing of third-generation contraceptive pills is the more questionable as the pills are not only more expensive but also riskier than the generic preparations offered free of charge in the public health system.

IV Where to go?

The present patent system does not present an inventive for companies to direct their research activities at the actual worldwide need. Thus the time has come for trying new ways, as is also demanded by the WHO. Research projects supported by the state, public invitations to tender for research projects or patent pools are conceivable models to boost the research of neglected diseases.

Access to important essential drugs is better ensured by the Indian generic companies than by German brand-name companies. Stricter patent protection which could result from the currently negotiated free trade agreement between the EU and India would therefore be fatal. It could result in significantly deteriorated access to medical health care not only in India, but also in other poor countries.

However, the Indian government is also asked to ensure by an effective approval procedure that patients receive safe pharmaceutical products of high quality. Germany and the EU could support this process and refrain from associating generics with counterfeit drugs. Instead they should support the governments of poor countries in expanding their approval and control authorities. In this respect, it would also be exigent to set a good example. There are still numerous nonsensical, superfluous or even harmful preparations on the German market. That should also be changed!

Endnotes

1 *BUKO Pharma-Kampagne in Ingelheim, 17. Dec. 2010*
2 *atd arznei-telegramm (2011) Arzneimitteldatenbank. Bewertung Telmisartan.*
3 *arznei-telegramm (1994) Die Geschichte des Wirkstoffs Cyproteronazetat (in Diane u.a.) ... Von der "Pille für den Mann" zum "Hautpflegemittel mit Empfängnisschutz". Nr. 9, S. 84-6 und Rote Liste Diane 35®*
4 *arznei-telegramm (2002) Höhere Thrombogenität von Diane. Nr. 33, S. 130*
5 *http://www.cimsasia.com*
6 *arznei-telegramm (2009) Thromboembolierisiko Drospirenon-haltiger Kontrazeptiva (Yasmin u.a). Nr. 40, S. 100*
7 *Department of Family Welfare India. http://www.mohfw.nic.in/dofw%20website/family%20welfare%20programme/contra.htm#ORAL%20CONTRACEPTIVE%20PILLS*
8 *arznei-telegramm (2003) Stop-NIDDM-Studie mit Acarbose ... Schlamperei, Manipulation, Irreführung. Nr. 34, S. 73-74*
9 *Medline India. http://medlineindia.com/surgicals/dextrose.htm*
10 *National Pharmaceutical Pricing Authority. http://nppaindia.nic.in/index1.html*
11 *http://www.tnhealth.org/tnmscwar.htm*
12 *http://www.tnmsc.com/tnmsc/new/html/pdf/spldrug.pdf*
13 *http://locostindia.com/*
14 *World Contraception Day launched in India. http://indiablooms.com/HealthDetailsPage/healthDetails300910c.php*
15 *Dr. Roopa Devadasan, Dezember 2010*
16 *Patentnummer 215758*
17 *Handelsblatt (2010) Bayer unterliegt im Nexavar-Patentstreit in Indien auch bei Berufungsklage. 9.2.2010. http://www.handelsblatt.com/newsticker/unternehmen/absatz-bayer-unterliegt-im-nexavar-patentstreit-in-indien-auch-bei-berufungsklage;2527008*
18 *Clinical Trials. http://clinicaltrials.gov/ct2/results?term=Boehringer+India&pg=2*
19 *http://clinicaltrials.gov/ct2/results?term=Bayer+India*
20 *Bayer (2008) Nachhaltigkeitsbericht. http://www.nachhaltigkeit2008.bayer.de/de/Weltweiter-Zugang-zur-Medizin.aspx*
21 *http://india.bigpatents.org*
22 *Antragsnummer 4622/DELNP/2005 A*
23 *Patentnummer 215602*
24 *Antragsnummer 1928/DELNP/2004 A*
25 *Patentnummern 214010, 214011 und 185805*
26 *Patentnummer 215758*
27 *Boehringer Ingelheim: Boehringer Ingelheim further intensifies fight against AIDS. Press Release 15.5.2007. http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2007/15_may_2007.html*
28 *The Drugs And Magic Remedies (Objectionable Advertisements) Act, Act No. 21 of 1954. http://www.commonlii.org/in/legis/num_act/damraa1954459/*
29 *http://www.veoh.com/browse/videos/category/educational_and_howto/watch/v18795267fTQFYp9J*
30 *Interview in Hyderabad, September 2011*
31 *http://www.bayerscheringpharma.de/en/therapeutic_areas/products_/beware_of_counterfeits/index.php*
32 *http://www.your-life.com/en/home/index.php*
33 *http://www.facebook.com/pages/Bayer-Healthcare/111106282249022 http://www.facebook.com/pages/Baxter-Healthcare/110845842270072 http://de-de.facebook.com/boehringeringelheim?v=app_10339498918*
34 *http://www.facebook.com/yesicanindia?v=app_7146470109*
35 *John Mack (2009) Pharmaguy's Twitter Followers. What Do They Want and How Is It Relevant to You? Pharma Marketing News; September 2009 8(8). http://www.news.pharma-mkting.com/PMN88-03.pdf*
36 *http://www.cancercompass.com/message-board/message/all,19295,0.htm*
37 *http://www.maxhealthcare.in/services_facilities/our_departments/endocrinology/pdfs/project_hope_faq.pdf http://www.highbeam.com/doc/1G1-171130784.html*
38 *http://www.youtube.com/watch?v=OkQwfPZwZBo*
39 *http://www.andhranews.net/India/2010/February/4-Biocon-Bayer-54461.asp*
40 *http://indiablooms.com/HealthDetailsPage/healthDetails300910c.php*
41 *World Haemophilia Day 17.4.2010. http://www.wfh.org/whd/en/ http://www.baxter.com/press_room/features/2010/07_07_10_india_whd.html*
42 *http://www.hemophilia.in/new/?q=node/35*
43 *http://www.baxter.in/about_baxter/sustainability/*
44 *http://www.bayer.com/en/donations.aspx und http://bayergroupindia.com/corporate_resp.html*
45 *http://www.baxter.in/about_baxter/sustainability/index.html*
46 *Boehringer Ingelheim: Viramune® donation programme. http://hiv.boehringer-ingelheim.com/com/HIV/Information_material/Brochures.jsp*
47 *http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2007/15_may_2007.html*
48 *Access to Medicine Index 2010. http://www.accesstomedicineindex.org*

V. Annex: List of examined drugs

Drugs Boehringer Ingelheim 2010

generic name	brand name Boehringer Ingelheim	application form	ingredients	classification	package size	price MIMS/ CIMS/in Rs
alteplase	Actilyse	ampoule	20 mg	r	1*20 mg	14,000.00
alteplase	Actilyse	ampoule	50 mg	r	1*50 mg	37,500.00
aspirin, dipyridamole	Aggrenox	capsule	200 mg, 25 mg	i	30	926.40
aspirin, dipyridamole	Aggrenox	capsule	200 mg, 25 mg	i	60	1,706.00
bisacodyl	Dulcolax	suppository (rectal)	10 mg	r	5*10 mg	35.40
bisacodyl	Dulcolax	suppository (rectal)	5 mg	r	5*5 mg	30.50
bisacodyl	Dulcolax	tablet including dragée	5 mg	r	1,000	469.90
bisacodyl	Dulcolax	tablet including dragée	5 mg	r	10	13.95
clonidine	Catapres	tablet including dragée	0.15 mg	r	10	5.88
clonidine, chlorthalidone	Catapres DIU	tablet including dragée	0.1 mg, 15 mg	i	10	11.11
dipyridamole	Persantin	tablet including dragée	100 mg	i	10*100 mg	15.00
dipyridamole	Persantin	tablet including dragée	25 mg	i	10*25 mg	5.55
butylscopolaminium-bromid	Buscopan	suppository (rectal)	10 mg	i	5*10 mg	28.09
hyoscine butylbromide	Buscopan	tablet including dragée	10 mg	i	10	30.00
hyoscine butylbromide	Buscopan	ampoule	20 mg/ml	r	20*1 ml	9.74
hyoscine butylbromide	Buscopan	suppository (rectal)	5 mg	i	5*5 mg	
hyoscine butylbromide	Buscopan	suppository (rectal)	7.5 mg	i	5*7.5 mg	21.47
hyoscine butylbromide, paracetamole	Buscopan plus	tablet including dragée	10 mg, 500 mg	i	10	38.00
mexiletine hydrochloride	Mexitil	capsule	150 mg	i	10*150 mg	175.80
mexiletine hydrochloride	Mexitil	capsule	50 mg	i	10*50 mg	61.93
orciprenaline sulphat	Alupent	tablet including dragée	10 mg	i	10	32.20
orciprenaline sulphat	Alupent	suspension (incl. syrup and other internal liquid solution)	10 mg per 5 ml	i	5 ml*100 ml *10 mg	61.79
telmisartan	Micardis	tablet including dragée	40 mg	i	30*40 mg	860.00
telmisartan	Micardis	tablet including dragée	80 mg	i	30*80 mg	1,151.00
telmisartan, hydrochlorthiazide	Micardis plus	tablet including dragée	80 mg, 12.5 mg	i	30*80 mg	1,151.00
telmisartan, hydrochlorthiazide	Micardis plus	tablet including dragée	40 mg, 12.5 mg	i	30*40 mg	860.00
tenecteplase	Metalyse	ampoule	8,000 units	i	1	28,000.00

Drugs Baxter 2010

generic name	brand name Baxter	application form	ingredients	classification	package size	price MIMS/ CIMS/in Rs
amoxicilline clavulanic acid	A.C.mate	IV-solution-bottles	1,2 g	e r	100 ml	
atracurium besilate	AcuBax	ampoule	10 mg/ml	i	2.5 ml	120.00
atracurium besilate	AcuBax	ampoule	25 mg/ml	i	2.5 ml	
atracurium besilate	AcuBax	ampoule	50 mg/ml	i	2.5 ml	
atracurium besilate	Atracade	ampoule	10 mg/ml	i	2.5 ml	120.00
atracurium besilate	Atracade	ampoule	25 mg/ml	i	2.5 ml	
atracurium besilate	Atracade	ampoule	50 mg/ml	i	2.5 ml	
cefoperazone, sulbactam	CefMate	IV-solution-bottles	500 mg, 500 mg	r	100 ml	343.00
ciprofloxacine	Ciprofloxacine	IV-solution-bottles		e r	100 ml	
comp sodium lactade	Comp Sodium Lactade	IV-solution-bottles		e r	500 ml	
comp sodium lactade	Comp Sodium Lactade	IV-solution-bottles		e r	1,000 ml	
cyclophosphamide	Endoxan N	ampoule	1 g	r	1*1 g	118.47
cyclophosphamide	Endoxan N	ampoule	200 mg	r	1*200 mg	34.10
cyclophosphamide	Endoxan N	tablet including dragée	50 mg	e r	10	36.65
cyclophosphamide	Endoxan N	ampoule	500 mg	e r	1*500 mg	72.80
desflurane	Suprane	inhalative anesthetics	99.9%	r	240 ml	7,950.00
dextrose	Dextrose FFS	IV-solution-bottles	5%	e r	250 ml*10% FFS	69.00
dextrose	Dextrose FFS	IV-solution-bottles	5%	e r	500 ml*5% FFS	82.00
dextrose	Dextrose FFS	IV-solution-bottles	5%	e r	1,000 ml*5% FFS	
dextrose	Dextrose Viaflex	IV-solution-bottles	5%	e r	100 ml*5% Viaflex	45.00
dextrose	Dextrose Viaflex	IV-solution-bottles	5%	e r	500 ml*5% Viaflex	69.00
dextrose	Dextrose Viaflex	IV-solution-bottles	5%	e r	500 ml*10% Viaflex	69.00
dextrose	Dextrose Viaflex	IV-solution-bottles	5%	e r	1,000ml*5% Viaflex	
dextrose	Dextrose Viaflex	IV-solution-bottles	5%	e r	1,000 ml*5% FFS	
dextrose normal saline	Dextrose Normal Saline	IV-solution-bottles	5%, 45%	e r	500 ml	69.00
human albumin	Buminate	IV-solution-bottles	20%	r	100 ml*20%	5,600.00
human albumin	Buminate	IV-solution-bottles	20%	r	50 ml*20%	2,800.00
human albumin	Human Albumin	IV-solution-bottles	20%	r	100 ml*20%	5,600.00
humanalbumin	Human Albumin	IV-solution-bottles	20%	r	50 ml*20%	2,800.00
human albumin	Human Albumin 5% vial	IV-solution-bottles	5%	r	250 ml*5%	2,820.00
ifosfamide	Holoxan	ampoule	1 g	e r	1*1 g	322.21
ifosfamide	Holoxan	ampoule	200 mg	r	1*200 mg	406.00
ifosfamide	Holoxan	ampoule	2 g	e r	1*2 g	
ifosfamide	Holoxan	ampoule	40 mg/ml	r	1*40 mg	
ifosfamide	Holoxan	ampoule	500 mg	r	1*500 mg	
imipenem, cilastatin	ImiMate	IV-solution-bottles	500 mg, 250 mg	r	100 ml	
isofamide, mesna	Holoxan Uromethixan	ampoule	1 g, 200 mg	r	combipack	406.00
isoflurane	Aerrane	inhalative anesthetics	99.9%	r	250 ml	
isoflurane	Aerrane	inhalative anesthetics	99.9%	r	100 ml	2,062.00
isoflurane	Forane	inhalative anesthetics	99.9%	r	250 ml	2,750.00
isoflurane	Forane	inhalative anesthetics	99.9%	r	100 ml	2,075.00
lactad ringer	Lactad Ringer	IV-solution-bottles		e r	1,000 ml	99.00
lactad ringer	Lactad Ringer	IV-solution-bottles		e r	500 ml	68.00
lactad ringer, dextrose	Lactad Ringer, Dextrose	IV-solution-bottles	5%	r	500 ml	77.00

generic name	brand name Baxter	application form	ingredients	classification	package size	price MIMS/ CIMS/in Rs
lorazepam	Ativan	tablet including dragée	1 mg	r	10*1 mg	22.49
lorazepam	Ativan	tablet including dragée	2 mg	r	10*2 mg	26.86
mannitol	Osmitrol	IV-solution-bottles	20%	e r	350 ml FFS	65.52
mannitol	Osmitrol	IV-solution-bottles	20%	e r	100 ml FFS	72.80
mannitol	Osmitrol	IV-solution-bottles	20%	e r	100 ml Viaflex	72.80
meropenem	MeroMate	IV-solution-bottles	1 g	i	100 ml*1 g	2,388.00
meropenem	MeroMate	IV-solution-bottles	500 mg	i	100 ml*500 mg	1,288.00
mesna	Uromitexan	ampoule	100 mg/ml	e r	3*2 ml	83.79
metronidazol	Metronidazole	IV-solution-bottles		e r	100 ml	
multiple elektrolyte	EM	IV-solution-bottles		r	1,000 ml em	
multiple elektrolyte	EM	IV-solution-bottles		r	500ml em	76.00
multiple elektrolyte	EP	IV-solution-bottles		r	500ml ep	76.00
multiple elektrolyte	Plasmalyte 148	IV-solution-bottles		r	500 ml plasmalyte 148	
multiple elektrolyte	Plasmalyte A	IV-solution-bottles		r	1,000 ml plasmalyte A	
multiple elektrolyte	Plasmalyte A	IV-solution-bottles		r	500 ml plasmalyte A	
multiple elektrolyte, dextrose	Plasmalyte 56	IV-solution-bottles	5%	r	500 ml	
ofloxacin	Ofloxacine	IV-solution-bottles		i	100 ml	
piperacillin, tazobactam	PiptaMate	IV-solution-bottles	4 g, 0.5 g	i	100 ml	750.00
antihemophilic factor VIII (recombinant)	Recombinate	ampoule	250 IU	e r	10 ml	
antihemophilic factor VIII (recombinant)	Recombinate	ampoule	500 IU	e r	10 ml	
antihemophilic factor VIII (recombinant)	Recombinate	ampoule	1000 IU	e r	10 ml	
sodium chlorid	Sodium Chlorid Viaflex	IV-solution-bottles	0.45%	r	100 ml	
sodium chlorid	Sodium Chlorid Viaflex	IV-solution-bottles	0.45%	r	500 ml Viaflex	
sodium chlorid	Sodium Chlorid Viaflex	IV-solution-bottles	0.45%	r	2,000 ml Viaflex	
sodium chlorid	Sodium Chlorid Viaflex	IV-solution-bottles	0.45%	r	1,000 ml Viaflex	
sodium chlorid	Sodium Chlorid Viaflex	IV-solution-bottles	0.9%	e r	500 ml Viaflex	69.00
sodium chlorid	Sodium Chlorid Viaflex	IV-solution-bottles	0.9%	e r	2,000 ml Viaflex	95.00
sodium chlorid	Sodium Chlorid Viaflex	IV-solution-bottles	0.9%	e r	1,000 ml Viaflex	28.00
sodium chlorid	Sodium Chlorid	IV-solution-bottles	0.9%	e r	100 ml	45.00
sodium chlorid	Sodium Chlorid FFS	IV-solution-bottles	0.9%	e r	500 ml FFS	69.00
sodium chlorid, dextrose	Sodium Chlorid, Dextrose FFS	IV-solution-bottles	0.2%, 5%	r	500 ml*0,2% FFS	42.00
sodium chlorid, dextrose	Sodium Chlorid, Dextrose FFS	IV-solution-bottles	0.33%, 5%	r	500 ml*0,33% FFS 500 ml	88.00
sodium chlorid, dextrose	Sodium Chlorid, Dextrose FFS	IV-solution-bottles	0.9%, 5%	e r	500 ml Viaflex	69.00
sodium chlorid, dextrose	Sodium Chlorid, Dextrose FFS	IV-solution-bottles	0.9%, 5%	e r	500 ml FFS	69.00
tinidazol	Tinject OD	IV-solution-bottles	200 mg	r	400 ml	55.00
vancomycin	VancoMate	IV-solution-bottles	500 mg	e r	100 ml	389.00

Drugs Bayer 2010

generic name	brand name Bayer	application form	ingredients	classification	package size	price MIMS/ CIMS/in Rs
acarbose	Glucobay	tablet including dragée	25 mg	i	10*25 mg	42.00
acarbose	Glucobay	tablet including dragée	50 mg	i	10*50 mg	76.00
human albumin	Plasbumin	IV-solution-bottles	20%	r	100 ml	
human albumin	Plasbumin	IV-solution-bottles	20%	r	50 ml	
human albumin	Plasbumin	IV-solution-bottles	25%	r	100 ml	
human albumin	Plasbumin	IV-solution-bottles	25%	r	50 ml	
human albumin	Plasbumin	IV-solution-bottles	5%	r	100 ml	
human albumin	Plasbumin	IV-solution-bottles	5%	r	50 ml	
alkoholic tonic	Bayer's Tonic	suspension (incl. syrup and internal liquid solution)		i	200 ml	65.00
alkoholic tonic	Bayer's Tonic	suspension (incl. syrup and internal liquid solution)		i	250 ml	83.65
bifonazole	Mycospor	crème, ointment, paste, powder or gel	1%	i	10 g cream	49.50
bifonazole	Mycospor	crème, ointment, paste, powder or gel	1%	i	10 g powder	49.50
bifonazole	Mycospor	crème, ointment, paste, powder or gel	1%	i	10 ml solution	49.50
cetirizine hydrochloride	Incid L	tablet including dragée	10 mg	r	10*10	340.00
cetirizine hydrochloride	Incid L	tablet including dragée	10 mg	r	10	29.20
cetirizine hydrochloride	Incid L	suspension (incl. syrup and internal liquid solution)	5 mg/50ml	r	60 ml	28.00
chloroquine	Resochin MD	suspension (incl. syrup and internal liquid solution)	100 mg/10 ml	e r	60 ml	13.94
chloroquine	Resochin	tablet including dragée	250 mg	e r	12*250 mg	6.79
chloroquine	Resochin	ampoule	40 mg/ml	r	30 ml	16.10
chloroquine	Resochin	ampoule	40 mg/ml	r	5 ml	4.82
chloroquine	Resochin DS	tablet including dragée	500 mg	r	6*500 mg	7.20
ciprofloxacin	Baycip	tablet including dragée	100 mg	r	10*100 mg	8.00
ciprofloxacin	Baycip	tablet including dragée	250 mg	e r	10*250 mg	32.00
ciprofloxacin	Baycip	tablet including dragée	500 mg	r	10*500 mg	65.87
ciprofloxacin, tinidazole	Baycip TZ	tablet including dragée	500 mg, 600 mg	i	10	75.32
clotrimazole	Canesten VAG	crème, ointment, paste, powder or gel	1%	e r	15 g*1%	37.50
clotrimazole	Canesten	crème, ointment, paste, powder or gel	1%	r	15 ml*1%	38.50
clotrimazole	Canesten VAG	crème, ointment, paste, powder or gel	1%	r	10 g*2%	60.50
clotrimazole	Canesten	crème, ointment, paste, powder or gel	1%	r	15 g*1%	37.50
clotrimazole	Canesten V6	suppository (vaginal)	100 mg	e r	6*100 mg	38.50
clotrimazole	Canesten S cream	crème, ointment, paste, powder or gel	10 mg, 0.25 mg	r	10 g	38.25
cyproterone acetate, ethinyl estradiol	Diane 35	tablet including dragée	2 mg, 0.035 mg	i	21	231.40
drospirenone, ethinyl estradiol	Yasmin	tablet including dragée	3 mg, 0.03 mg	i	21	360.00
levonorgestrel, ethinyl estradiol	Triquilar	tablet including dragée	30 mcg, 50 mcg	r	21*30 mcg, 50 mcg	54.63
levonorgestrel, ethinyl estradiol	Triquilar	tablet including dragée	30 mcg, 125 mcg	r	21*40 mcg, 75 mcg	
levonorgestrel, ethinyl estradiol	Triquilar	tablet including dragée	40 mcg, 75 mcg, 125 mcg	r	21*40 mcg, 75 mcg	
fludarabine phosphate	Fludara	tablet including dragée	10 mg	i	20	3,3315.00
fludarabine phosphate	Fludara	IV-solution-bottles	50 mg	r	1	9,580.29
gadopentetate dimeglumine	Magnevist	ampoule	469 mg/ml	r	1*10 ml	1,444.45
gadopentetate dimeglumine	Magnevist	ampoule	469 mg/ml	r	1*20 ml	2,666.67

generic name	brand name Bayer	application form	ingredients	classification	package size	price MIMS/ CIMS/in Rs
glimepiride, metformin	Gimibay	tablet including dragée	1 mg, 500 mg	i	10*1 mg	42.00
glimepiride, metformin	Gimibay	tablet including dragée	2 mg, 500 mg	i	10*2 mg	64.00
hydroxyprogesterone caproate	Proluton Depot	ampoule	250 mg/ml	i	1 ml*250 mg	43.85
hydroxyprogesterone caproate	Proluton Depot	ampoule	500 mg/ml	i	2 ml*500 mg	69.35
interferon beta-1b	Betaferon	prefilled syringe	0.25 mg/ml	r	15	116,300.00
iopromide	Ultravist 300, Ultravist 370	IV-solution-bottles	0.623 g	r	100 ml*0.623 g	1,377.78
iopromide	Ultravist 300, Ultravist 370	IV-solution-bottles	0.623 g	r	20 ml*0.623 g	377.78
iopromide	Ultravist 300, Ultravist 370	IV-solution-bottles	0.623 g	r	50 ml*0.623 g	744.45
iopromide	Ultravist 300, Ultravist 370	IV-solution-bottles	0.769 g	r	100 ml*0.769 g	1,533.34
iopromide	Ultravist 300, Ultravist 370	IV-solution-bottles	0.769 g	r	50 ml*0.769 g	877.78
lansoprazole	Lancibay	tablet including dragée	30 mg	i	10*30 mg	46.90
levocetirizine dihydrochloride	Incid MD	tablet including dragée	5 mg	i	10	50.00
mesterolone	Provironum	tablet including dragée	25 mg	i	30	446.52
multi vitamines	Edinol	capsule		i	20	13.04
multi vitamines	Edinol	capsule		i	100	55.95
multi vitamines	Multibay	capsule		i	100	43.50
multi vitamines	Multibay	capsule		i	20	10.55
nifedipine	Adalat-ORS	capsule	10 mg	e r	10*10 mg	11.76
nifedipine	Adalat-ORS, Adalat retard, XT Release	capsule	20 mg	r	10*20 mg	14.60
nifedipine	Adalat-ORS, Adalat retard, XT Release	capsule	30 mg	r	10*30 mg	260.00
norethisterone	Noristerat	prefilled syringe	200 mg/ml	i	1	126.04
norethisterone	Primolut-N	tablet including dragée	5 mg	i	10	60.00
olmesartan medoxomil	Xirtam	tablet including dragée	20 mg	i	10*20 mg	73.00
olmesartan medoxomil	Xirtam	tablet including dragée	40 mg	i	10*40 mg	125.00
olmesartan, hydrochlorthiazide	Xirtam H	tablet including dragée	20 mg, 12.5 mg	i	10	73.00
phenobarbital	Luminal, Luminalettes	tablet including dragée	100 mg	r	250*100 mg	21.59
phenobarbital	Luminal, Luminalettes	tablet including dragée	100 mg	r	50*100 mg	5.25
phenobarbital	Luminalettes	tablet including dragée	15 mg	e r	30*15 mg	1.33
phenobarbital	Luminalettes	tablet including dragée	15 mg	e r	500*15 mg	10.11
phenobarbital	Luminal, Luminalettes	tablet including dragée	30 mg	r	25*30 mg	3.03
phenobarbital	Luminal, Luminalettes	tablet including dragée	30 mg	r	500*30 mg	29.96
sorafenib	Nexavar	tablet including dragée	200 mg	r	120	280,430.00
testosterone enanthate, testosterone propionate	Testoviron Depot	ampoule	110 mg	r	1*110 mg	65.89
testosterone enanthate, testosterone propionate	Testoviron Depot	ampoule	110 mg	r	10*110 mg	490.00
testosterone enanthate, testosterone propionate	Testoviron Depot	ampoule	250 mg, 250 mg	r	1*250 mg	117.75
vitamin C	Redoxon	tablet including dragée	500 mg	e r	10	8.16
vitamins, minerales	Supradyn	tablet including dragée		i	15	16.04
vitamins, minerales	Supradyn	tablet including dragée		i	15	16.04

BUKO Pharma-Kampagne and IPH Bangalore have made a survey of the business behavior of Bayer Health Care, Boehringer Ingelheim and Baxter in India. The results: these companies sell many irrational preparations and offer only few essential innovations. Bayer and Boehringer Ingelheim conduct numerous clinical trials in India, but they prefer to search for new applications of their blockbusters instead of doing research in the field of neglected diseases. Especially Boehringer Ingelheim has a poor pharmaceutical portfolio with 70% of irrational drugs and no essential preparation. On the other hand, the company renounce to strictly assume their patent rights in the case of nevirapine. This important Aids drug can therefore be generically produced in India at a low price, which ensures access to this drug for poor countries, in particular in southern Africa. Whereas 64% of Bayer products sold in India are rational, the aggressive patent policy of that German company blocks access to the innovative cancer drug sorafenib (Nexavar®). The company Baxter has a quite good product portfolio with 88% of rational products including 44% of essential drugs. But many of those products do not have a generic alternative in India. Their price is high and excludes the poor from access.

BUKO Pharma-Kampagne

BUKO (Federal Coordination Internationalism) is a network of around 200 solidarity groups and individuals. In 1981 BUKO started a campaign against global malpractices in drug marketing by multinational pharmaceutical companies. Until today our focus is to stop unethical drug marketing practices and to foster rational use of drugs all over the world. We work with medical students, doctors, pharmacists and medical scientists through campaigns, publications, press work, public debate and dialogue.

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Institute of Public Health, Bengaluru

The Institute of Public Health, Bangalore is a public health research and training institute based in Bangalore, India. We are a non-profit organization established with a vision of creating an equitable, integrated, decentralized and participatory health system within a just and empowered society. IPH is mainly involved in health systems research and is committed to improving service delivery in the government health services with the aim of improving health care for the community.

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