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## **Disputing Distribution: Ethics and pharmaceutical regulation in Nepal**

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### **Introduction**

On July 17<sup>th</sup> 2007, the Government of Nepal, through its Department of Drug Administration (DDA) released its Guidelines on Ethical Promotion of Medicine<sup>1</sup>. The editorial of the August – November issue of the Drug Bulletin of Nepal, published by the DDA and entitled “Ethical promotion of medicine: Benefit to consumers” outlined the rationale for this<sup>2</sup>. Acknowledging that the pharmaceutical industry has to promote its products as it is a business, the editorial locates the tensions between this and an “ethical” practice of rational prescribing. A particular concern is raised in that the practice of “substituting the prescription” has been increasingly pushed by producers, and that this is driven by a system of giving discounts and free samples of medicines. The rise of the practice of giving “bonuses” to retailers seems to have increased to the extent that now consumers are aware of it and this image is a problem for the industry, as they wonder if quality is being compromised for profit it states. Acknowledging that what is ethical to one group may not be so to another the guidelines have been produced (after consultation with unnamed “stakeholders”) to clarify this. Although starting as guidelines, the editorial goes on to state that these will need to be enforced by law and they will go on to become a “code”. After stating that all the stakeholders were in agreement with this, the editorial concludes: “We have confidence that with the implementation of guidelines on Ethical Promotion of Medicine, all concerned along with the consumer will be benefited. We urge everyone concerned to cooperate DDA for the implementation of the Guidelines, so that ethical promotion will be enhanced and medicine sector will be as respectable as it was in the past” (Thapa 2007: 4).

In this paper we examine the release of these guidelines and examine the response to it to explore the discourses around, and the vested interests in the pharmaceutical sector in the context of Nepal. It is divided into two broad sections. Firstly we will present some ethnography of the distribution chain, and relations around the production and distribution of drugs. This thick description of the relations between actors in the pharmaceutical chain of distribution – from retailers, and pharmacists, to wholesalers and medical representatives as well as doctors and government officials – provides the ethnographic backdrop for the second part of the paper, focusing in more detail on the

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<sup>1</sup> See Annex one for the full guidelines.

<sup>2</sup> Available at: [http://www.dda.gov.np/publication/dbn\\_19\\_1.pdf](http://www.dda.gov.np/publication/dbn_19_1.pdf) (accessed 22nd Feb. 2009).

ethical guidelines themselves, their release and the chain of events this set in motion. This “critical event” (Das 1995) is the catalyst that allows us to see more clearly the fault lines and areas of conflict within this distribution chain, to see where the vested interests in the pharmaceutical industry lie. In this second section, then, we present the main points of the guidelines, emphasising the “bonus” issue. The position of representatives of the Graduate Pharmacy Association of Nepal (GPAN) is presented, and the rationale for the research they conducted and from which the ethical guidelines emerged. The Nepal Chemists and Druggists Association (NCDA) who most vehemently resisted the guidelines is next presented and followed by the response of the Nepal Medical and Sales Representative Association (NMSRA), the Association of the Pharmaceutical Producers of Nepal (APPON) and the medical professions representative organisations, the Nepal Medical Association (NMA) and the Nepal Medical Council (NMC). The final part in this section is the Department of Drug Administrations tentative response to the varied vested interests in response, and how they perceived the issues that emerged.

The paper then points to the following issues in relation to the ethical regulation of pharmaceuticals in Nepal. Firstly, “ethical promotion” is articulated as being distinct from “business” practice and that in the context of increased competition, business practices have recently flourished. These are described in some detail in the ethnographic section of the paper. However, ethical promotion is repeatedly reified because the pharmaceutical industry is seen to be quite different to other businesses. The welfare of the public and consumers are mentioned as the most important issue. Secondly, within the complexity of the system for the distribution of pharmaceuticals a range of vested interests emerge. This is seen most clearly in response to the release of the guidelines. “Ethical” pharmaceutical promotion is articulated as a relative phenomenon, depending on the position of, and the vested interests of the parties involved. Thirdly, the system is also so complex and dependent on so many actors (producers and their medical representatives, wholesalers and retailers, pharmacists, and medical practitioners) that when “unethical promotion” (for example bonuses and substitution) is mentioned there is a tendency to blame other groups in the chain for the problems, rather than reflect on their own practices. This tendency to be defensive of ones own practices and the protection of various vested interests points to the difficulty of regulation. As such and fourthly, the question still remains as to how to regulate? Regulation seems to be a marginal concern. It was articulated by many, including government representatives, that it was not really the job of the government to create the guidelines as they did, but that the situation demanded that someone did something and so they took the lead. How then should regulation be undertaken? We ask whether regulation should develop further from increased consumer pressure. Fifthly, what is at stake here is the emergence of the Nepalese pharmaceutical industry trying to capture the markets in Nepal. While the question of the Indian producers and distributors does arise, the issue is not about multi national companies and the control of patents, rather it is around the struggle for the generic market, but one where “branded generics” are produced, marketed and prescribed. Within this situation of an emergent Nepali pharmaceutical industry, this includes a strong nationalist dimension to the idea of “regulatory capture” (Abrahams 1995).

The concluding section suggests that by focusing on the “pharmaceutical nexus” (Petreyna et. al 2006) we can see a range of emergent and uncertain ethical, political and economic concerns within a Nepal “in transition”.. The role of the state looms large, as does the relation of the state to the arrival of a new professional force – that of professionally trained pharmacists – relative to other vested interests in the sale of

medicines. It finishes with the question of public interest, and poses the question as to what the responsibilities of the researcher are in this situation?

### Encountering MRs - an ethnographic start

IH is standing in the psychiatric outpatients of the outpatients of a large hospital in Kathmandu in late 2006. This crowded space has four doctors receiving patients, and their families as they interview and diagnose, then recommend treatments and prescribe. It had been pointed out to us that you can recognise the Medical Representatives (MRs) of the drug companies in the waiting rooms, as the (men) have ties, and they all have motorcycle helmets and the requisite leather bags for holding their flipcharts and samples. There are a number outside. As the outpatient squeeze diminishes with the last few patients leaving, the representatives come in one by one, performing a ritual we are to witness time and again. The bag pops open, and the flip chart comes out. The first is for Xectin, the fluoxetine brand that the Nepali company Genesis market. The young MR is nervous and rushes through its uses, and is immediately asked for samples. She has some anti-allergic medications, and IH is asked if he needs any for family or friends by one of the residents? This resident later explains that this is how they get the medications that they need for family and friends, and he added, for the poor as well.



This pattern is repeated and witnessed in other encounters. The various products are quickly gone over and the MR tries to persuade the doctor to prescribe and use their products. While many doctors seem not to listen much, one explains: “The information on the flipchart about the drugs makes it easy for the health workers to prescribe”. Samples are given and support for the companies is elicited. Newer companies try to persuade the doctors to use their products over and above the others.

Back in the outpatients above, IH finds a copy of the Indian CIMS on a desk (one of the Indian pharmaceutical guides – it is six years old) and writes down the 20 listed brands for Fluoxetine, even as one of the residents asks why he is doing that as it isn’t used here. IH asks one of the residents to list the ones that he knows and he writes down eight that he is aware of, writing whether the company is “Nepali” or “multinational”. He asterisks

the ones that he uses, and says that he tends to use the multinational ones as he trusts their efficacy better. Asked why he bothers to listen to the reps then, as he knows what he prescribes, he reflects that this is a good question. He says that the reps tend to advertise on the quality first, then push the reputation of the company and finish with whether or not they have done any clinical trials. He emphasised, however, that if a patient doesn't respond to treatment then their first thought is of the quality of the compound.

The bulk of the sales of pharmaceuticals in Nepal are for “branded generics”, that is off patent formulations marketed and sold as brands. An initial difficulty IH experienced in Nepal, (having been trained in the NHS where we only ever learnt about generics), was having to reorient to the extent to which brands – prescribing, and sales – dominate such an “unregulated market” and inform its every direction and twist. The reality of this branded domination is something that even the main teaching hospital in Nepal has had to adapt its own training towards. A senior doctor responsible for the training of post-graduates explains: We were talking about the sheer variety of brands of antidepressants on the market, and that he is seeing brands of amitryptilline he has not heard of before appearing. How do we know that their quality can be assured, he asked rhetorically? He answered by saying that they have to teach the students to write the brand names of the drugs for prescriptions that they trust. He appreciated that while they try to start doctors off with good habits, they have to deal with reality of “company bombardment” when they are out on their own<sup>3</sup>.

### **The Nepal pharmaceutical industry, and the emergence of the “gift” and “bonus” systems**

Until about 1970 the Nepal market was dominated by Indian companies, when Royal Drugs Nepal was set up. The total market size at this time was about 10,000,000 rupees, and there were very few retail outlets, although there has been an “explosion” of these in the last few years as described by one producer. The DDA currently reports now somewhat over 6,000 registered outlets, and the NCDA more than 20,000 (Harper et. al 2007 Working paper). In one interview with a CEO of a company thinking of trying to enter the Nepal pharmaceutical market (sales) to be worth about 100 million dollars in 2006.

Many people we interviewed talked of the split between Nepali products and Indian products on the market currently as being 30:70 (producers would talk of reversing this figure to capture 70% of the market with Nepali products; indeed one of the lobbying issues that the Nepali companies were doing with the DDA were around “non-tariff barriers” to Indian imports, by having labels for all products sold in Nepal in Nepali). The number of registered Indian companies has dropped in recent years to the current 200 or so (it was over a thousand in previous years), and there are now over 40 Nepali companies. Unlike the situation in India, where we see both bulk drug production (that is production of the active ingredients) and formulation production (Chaudari 2005), Nepal has only the latter (the process of processing into dosage forms like capsules, tablets and the like). As of 2008, no Nepali company had managed to export any products to India

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<sup>3</sup> As far as we know the only successful attempt at generic prescribing has been in Mission Hospitals, and Patan Hospital – noteworthy for the lack of private pharmacies outside its main entrance – was the most successful at this. It was frequently held up by those we talked to as a example of what is possible.

or elsewhere, and so the market for their products is, at present, internal. Figures for 2001-2 showed that Nepal was worth about 3.02 % of the Indian formulation export market and is categorised by Chaudari as an “unregulated market” (Ibid: 180-1).

A Medical Representative working for an MNC, who wished to remain anonymous, told us that their company made a point of pushing solely for prescription based dispensing practices, and only approached medical doctors. They are acutely aware of the image problem that they have and cannot be seen to behaving “unethically”. He suggested that it is only Nepali and smaller Indian companies who market direct to retailers for example (several retailers in interview admitted that MRs do try to incentivise them with gifts and bonuses). He explained that as the government regulations state that only 16% margin can be put onto the wholesale price, then it is only with the “incentives”, particularly bonuses, that retailers can make a decent profit. As the Nepali companies have moved into what he called the “general market”, that is for drugs that can be produced cheaply and have a high potential profit margin (like anti-inflammatory, antibiotics, vitamin syrups, cough syrups and the like) then they have been increasing these practices. These include, amongst others: giving cars and motorcycles; companies paying the wages of middle level doctors; aeroplane flights (in other interviews the list varied slightly, but there was general agreement that these practices had increased in recent years).

The MRs themselves lay the blame for the gift culture at the door of the doctors and their greed. An MR who works of a small Nepali company explains. It is a problem she said of the intense competition in the market now (this issue, of the intense competition driving these practices came up again and again in interviews with all stakeholders). She described how she had just come from seeing a doctor who had dismissed her saying that he had his daughter going to the US to study a Masters degree and that she should go and see her boss and return with the aeroplane flights, or he wouldn't see her again. She said that these gifts were now increasingly demanded. While denying that she, and her company gave large bonuses (and saying that Indian companies were the main culprits) she said that up to 100% bonuses are given for certain products. The wider the gap between production costs and maximum retail price (MRP) then the more money they will put into “marketing” she explained.

“Substitution” is the practice of substituting one brand for another at the point of the retailer. Some people we interviewed even described molecule substitution as well. An MR explains: If a retailer has been given a lot of “gifts” of another brand, then they will substitute this for the prescribed brand. It was explained to us that with the dense networks and relations that the MRs form, that they know which retailers do this, and who are “good” and “bad”. The area around the large and busy hospitals is particularly bad we were told, stating that one of the reasons is the very high rents that they pay there for their small shops.

We had targeted a number of large hospitals as one area of research and conducted interviews in clinics, with doctors and others. Clusters of retailers are found in these areas, frequently with spaces where doctors, working in the hospitals, come and run private clinics. These spaces are provided free by the retailers. At one site the retailers here were defensive of this accusation – circulated widely in the press - that linked high rents to the increase in substitution. Instead, one retailer countered that because the “media can write whatever they want”, and that they wrote about the bonus system, and the price hikes in medicines, that consumers have now started asking for discounts. He said that this is not true for every medicine, and yet that is what was expected from the

consumers, and that they now offer 5-10% level in discounts. Another of these retailers also emphasised how, because of increased awareness amongst consumers on bonuses, demands for discounts have increased<sup>4</sup>. Again he highlights how this is the consequence of competition, and the sheer increase in number of retailers in the market. He sees the DDA as giving them a hard time, fining them on the spot, and confiscating the samples. The retailers have no redress when these events occur to them he emphasised.

One retailer who runs a pharmacy inside a hospital defends these practices in this way:

“It's been three years that I opened this shop. We get the space here through tender system by the hospital. The rent here is also very high. It is 4 lakhs per month. And that's not the only investment. We need to pay a rent of one year in advance and the hospital call tender every year. Now apart from rent we have to pay the staffs as well. So we have to pay rent, pay staff and then earn profit as well. So where should we focus on? Should we focus on public needs? That is why this business is becoming an unethical one...”

He went on to say that while high rent is one reason for substitution, it is not the only one. There is also the internal competition between the pharmaceutical producers, as well. He states if a doctor prescribes a branded antacid, but a retailer is getting a 50% bonus on another brand, then of course he is going to substitute. He is more concerned on the increasing risk of violence against retailers and health workers, citing recent violence in Butwal. He asks why there is all this focus on unethical practices, and the financial motive aspects of the work, yet no-one looks at the social responsibility perspective.

Elsewhere, another retailer explains:

“We have to practice substitution. Doctors prescribe such medicines as are not available in the market, for example NIKO. Certain Indian companies products have stopped coming into the market as they didn't pay the tax and doctors prescribe such brands then from where will we get such brands when it has stopped coming into the market....”

He went onto to explain to us that they buy products from those companies that provide the most bonuses as the way that they can maximise their profits. He cited competition – indeed nearly all the retailers we interviewed cited this as the biggest problem they face - and the rise in the number of retailers as his biggest problem over the last few years. He said they see between 10-20 MRs per week, and that they ask them about the sales of their products in the market.

A retailer next door also cited competition as their main problem now, and that substitution was performed when the drugs that doctors prescribed are not in the market. He qualified that they always try and find that brand in another shop first, and then only do so with the permission of the patient (observation by one of the team on this suggests

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<sup>4</sup> One wholesaler pointed out that there is now an advert on the radio every Sunday morning at 7:30, and on the TV, saying “While leaving here is an important message: While buying medicines do not forget to forget to bargain like you bargain while buying vegetables”, and that these adverts are arising because of awareness of the bonus system.

that it is in fact much more forceful, the way that some retailers try to substitute)<sup>5</sup>. One retailer even said that he stocked illegal medicines not registered in Nepal, and that he had brought them in from India because they are life saving drugs prescribed by doctors in the hospital (he was talking about streptokinase). Others said that they would like to substitute, but they cannot convince the patients to take on a different brand<sup>6</sup>. Another, in light of increasing competition, substitution, and increasing bonuses, says that for his clientele, they trust him because he has been around for a long time and that is why local people come to his rather than others (cf Subedi 2000, for more on over the counter contact and personal networks). Another agrees:

“I think that is an immoral practice, and I don’t do that here. Our customers trust us and that is why they come here. For my patients, if I do not have a particular brand, we provide them through our friends; I bring them from my friends from other pharmacies near here and give it to them. I don’t give substitutes”

He thinks that the sheer number of retailers is outrageous, and that the failure to regulate numbers lies with the DDA.

A wholesaler, describing to us the system of distribution says that the bonus system has increased in the last few years. Retailers buy from those wholesalers who pass on the bonuses to increase their profit margins. It has come down to the fact that if you cannot offer bonuses, then your products won’t be sold. This has become compounded by the growth of the “credit systems” where increasingly retailers buy on credit from wholesalers against future sales, and, then frequently change wholesaler without paying the debts.

A CEO of a company thinking of investing in the pharma market is doubtful of his chances of success in this current climate. The problem is that as it is so “highly unregulated”. He talked of how the current going price to register a new product is 25,000 rupees. Once registered there is then the difficulty with bonuses, which can be as high as 100-120 percent, he explained, and that with some companies now providing drugs on “credit” for five to six months in advance, the whole system is blocked up. It has led to the emergence of a great deal of “unscrupulous practices”. The nexus of various organisations that support the producers and distributors he described as “mafia” (a description that came up regularly in the research). He saw no way into the market,

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<sup>5</sup> Interviewing this retailer highlighted a particular difficulty with these interviews and the need to see beyond just how they responded. He cited that they only stock those medicines that were prescribed by the doctors, but when a woman came up during the interview asking for amoxicillin tablets, he just asks her how many she would like and when she says 4, he says that is fine, giving her four capsules from a strip and charging her 33 rupees. Also when asked if he had any anti-tuberculosis drugs, he said no as these were available from the government clinics. When I pointed out that he a Lupin product AKT-3 (a three dose combination variety) on the shelves behind his head, he changed his tune stating that sometimes patients from NORVEC come to purchase these, as they don’t all want to go onto the daily observation regime that the government demands to get the free drugs.

<sup>6</sup> This issue is important. As we tracked drugs from Pokhara and Butwal into the hinterlands, it became evident that for antidepressants, the brand stocked in the Mission Hospital there was demanded widely, increasing the market potential for this brand. Each year the hospital puts out a tender, and the winning companies products are then stocked in the areas surrounding retail outlets. Many patients put on antidepressants did not bother to go back to the hospital for follow-up using instead their old packets and notes to get the drugs direct from the pharmacies. This is common practice.



and indeed the ideas that he did have might even be dangerous because of the vested interests that would have to be broken.

Another senior figure who ran a company said that he wanted to set an example of good practice for other companies, said that this almost sent him broke. The incentive systems result in bribing of chemists he said, and these bonuses encourage substitution. He came from a prescription culture (he had lived in Britain for a while), but he found that all his products were being substituted at the retailer level. 40-50% bonuses is now the norm for companies that want to stay in the market, and now that many companies are having to upgrade their facilities in line with GMP, there is little money to go into these infrastructural developments, as it all goes into “marketing”. This compounded with high rents has meant that corruption has become rampant he concluded.

Such “unscrupulous” practices abound. A member of a board on retail outlet outside one large hospital explained that they pay 120,000 rupees rent per month, and that others there pay as high as half a lakh. Asking to remain anonymous he described how commissions were given to the pharmacy inside the hospital, so that they wouldn’t stock certain products, particularly the high priced ones. Some drugs then are deliberately not sold so that the patients (all of whom have to buy their own drugs and products prior to treatment) have to go outside into the market place. He stated that the “commission structure” goes all the way to the top, so that even the vice chancellor gets a commission as well (I was later told of how difficult it is for well meaning hospital directors to stop all this, as if they try to ban these practices, it is the lower staff who complain – the peons and the cleaners – as they also suffer with not getting their kick backs. Corruption, if we want to call it this, is systematic). As one MR pleaded when interviewed, please highlight in the writing that it is systemic and don’t blame individuals.

### **The reification of the ethical**

We turn now specifically to the question of ethics, and how this was discussed. The managing director of a small Nepali company said that marketing was all about presentation of the product, promotion of this, and the company reputation. He divided this marketing into two paths; “ethical marketing” – visiting doctors several times a month to educate and persuade them of the products - and the “business track”, which involves giving gifts and bribes to doctors, and more and more companies now follow this route. “In business and war everything happens”! This reification of the ethical, occurred again and again in interviews. A board member of a small Nepali company states:

“The marketing strategy of our company is that we make doctors write prescriptions for our products. We go for “ethical marketing”, which means that we do not give any deal or bonus to chemists and we go to doctors, convince them about the quality of our products, and then they prescribe them.... We explain to them about the quality of our production site and about our products...

Many of the retailers see the problem as lying squarely with the government, and their inability to properly regulate. One of the pharmacists in a Mission hospital explains that there is much resistance to change from the retailers themselves, and the DDA is incapable of regulating as they never visit the retailers to check up. They will give you anything you wish for, regardless of whether it is indicated or not he explains. It’s the DDA that needs to take responsibility in his opinion. In this hospital they banned MRs

from entering the hospital to visit their doctors, and they have to come only to the pharmacy.

In this section we have seen some of the relations and issues around the distribution and sale of medicines. The problem of ethical promotion and practices is perceived as systemic, and not the domain of individuals or particular groups. A combination of high rents, and increased competition, has led to a number of practices at the retail outlets – particularly the giving of bonuses and substitution of brands. The government's role is seen as ambiguous. In the next section we turn to the government's attempt to regulate these issues.

### **The Ethical guidelines in detail, and the response to this**

The ethical guidelines on the promotion of medicines were released following research done by the Graduate Pharmacy Association of Nepal (GPAN)<sup>7</sup>. The president of GPAN, who has also worked in the DDA for the last 28 years where he was based at the time of interview, as Drug Administrator, described the evolution of these in the following way:

“In 1988, WHO had published a concept on Ethical Criteria for Medicinal Drug Promotion. The basic objective of this concept was to support and encourage the improvement of health care through the rational use of medicinal drugs. Although the concept and interpretation of what is ethical varies from context to context and society to society, there are some similarities in many countries and contexts. Following the situation of Nepal, DDA wanted to conduct the workshop on Promotional practices of Pharmaceutical industry in Nepal. A group of pharmacists were assigned to conduct the study.... The team decided to collect information from a minimum of 15 Nepalese Pharmaceutical companies and 15 Indian companies. The focus was given to the aspects of promotional practice. In January 2007, a workshop was held in Dhulikhel to share the findings.

He describes the main findings as follows:

“It was found that there is a wide variation in bonus scheme offered by the companies. In some products, for example, cardiac drugs were found without bonus. Products like Amoxicillin and Ciprofloxacin were in the market with free offers which ranged from 10 percent to 100 percent. Albendazole 400 mg was another product in the market with wide bonus range from 20 percent to 100 percent. Vitamin B complexes were in the market with as high as 60 percent bonus offer especially for 200 ml packs. The 100 ml packs are sold at the bonus offer half of that offered for 200 ml packs. Even products such as cough formula, and ORS were having bonus system. The basic concept on bonus was found as 10 percent by every company and 70-100 percent in exceptional cases with certain products. However some companies had been practicing no offer system in sale of some selected products.

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<sup>7</sup> See <http://gpan.com.np/abo.html> for more on this organisation and the full list of their aims and objectives.

The research team also found that gift items were being offered and included carpets, pens, blankets, bed sheets, irons, calculators, TVs etc. Some companies were also found to be offering good bonus for products which some of the Nepalese hospitals had already band as “irrational combinations” (He said that the names of the companies was highly confidential, which may explain why we could not get a hold of a copy of the research).

“The conclusion of the study was that the pharmaceutical companies need to be fully committed to ensuring that their business practices meet high standards of ethics and legal compliance and that their employees behave with honesty and integrity. It was also concluded that the way they do their business affects the patients and their families who use and buy their products.

The guidelines (See Annex1) were released in July 2007. The response from the Nepal Druggist and Chemist Association was immediate. This organisations main objective is described as to “develop and safeguard the pharmaceutical trade” and there stated aim is “enforcing the price uniformity of drugs within the country”. It is a non-governmental umbrella organisation, and it seems that to be a retailer or wholesaler you have to be a member. Thus it represents the interests of the retailers, wholesalers and importers. In short, they released their twelve point demand to the Minister of Health on the 26<sup>th</sup> July 2007. This included the immediate abrogation of these ethical guidelines as their first point, as well as a broad range of other demands (See Annex 2). On the 10<sup>th</sup> of August they held a press conference at the Sangam Hotel, Bagbazzar, Kathmandu; on the 12<sup>th</sup> to the 14<sup>th</sup> they pushed a series of agitations involving all “the entrepreneurs” putting on black arm bands and to let the consumers know about the demands. Every drug store was asked to paste the demands on their store. On the 15<sup>th</sup> they picketed the DDA; on the 16<sup>th</sup> shifting up a gear to rally and picket the MoH. On the 17<sup>th</sup> all NCDA zonal branches and sub-branches held a rally and they handed a memorandum to the Office of the Prime Minister through the District Administration Office<sup>8</sup>. In short, they stopped the supply of drugs for a few days, at which point the MoH started to take their demands seriously and an agreement was signed. This was immediately reacted against as well, this

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<sup>8</sup> This particular protest stopped short of direct strike action. However health workers are regularly involved in strike action in Nepal. In August 2006, paramedical workers went on strike demanding, amongst other things “promotions, allowances for those working in a risky environment, free treatment in all state-run medical institutions and... to put an end to the process of handing over the health institutions to the community” (<http://www.kantipuronline.com/kolnews.php?&nid=83217> Accessed 22<sup>nd</sup> Feb. 2009). (NB need to check this, but this was the same protests that resulted in a pitched battle with NCDA members outside the MOH because one of their demands was that CMAs should be allowed to sell medications as well). In July 2008, the Nepal Medical Association announced a strike by doctors after violence broke out against members following the death of a patient at the Everest Nursing Home. They demanded the implementation of the Health Professionals’ Protection Act which despite cabinet endorsement was stuck with the Ministry of Law, Justice and Parliamentary Affairs. It was resolved after “health ministry Thursday formed a committee including representatives from health and home ministries, NMA, Nepal Medical Council (NMC), the Consumer Rights Forum and private hospitals and nursing homes. Similarly, NMC has at the request of the health ministry already formed a seven-member committee to investigate the ENH incident” (<http://www.kantipuronline.com/kolnews.php?nid=153204>). Amongst other things direct strike action – frequently violent - has become one of the few ways to move political process (a form mimicked from the success of the Maoist movement).

time by organisations representing the interests of pharmacists, and the agreement was then – in part at least – rescinded on<sup>9</sup>.

A wholesaler, agreeing to the NCDA resistance, described the release of the ethical guidelines as follows: “When someone hits you, you are hurt. And when one is hurt you need to look for a redressing mechanism”. The main issue it seems is the question of bonuses as he (and others) explained. He gets samples and bonuses from medical representatives, and the consumers need to buy these, but even being salaried he still needs to feed four people he explained. The system of margins within the distribution chain is fixed by law, and so the only way to really increase profits is through the bonus system. His main issue is that if they are no longer to receive bonuses, then the companies should reduce the price of the drugs. Unless this happens, as was repeatedly emphasised to us, any benefits from the guidelines just goes to the pharmaceutical companies. This effect gave rise to the perception, true or not, that the DDA and the drug companies were in cahoots<sup>10</sup>.

“The ethical guidelines favour the manufacturers, but not the retailers and distributors and consumers... Our demand is very clear. We say, if you control bonuses then the price of medicines should be lowered. Otherwise profits go only to the manufacturers. This is wrong and we don’t agree with it... (he argues that the government can work out and fix the price of some drugs once bonuses are taken away, but they wont do this...) Various companies have given shares to the policy makers, planners and decision makers in authority and this is why the ethical guidelines have been made for the benefit of companies. Consumers should get the benefits; poor patients should get the benefits”

Another wholesaler saw the issue as one of the control of the black market across the border, and that the DDA should focus on that not on the bonus system. Another wholesaler describes this process as he witnessed it in the Tarai, and that it is linked with the problem of fake drugs:

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<sup>9</sup> <http://www.kantipuronline.com/kolnews.php?nid=122584> “Ministry of health and population has decided to review the agreement that was signed between the ministry and Nepal Chemist and Druggist Association (NCDA) after the association stopped the supply of drugs for several days. On Friday, after hours of talks between the ministry officials and representatives of the organizations that were protesting against the 12-point agreement, it was decided that the agreement would be reviewed. Expressing reservations on different points, particularly the sixth one, nine different organizations including Nepal Pharmaceutical Association, Graduate Pharmacist Association Nepal, Nepal Pharmacy Association, and Diploma in Pharmacy Students Association have been protesting. They have been demanding that one should have to have at least Intermediate degree in Pharmacy to open medicine shops in any part of the country. However, the sixth point of the agreement reached last week says that short term medicine sales training, which had been stopped since 1997, would be reopened. The organizations have been objecting to this. Citing that the 72 hours to three months short-term orientation training that used to be given to those willing to open medicine shops or clinic is inadequate, the ministry had stopped the training six years ago and permitted diploma in pharmacy course. The protesting medicine shop operators are diploma holders”.

<sup>10</sup> The director of one of the importers (“super-distributor”) for a large MNC explained that this “regulatory capture” as Abrahams would describe it, is also linked to the Nepali companies, and that DDA is biased towards the local Nepali companies. They place “road blocks” in the way of Indian companies he explained. APPON, the Association of Pharmaceutical Producers of Nepal, and has powerful connections with the DDA; they had been lobbying for “non-tariff” barriers like that all labels for all products marketed in Nepal will be in Nepali.

“There is one company called Boros Welcome (an MNC i.e. Indian company that exports to Nepal), and one of its products is called Cifran... an antibiotic. This drug is in demand in Nepal. One man from India was carrying a big bag and he went to my friend’s shop. This person offered my friend that if he buys 10 boxes of Cifran then he can have two free, and the cost of the medicine was also very cheap.

They later had the product checked and it was chalk powder, and in the absence of the DDA doing anything they took the man to the police who beat him up. He promised that he would not do this again, he reported.

Another wholesaler and executive member for the NCDA sees it as a question of rights:

“Our rights are being curtailed. Say for instance a house is to be built. Is it the responsibility of the architect and the engineer only? What about the overseer and the other workers? They are equally involved in building the house... The guideline has been implemented unilaterally, but it has to be done in a bilateral way. And you can’t implement instantly what is happening today....

This wholesaler again reiterated that the role of the NCDA is to advocate that “drugs should be available to the people and they should be affordable”. He goes on therefore to cite this as a justification for bringing back various combinations of drugs that the DDA had recently banned on the market – this encourages unnecessary poly-pharmacy - stating that if a poor man from the hills has only ten rupees, and he needs three drugs then why shouldn’t he buy them all in one cheaper combined tablet? He says that he has heard that a deal has been done between the DDA and the pharmacy colleges, and that they bribed the DDA to implement the guidelines. He asks, rhetorically (as did others) how many pharmacists will go and work in retail outlets in the rural and remote parts of the country?<sup>11</sup> He goes on to say that the Nepalese mentality is deteriorating, and that the guidelines are necessary and needed, but that it was introduced in the wrong “unilateral” way.

In an interview with one NCDA member, who had been a retailer for 26 years (although he had just in the last few months branched into the wholesalers business) he explains that there are “people”, including the DDA who are trying to denigrate their reputation by raising the issue of “deal bonus” in a bad light. He added that the Ethical Guidelines were prepared by a handful of DDA affiliated people and only after it was prepared was the Central President of NCDA called and told that the deal bonus would be lessened. He stated that in that meeting the DDA only talked about the “deal bonus” but refrained from discussing several issues that NCDA wanted to put forth: First and foremost, that the NCDA members and officials were not consulted during the preparation phase of the Ethical Guidelines; secondly that they wanted to amend some clauses within the Ethical Guidelines and thirdly the introduction of the Ethical Guidelines were done unilaterally. In short, the resistance to the guidelines, at the level of rhetoric at least, was rejected on grounds of process.

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<sup>11</sup> A persistent and emphatic criticism of the new guidelines made by those running shops, but without pharmacy degrees made in numerous interviews with wholesalers and others.

He went on to give an example, drawing on the British Medical Journal. In England it was the barbers who opened up the flesh of the patient when they needed to be operated on he said. When this was in vogue the doctors held a meeting to decide what should be done to the barbers. This meeting came out with three propositions: the first was to introduce stringent laws to stop barbers from operating; the second was to educate the barbers and the third was to let the barbers know the severe consequences that may arise if people other than doctors operated. Among these three propositions the doctors chose the third one. When this happened the barbers realized that they were doing something that they were not supposed to do and that their behaviour posed a lot of risks. In this way the barber refrained from operating without the implementation of any stringent laws. Giving this example he stated that the Ethical Guidelines should have been introduced in this way, not evoking the law.

He further added that the Ethical Guidelines talked about scrapping the deal bonus, but he stated that just by bringing out the Ethical Guidelines one cannot be sure that the deal bonus scheme will be halted. He said that at least the deal bonus is recorded on bills at the moment, and thus still possible to monitor it. He then asked can anyone be sure that there won't be any "under the table activities"? His main problem was that the Ethical Guidelines does not represent "*desh ani paristhiti*" (the country and its existing situation) and added that there are more unregistered medical halls than registered ones with the increase in Auxiliary Nurse Midwives (ANMs), Community Medical Assistants (CMAs) and Health Assistants (HAs) moving into this area of work . So he again posed the question: "Will the unregistered ones follow the guidelines?" He further said that the medicines intended for hospitals (the so-called hospital supply) are sold in the market without any difficulty, and he asked has the DDA looked at this? He claimed that time and again the NCDA had asked the DDA to bring out a rule that would require hospital supplies to have different labels, but that the DDA have done nothing about it so far. Hospital supplies come out in the market and are sold cheaply and the whole blame is thrust on the retailers<sup>12</sup>.

The president of the NCDA said at interview that their fight was with the government, and that the Ministry of Health and the DDA needed to solve their issues and demands. In this interview he clearly shows how political networks are very important for achieving these aims, stating that he went to see the Secretary for Health, and that he had suggested that in the face of inflexibility then the NCDA should show their strength as it is a strong organisation. He stated:

"We are facing legal difficulties in our trade but we are businessmen as well and our main objective is profit. But our trade is very different from other trades; it's not like being a vegetable vendor. There are legal and practical difficulties in our trade and we even face problems with capital and policies and programs. But the concerned ones who are to be responsible seem to be motivated by their own class interests... The ones who wanted to destroy our trade even tried to infiltrate among us but were not successful. But now such an unusual situation has arisen... This time around the issue of bonuses has taken centre stage. They are now stating that bonus is causing the price of the medicine to go up. They thought if they raised the issue of bonuses the public would support them and at

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<sup>12</sup> He also feels that fixing the prices of medicines is also a "drama" as no-one knows the costs of producing the medicines except the companies. He asked "euta bhaishiko ra arko bhaisi ko dudh eutai huncha ra?" (Will the milk coming from different buffaloes be the same?)

the same time it would create a rift among us. But we don't ask for bonuses, there is a unit in our organization, which have fixed the rate of margin. For the last 16 years the margin rate is 16 percent, whereas the law of the land has put the margin up to 20 percent. Bonuses are a promotional activity employed by the manufacturing company and we told the officials to talk to the manufacturing company.

As he describes it, a letter from the DDA appeared out of the blue in relation to the guidelines:

“In the letter forwarded by the DDA it had also thanked us for the support we had given for the implementation of the guideline! But the guideline has not been supported by us nor have we assented to it, so we are not satisfied with it. As I see it, the issue of bonuses was to create a rift among us and the DDA told us that the issue of promotion was not of our concern but with the manufacturing company. Given this scenario, we asked about the problems we were facing and asked for suggestions from all the 14 zones. After the problems faced by our members in all the zones were accumulated, we put forward our 12 point demands. The first demand was the abrogation of the Ethical Guideline.

The reasons for this were articulated as follows, particularly as an issue in relation to the Indian drug producers that produce all the “life saving and essential drugs”. Arguing that 65% of the drugs come from India, this market should not be disturbed he said. As he described it, this will create a differential in bonus giving and upset this supply. He is not against eliminating bonuses as such, just that the practice needs to be changed everywhere, particularly India. In response to the direct question that we had heard that the NCDA is overly influenced by the Indian pharmaceutical companies, he responded:

“I don't agree with this statement. This is blame. If the NCDA had not helped Nepali companies, would it cover 35 percent of the Nepali market? We are confident about the quality of the drugs produced by the Nepali company. We have even declared to promote the drugs produced by the Nepali company in our national convention.....

However, for companies which produce and market drugs not manufactured by Nepali companies he says:

“There are many products like insulin, which the Nepali companies have not been able to produce. Given this milieu, we have the responsibility to protect the Indian company, since such drugs are important for the people. That is why we have been telling the Nepali company to diversify their product base. Why is the Nepali company focusing on only one product, why not other molecules so that imports can be lessened?... We just can't make laws that look good on paper, we need to see how practical it is.

He goes on to complain that the numbers of retailers and wholesalers registered was less than 15,000, and with a new re-registering process introduced it went down to 6303, despite 35,000 operating in the whole of Nepal. Does the DDA have a mechanism to jail us all, he asked rhetorically? He argued for a more organic less legalistic approach, and that as the number of pharmacists increase, so then the levels of untrained retailers will fall away. Stating that there are currently only 500-600 pharmacists, as it stands Nepal just

cannot afford to have pharmacists operate all the retail outlets<sup>13</sup>. He cited other examples of how the new and emerging pharmacists are being given preference by the DDA over and above the NCDA on a range of things. He then complained that the quality of the pharmacy college isn't regulated and those being produced are not good anyway. They want the reinstatement of a training that allows those currently running retail outlets, and their relatives, to continue to do so, but this was denied. In the interview we asked about each of the demands, and for each the response was one which clawed back the interests of their members, while evoking the name of the public and people who required safer and cheaper medicines.

If we turn to the The Nepal Medical and Sales Representative Association (NMSRA) members acknowledged in interview that the ethical guidelines are very important and that they are committed to them. The MRs are the main point of contact with the doctors and the medical profession they acknowledged. However, their main issue is with the protection of the interests of the MRs, and particularly that they should be registered in the DDA:

“We have been requesting to the DDA that the Medical and Sales Representatives should be registered in the DDA. This process would help the government in various ways. It makes Medical Representatives more accountable towards the rules and regulations of the Government of Nepal. Nobody is hearing our voice.

The rationale for this, it seems, was mainly linked to the question of having well qualified representatives:

“In the Ethical Guidelines, the DDA has clearly mentioned that medical representatives should be science or applied science graduates. We agree with this provision but how to verify the educational status of our colleagues if we don't develop any mechanism to monitor it? We have been hearing that some Medical Representatives are under qualified.

It is also linked to the issue of clawing back some control from the Indian companies, and that Nepali MRs who work for them are eligible to pay Indian taxes, which they perceived as unfair.

“In this context, a positive point of the ethical guidelines is that the foreign companies exporting their products to Nepal should either open their office in Nepal or the importer is made responsible on their behalf. It is also mentioned that the Name of the chief of the marketing of domestic as well as foreign companies must be provided to the DDA and any change of person should be notified as soon as possible. If DDA implements this properly along with the registration of MRs, 60% of the ethical concern will be solved. For the remaining 40% concerns are related to the behaviours of the prescribers and the retailers.

They perceive the issue as the Association of Pharmaceutical Producers of Nepal (APPON) being the ones against them:

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<sup>13</sup> We interviewed a registered retailer who gave his name as the registered owner of several premises and attained the licence, for a fee, and then allowed non registered practitioners to run the shop.



“This is not the issue of [DDA being...] understaffed or overstaffed but it is an issue of professional and system development. APPON is against our demand. APPON and individual manufacturing companies want to make our job less secure. Different companies have different rules and regulations about our salaries and other benefits. We want to make some form of standard on it. APPON is not supporting us. APPON does not want to see a strong NMSRA in Nepal.

Finally they wanted the link between pay and sales levels rescinded. This definitely encourages non-ethical practices we were told. They said that they are often put under pressure by the companies to visit retailers and wholesalers, and to push bonuses and samples. On the regulation of prices, and curbing the bonus system, they said that a group composing the DDA, APPON and NCDA has been set up, and that they have not been invited to discuss these things, despite being the ones who know most about it.

The president of APPON, in turn, phrased his response as follows. Linking the rise of competition to the rise of gift and bonus giving, he also said:

“Ethical marketing or Ethical Promotion of medicine has been one of the most concerning issues in Nepal. The regulatory mechanism of Nepali pharmaceutical market is yet to be developed. The implementation of uniform code of conduct has been one of the major concerns of the DDA. However, pharmaceutical producers in Nepal are from different socio-cultural and economic backgrounds. They do have their own code of conduct and ethical guidelines for the marketing of their drugs. For example, an MNC working in India, Bangladesh and India may have certain norms about the promotion of the drugs. These companies might feel uncomfortable to implement the guidelines developed by the government of Nepal without the proper consultation with them. Thus, a bilateral talk among various companies, be it Indian, Bangladeshi, or MNCs should be started before developing the code of conduct for ethical marketing in Nepal... Discussions were held in this matter with various stakeholders like representative from Ministry of Health and Population, Graduate Pharmacist Association, Nepal Pharmaceutical Association, APPON, Nepal Pharmacy Council, Nepal Medical Association etc. before actually implementing the ethical guideline. Later on NCDA did not agree with the government decision.

An ex-president of APPON had the following to say. He saw medicine as different to other businesses, and burdened with these issues as are other countries, yet he saw the issue of Nepali companies giving more commissions than Indian companies:

“The ultimate victims of such types of business are the common people who are supposed to buy medicine from their own pocket. This strategy adopted by the domestic pharmaceutical companies is gravitated towards the promotion of domestically manufactured drugs. In this matter it is of immense pleasure to mention that almost all the pharmaceutical companies of the country are moving ahead by honouring the rules fixed by the DDA. Despite this, the government has annulled the provision regarding the 5-years moratorium in imports of raw materials. Similarly, the DDA has never been friendly towards the domestic pharmaceutical companies. If we implement this code of conduct properly, the price of the medicine would decrease, and we are agreed to do so. We are always

ready to implement this ethical guideline, and are ready to cooperate with the government and the ministry.

Other responses to the release of the guidelines include the following, from the CEO of the importer of a large MNC's products: he highlights that it is a problem, in that they say that there should be no deal bonuses in the market. This is impossible, as if you do not do deals then it is impossible to compete he argued. Even if the practice stops here, which it won't be added, then there is still the question of it going on in India where it is a rampant practice. If Indian companies haven't agreed to do this, then the result will just be the increase in smuggling of products across the border...

A senior Nepal Medical Association representative responds normatively to the guidelines as follows, in which he highlighted that the doctors are not to blame<sup>14</sup>:

“Department of Drug Administration (DDA) has formulated the drug regulations in order to bar doctors from receiving expensive gifts from drug companies. This is a correct move to ensure ethical practice in the medical sector of the country. The blame that majority of the doctors unethically take bribes from some pharmaceutical companies to prescribe their drugs does not hold any ground. While entering into the profession, the doctors take an oath to perform their duties with humanity, compassion, and dedication to the welfare of the sick people according to the best of their ability and judgment. To promote their brand, medical representatives provide samples of medicine to the doctors which is not unethical. Some companies give calendars, pens, diary to the doctors. This has been very common these days. This is not secret and is widely acceptable all over the world.

The main people that the guidelines needs to focus on, he suggests are the retailers and the manufacturers. The price would come down should it be implemented well, and they are in favour of them he suggested. He highlighted that doctors are not taking gifts, and nor are retailers but that these are being pushed by the manufacturers and it is this that should be stopped.

“It has been very urgent to develop prescription substitution control mechanisms particularly prescription substitution prone areas like major hospitals.... A strong monitoring team comprising of APPON, NCDA, Nepal Medical Council, Nepal Medical Association, Nepal Pharmaceutical Association, Nepal Medical and Sales Representative Association and the independent professionals should be formed and the cheaters must be penalized. The DDA has started a correct move and the

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<sup>14</sup> He also describes the difference between the NMC, and the NMA: There are some similarities and some differences. “The Nepal Medical council is a government body and the Nepal medical association is a non profit, non governmental organization. Nepal Medical Council has many rights and responsibilities related to the degree of the medical graduates, their registration in Nepal, examination, requirement of the medical schools and other related issues. Nepal Medical Association focuses on the professionalism of the medical doctors. Nepal Medical Council is formed based on the Nepal Medical Council Act, and the executive body of the Nepal Medical Association is formed based on its own constitution which is registered in the Chief District Office of Kathmandu district. However, there are some similarities between these two organizations. They are: professional development, technical competency, social responsibility and moral values.

all stake holders should come together and find out ways and means to dismiss malpractices.

We also interviewed the Nepal Medical Council<sup>15</sup>. They were particularly concerned with the security of the medical practitioners in the country at the time.... Doctors are legally bound to the code that they sign up to (in theory at least), and are not allowed to sell drugs for example:

“It is clearly mentioned in the Code of Ethics<sup>16</sup> of the Nepal Medical Council that a doctor should not run a shop for dispensing prescription prescribed by other doctors. They are not allowed, at least in our Code of Ethics, to sell medical or surgical pieces of equipment”.

On the specific issue of the new ethical guidelines he had the following to say:

“Ethics is related to the moral value of the people. It is also related to social justice and human rights and a democratic society. Ethical promotion of pharmaceutical products in Nepal is a more recent phenomenon.... The DDA is the responsible body to regulate the pharmaceutical related issues. The DDA invited various stakeholders and highlighted the need of the ethical guidelines for the development of professionalism in Nepalese context. The Chief Drug Administrator mentioned that the fierce competition of the domestic pharmaceutical companies for common products has been a serious issue in Nepal and this has hampered the domestic companies from introducing specialized products. Participants from the various organizations agreed to his highlighted points. He had also mentioned that ethical prescription, ethical marketing, ethical promotion and marketing training in Nepal. Discussion was held in a very healthy manner... When people sit together they agree on the issues but when they start to look the issues from their own point of view they do not follow the rules and regulations. Representatives of the manufacturers also agreed that there should be fair competition among the domestic pharmaceutical companies. This has happened in almost all areas in Nepal.... If the government is strong and committed and professional organizations are also committed for the betterment of the citizens, it can be implemented easily. Otherwise, this will not work. We should also be very clear that it is not an Act, it is a guideline. It is

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<sup>15</sup> His description of the NMC is as follows: “The history of Nepal Medical council is not that much long if we compare with the western countries. The Nepal Medical Council was established in accordance with the Nepal Medical Council Act 1964. Initially the Nepal Medical Council had and still has two objectives. One of the important objectives of Nepal Medical Council was to register the record of the medical graduate in Nepal, give them registration number to practice in Nepal. The second objective was to provide the quality of health services in Nepal. Under this objective, quality issues were considered. This has been focus on the faculty, hospital requirement, instruments, space and other facilities required for the medical school in these days as there have been many medical schools from the private sectors in Nepal. Without getting the approval from the Nepal Medical Council, medical schools are not supposed to start in Nepal. Otherwise they would not get recognition from the Nepal Medical Council. In this context, Nepal Medical Council has been focusing on the quality aspect of the medical education in Nepal. Like in Other countries, Nepal Medical Council has passed a medical code of ethics which all doctors registered under it are supposed to abide. This is not a big organization; doctors are consulted as and when necessary. This is how, however, an authorized autonomous body. We do have own code of ethics.

<sup>16</sup> See <http://www.nmc.org.np/code/Declaration.php> for these in full.

difficult to implement the guidelines forcefully. It takes time. Secondly, professional commitment and fair business is related to the overall political situation of the country.

On the question of the role of the NMC to curb the asking for, and taking of gifts from drug companies, he said that they are ready to punish corrupt doctors, yet:

“Some doctors might have very good relationship with the specific companies, brand and products. They might trust one specific company based on their own experience and not because of the gift and other benefits. Other people could say that Dr. X is getting advantage from the company Y so that he/she prescribes specific brand. This might not be true. We have been talking very much about our rights but we have been forgetting our responsibilities. The DDA is the main responsible body for the quality control but it has its own limitations. Inadequate human resources, incompetent human resources, lack of the support from other stakeholders and lack of the commitment of the people who are responsible for the various activities are some of the limiting factors of the DDA. Likewise, the association of the manufacturers (APPON) should monitor about the fair business within the companies. One of the important points is that we are still depending upon the Indian companies and Multi National Companies, they have their business policy and we have not been able to enforce them for the ethical promotion of pharmaceutical products. We even do not know their promotional strategies.

He further highlighted that the issue of bonuses was only one of a range of issues covered in the guidelines. This he perceived as the responsibility not of the NMC, but of APPON and the individual companies.

To finish this section we turn to a long interview with a senior member of the DDA after the release of the guidelines, and the various responses to it. During the research we had met with him half a dozen times, and the research relationship had started with him reviewing the proposal sent by the Nepal Health Research Council. In a revealing and open, yet diplomatic interview he started by stating that it really should not have been put forward by the government, and should have been made by the companies. However, they were doing nothing, and there were so many “brikiti” (anomalies) in the market that something had to be done, in part because of the governments “open policy”:

“The government does not know by how much the prices of medicines have increased. In order to gain from the hike in prices of medicines the concerned have resorted to practices that would bring about maximum sales for instance, by giving bonuses. This bonus may come in the form of products or it may be an agreement where by gifts are given for a certain number of sales of the product and these things are paid from the price of the medicines. So, in a way the market is being promoted in a “galat” (wrong) way....

He said however, that once it is put into effect shifting from guideline to code, then everyone should abide by it, and that it had been three years in the development. He claims that Nepali companies have abided by it, but that there is some confusion with regards to the importers (NB as represented by the NCDA). As such, the status (as at time of interview in May 2008) was that the guidelines were “partially” in effect, and had not yet been fully implemented. They will call some meetings to thrash out what needs to

be changed. A committee had also been agreed to be formed of stakeholders to look at the issue of the fixing of prices for 22 items, but that the government hadn't yet decided who should be the "president" of this. The problem, he said, has been with the ownership of the guidelines, which should be born by the producers and the importers. He would really rather not see it as a code and as legally binding.

He sees the problem with bonuses with Indian companies as increasing the illegal flow of medicines into Nepal. The DDA wants price reductions, not bonuses, and was clear on the link between substitution and bonuses. The producers he said were amenable to the guidelines, but had negotiated that the bonus system not be removed completely but capped at 10-20%. He acknowledged that this hasn't worked, and that it has sent the bonus system under the table:

"This is what we agreed upon and put it in the guidelines but this was not adhered to when it came to practice. Those who are ethical then refrained from giving more than what was agreed upon, but the ones whose practice was "unethical" they started giving more. However, when it came to billing, these people limited themselves to the agreed criteria of bonus but still resorted to under the table activities. And when the DDA found that some of the concerned had not adhered to the criteria what we told them was that the DDA needed their commitment when it came to practicing the guidelines. But what they are saying...what problems they put forth is that in words everyone seems to agree to abide by it but when it comes to practice what they say is the company which have not provided bonuses their products have failed to generate sales in the market... Yes, for most of the companies that have agreed to practice "ethically" so these companies have claimed that the effect of the guidelines has been the reverse, since it's the companies following the guidelines that are bearing the brunt.

He went on, as he articulated how he perceived the various responses to the guidelines that the doctors' main concern was with "prescription substitution". It is only the NCDA, he said, who have said that will not actively abide by the guidelines:

"Currently, we are focusing on one thing... on curbing bonuses and decreasing market price...trying to put a stop on "unethical" promoting... If this is what we are focusing on then, how do we go at it?... One of the grievances put forth by the NCDA is that what the DDA has been saying is that the foreign companies have not been "responsible" towards Nepal...who is accountable for the products of the foreign companies in the Nepali market, either the company itself should be responsible or it is the importer that should own up the responsibility. But what the importer says is that they cannot be held responsible for foreign companies. So, what the DDA have stated is that then if that is the case then the foreign companies needs to open up an office in Nepal. But again what the importers state is that if the foreign companies open up an office in Nepal then the importer will have no significance so that is why they have refrained to agree on this matter. So, again we told the importer to own up the responsibility of the drugs imported by the importers, but again the importers deny taking up the responsibility. This is where the problem has arisen since someone has to take up the responsibility for the products. This is one area where the NCDA have their reservations. But we are "flexible" in this matter as well. What we have told them is that the foreign company need not open their office in Nepal, but if there is

one importer for a company then that importer needs to take up the responsibility for the imported product...but what we don't mean by "responsibility" is that if the product is bad, we will put the importer in jail, but someone has to act as a liaison person so that we can get in touch with the manufacturer...the company representative needs to be here when DDA wants them...or if we file a case in the court the company representative needs to be here to defend the company...all that role needs to be fulfilled. So, this is one part but what we are saying is that if a company has more than one importer then which importer should we talk to...we will be thrown in confusion if this happens.

With regards to the question of having only trained pharmacists dispensing medicines, it became clear that the main issue is one of the government clawing back some control of the sheer proliferation of numbers of retailers, to provide some rationality into how many are required and limit the number. Once they know what numbers are required then they will select and train as appropriate. The NCDA, however, he acknowledged, want all current retailers to receive training and become legalised. In the interview he tended to – as is the case with most government authorities under a degree of stress and attack – defer to what will be done, and answer in a normative and general way.

In response to what specific difficulties they faced, he said that the whole issue has been overshadowed by the bonus debate. In short he feels that the guidelines have become too watered down and focused on the bonus issue at the expense of others. Commitment, however, from those with vested interests has not been forthcoming. If anything the reverse has happened, as highlighted above in some of the other interviews, with this behaving ethically losing their foothold in the highly competitive market.

He finished by deferring the possibility of change to some future point when the New Nepal with rise from the ashes of the old, and all will be well:

Now there is talk about "New Nepal" so maybe there will be a "New Thought" as to how this can be carried about. As of now what we have been doing is taking this issue forward from the departmental and organizational level but if we can garner political commitment in this, then implementing it won't be so difficult. So, in about 15 to 20 days we might have altogether a new structure in Nepal so that is why we are not pressing so hard at implementing this now. So, when a new structure is in place then we can again plan as to how we can go about it since we are in transition and the focus is in other things so that is why we aren't in a haste.

## Discussion

Focusing on the "pharmaceutical lens" allows a range of complex issues into view. Petreyna et al. (2006) point to how the "pharmaceutical nexus" aligns with and constitutes uncertain political, economic and ethical dimensions. This is why, we feel, the ethnography has to remain "thick", to allow what is at stake to emerge through this without over determining any particular position or what is at stake. Yet the limits of ethnography become apparent, as alone we cannot possibly capture what is happening. Too much here is going on off stage, at sites distant to, yet informing these local dimensions. But as Petreyna et al argue, the problem is one of relating the core elements

of the commercial, state regulation and public interest. We reiterate here the main points articulated in the introduction that emerge from the ethnography and interviews above:

- Firstly, “ethical promotion” is articulated as being distinct from “business” practice and that in the context of increased competition, business practices have recently flourished. Ethical promotion is repeatedly reified because the pharmaceutical industry is seen to be quite different to other businesses. The welfare of the public and consumers are mentioned as the most important issue.
- Secondly, within the complexity of the system for the distribution of pharmaceuticals a range of vested interests emerge. This is seen most clearly in response to the release of the guidelines. “Ethical” pharmaceutical promotion is articulated as a relative phenomenon, depending on the position of, and the vested interests of the parties involved.
- Thirdly, the system is also so complex and dependent on so many actors (producers and their medical representatives, wholesalers and retailers, pharmacists, and medical practitioners) that when “unethical promotion” (for example bonuses and substitution) is mentioned there is a tendency to blame other groups in the chain for the problems, rather than reflect on their own practices. This tendency to be defensive of ones own practices and the protection of various vested interests points to the difficulty of regulation.
- As such and fourthly, the question still remains as to how to regulate as so clearly articulated by the DDA? Regulation seems to be marginalised in the wake of vested interests in the market place. It was articulated by many, including government representatives, that it was not really the job of the government to create the guidelines as they did, but that the situation demanded that someone did something and so they took the lead. How then should regulation be undertaken?
- Fifthly, what is at stake here is the emergence of the Nepalese pharmaceutical industry trying to capture the markets in Nepal. While the question of the Indian producers and distributors does arise, the issue is not about multi national companies and the control of patents, rather it is around the struggle for the generic market, but one where “branded generics” are produced, marketed and prescribed. Within this situation of an emergent Nepali pharmaceutical industry, this includes a strong nationalist dimension to the idea of “regulatory capture” (Abrahams 1995).

Further discussion could develop along the lines of the state role in all this. At one level the development of the ethical guidelines on promotion was an attempt by the government to reassert its control over the pharmaceutical industry. But the capacity of the state to regulate comes into focus through the specificity of ethnography (Petreyna et al 2006). In many ways, the state has had some success in cutting the dependency on the Indian market, and has created the conditions under which the Nepali industry has begun to develop. But this has been associated with a degree of regulatory capture (Abrahams) by the Nepali companies. The emergence of a new professional force, in the form of pharmacists, and their relation to the state also creates a degree of instability in the entire pharmaceutical edifice as it has developed.

The very process of resistance from the NCDA also mimics those other forms of political resistance so visible in Nepal over the years since the emergence of the Maoist insurgency as the dominant political procesural form. You achieve your ends, not through negotiation, but through grinding things to a halt, through rights based discourses and direct action, where every interest group pushes its perspective at the expense of others. The state is constantly trying to act as a broker between these competing positions, but has difficulty in asserting itself. While beyond the scope of this paper, this seems similar to other uncertain domains in Nepal at present, and results in the political process grinding to a halt (like defining the new constitution, and who should be involved in this process).

There are also subtle theoretical issues at stake here beyond the idea that Nepal acts as an unregulated market for the expansion of MNCs and the unmaking of sovereign states, or shifts in sovereignty. This does not seem to be the case here, as what is at issue is the emergence of the Nepal industry: At stake here are unfinished, complex and the frequently misunderstood issues. For example, in Nepal the focus of some debates on access to medicines and more generalised critiques about patents clearly seems to miss the mark. This issue is around generic medications and more particularly branded generics. Intense local competition and not that of MNCs, are driving the practices of bonuses, gifting and substitution (as most of those in the production and distribution chains readily acknowledge). Central too in this arena is the question of trust of companies and brands, in a socio-political arena where trust has become severely compromised. The government has lost its capacity to inspire trust. And even international regulatory protocols are not trusted; in such an environment trust in the efficacy of a drug boils down to personal empirical relationships with companies and brands, both by practitioners and consumers. And yet this is difficult to fathom as this can be compromised by the size of the rewards (gifts, bonuses) for using particular brands over others. An issue, perhaps, related to the sheer weight of commoditization and the commercial dimensions.

The place to finish should perhaps be that of the pubic interest and to focus on the public health dimension of all this as it is the bodies of the public, and frequently marginal, who bear the brunt of all this, medically, pharmaceutically and financially. This then links to the question of how, and at what level to intervene, given all the complexity. Should we lend our support to consumer groups and local activists like the Consumer Rights Forum in Nepal, as they struggle with consumer rights issues in relation to the pharmaceutical industry (articles published in local papers on these issues were capable of reducing the prices of drugs through direct consumer action, as some of the pharmacists complained about). What political possibilities then emerge from an ethnographic understanding of this nexus?

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## **Annex: 1**

Guidelines on Ethical Promotion of Medicine, 2007  
(Unofficial document; official in Nepali Version)

### **Introduction**

The ethical promotion of medicine is vital to the pharmaceutical industry's mission of helping patients for better healthcare. Ethical promotion helps to ensure that healthcare professionals have access to information they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

The pharmaceutical industry has an obligation and responsibility to provide accurate information about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of medicines. Through the effective implementation of this guideline, it is expected to establish ethical promotional practices throughout the country in alignment with acceptable international norms and codes.

There is evidence that drug utilisation problems are increasingly encountered in many developing countries due to unethical practices of medicine promotion. Recently Graduate Pharmacists' Association -Nepal (GPAN) has conducted a study on promotional practices in Nepalese pharmaceutical market in collaboration with DDA and World Health Organization (WHO). The findings were presented in a seminar on 20 Magh, 2063 (3 February, 2007). The study results indicated the need for implementation of guidelines on ethical promotion. GPAN developed the guideline, based on Ethical Criteria for Medicinal Drug Promotion (World Health Organization, Geneva 1988) and Code of Pharmaceutical Marketing Practices, (2006 Revision)

(International Federation of Pharmaceutical Manufacturers Associations (IFPMA)).

The stakeholders discussed on the guidelines and formed a committee to revise the draft on the basis of the comments provided during discussion. Draft thus modified, with some editing from DDA, was sent again to stakeholders on 23 Jestha 2064 (6 June 2007) for further comment. The guideline is finalised after incorporating relevant comments received and has been issued from the department for implementation on 32 Asadh 2064 (16 July 2007). With some experience on implementation of the guideline, it will be approved as "Code on Sales Promotion of Medicine" - within Drug Registration Regulation, as per Clause 40 of the Drug Act 1978.

### **Guidelines on Ethical Promotion of Medicine, 2007**

#### *1. Objective*

1.1 The objective of this guideline is to promote ethical promotion of medicine to support and encourage the improvement of healthcare through the rational use of medicine and discourage unethical practices.

#### *2. Implementation of the Guideline*

2.1 This guideline is applicable to all medicines sold in Nepalese market. It applies to prescription and non-prescription medicines (over-the-counter drugs). They apply to all systems of medicine available in the country, and to any other product promoted as a medicine. The guideline is applicable to the pharmaceutical industry (manufacturers, distributors and retailers); the promotion industry (advertising agencies, market research organizations etc.); healthcare personnel involved in the prescription, dispensing, supply

and distribution of medicines; universities and other teaching institutions; professional associations; patients and consumer groups; and the professional and general media (including publishers and editors of medical journals and related publications). All these are encouraged to use this Guideline as appropriate to their spheres of competence, activity and responsibility. They are also encouraged to take the Guideline into account in developing their own sets of ethical standards in their own field relating to ethical promotion of medicine. All these bodies should monitor and enforce their standards.

### 3. Promotion

3.1 In this guideline, “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 medicine.

3.2 Active promotion should take place only with respect to medicine legally available in the country. Promotion should be in keeping with National Drug Policy and in compliance with Drug Act and regulations, as well as with voluntary standards where they exist. All promotion-making claims concerning medicine should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable medicine use or to give rise to undue risks. Claims for therapeutic indications and conditions of use must be based on valid scientific evidence and include clear statements with respect to side effects, contraindications, and precautions. The word “safe” should only be used if properly qualified. Comparison of products should be factual, fair and capable of substantiation. Promotional material should not be designed so as to disguise its real nature.

3.3 Scientific data in the public domain should be made available to prescribers and any other person entitled to receive it, on request, as appropriate to their requirements. Promotion in the form of financial or material benefits (including the deal, bonus and promotional schemes) should not be offered to or sought by health care practitioners and retailers to influence in the prescription or sale of medicine.

3.4 Scientific and educational activities should not be deliberately used for promotional purposes.

3.5 Information to physicians and health-related professionals

3.5.1. The wording and illustrations in information to physicians and related health professionals should be fully consistent with the approved scientific data sheet for the medicine concerned or other source of information with similar content. The text should be fully legible.

3.5.1. Information that make a promotional claim should at least contain summary scientific information. Information should usually contain, among others:

- \_ The name(s) of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug;
- \_ The brand name;
- \_ Content of active ingredient(s) per dosage form or regimen;
- \_ Name of all the excipients and their role in the dosage form;
- \_ Approved therapeutic uses;
- \_ Dosage form or regimen;
- \_ Side-effects and major adverse drug reactions;
- \_ Precautions, contra-indications and warnings;

- \_ Major interactions;
- \_ Name and address of manufacturer, and distributor, where applicable;
- \_ Reference to scientific literature as appropriate.
- \_ Date of production of the information;

### 3.6. Information to the general public

3.6.1. Information to the general public should be available as information leaflet or insert. Such information leaflet made available from the pharmacy should help people to make rational decisions on the use of over-the-counter medicines. While they should take account of people's legitimate desire for information regarding their health, they should not take undue advantage of people's concern for their health. While health education aimed at children is highly desirable, medicine information should not be directed at children. The information may claim that a drug can cure, prevent, or relieve an ailment only if this can be substantiated. They should also indicate, where applicable, appropriate limitations to the use of the medicine.

3.6.2. When lay language is used, the information should be consistent with the approved scientific data sheet or other legally determined scientific basis for approval. Language, which brings about fear or distress, should not be used.

3.6.3. The media employed should be considered when providing information to the general public. The following list serves as an illustration of the type of information:

- \_ The name(s) of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug;
  - \_ The brand name;
  - \_ Major indication(s) for use;
  - \_ Major precautions, contra-indications and warnings;
  - \_ Other relevant information supporting rational use of medicine, including Anupana and Sahapana in case of Ayurvedic medicine;
- Guidelines on Ethical Promotion of Medicine, Page 4 of 6
- \_ Name and address of manufacturer or distributor.

3.6.4. Information on price to the consumer and change of price should be informed to DDA.

## 4. Advertisement

4.1. Prescriptive drugs should never be advertised in any form of printing or electronic media targeting the general public. However, the company can inform the prescribers about the introduction of their brand (including its strength and dosage forms) in the market in allied professional bulletins or technical publications.

4.2. The provision of advertisement could be relaxed for OTC drugs but the information to be given in the advertisement should follow the instructions given in clause 4.6 and the text of the advertisement to be approved from DDA before going to the media.

## 5. Company Procedures and Responsibilities

5.1 Pharmaceutical industries should develop a manual on promotion of medicine to ensure full compliance with this guideline and to review and monitor all of their promotional activities and materials. A designated company employee, with sufficient knowledge and appropriate scientific or healthcare qualifications should be responsible for approving all promotional communications.

5.2 Manufacturer and distributors should have policy not to provide any kind of inducement in cash or kind, including but not limited to, free medicines to prescribers or dispensers or retail pharmacy as a promotional practice.

## 6. Medical Representatives

6.1. Medical representatives of pharmaceutical industry represent both their company and the pharmaceutical industry as a whole in the eyes of healthcare practitioners. They are the main point of contact between the pharmaceutical industry and other partners in healthcare sector. For this reason, the industry should establish and maintain high standards in the recruitment and selection of medical representatives, to ensure that well-qualified people are hired. Medical representatives should be science or applied science graduates.

6.2. Supervised training must be provided as per company's training manual developed prior to the recruitment to enable the persons to become familiar with and carry out their responsibilities. This training will require new employees to acquire both technical and scientific information on company products, as well as knowledge of the ethical principles and standards of conduct set out in this guideline.

6.3. From time to time, the companies shall conduct refresher courses for medical representatives. Companies should also encourage all medical representatives to take courses of study and self-improvement.

6.4. Medical representatives must display the highest professional and ethical standards at all times. Medical representatives are expected to understand and abide by established codes of conduct.

6.5. Medical representatives must provide full and factual information on products, without misrepresentation or exaggeration. Medical representatives' statements must be accurate and complete; they should not be misleading, either directly or by implication. Their assertions must be scientific and should not vary in any way from the official product monograph.

6.6. Company management shall work with representatives on a regular basis to ensure appropriate information exchange occurs regarding code of conduct and information on products.

6.7. Employers are responsible for the basic and continuing training of their representatives. Employers should also be responsible for the statements and activities of their medical representatives.

6.8. Under no circumstances shall medical representatives pay a fee in order to gain access to a healthcare practitioner. They should not offer inducements to prescribers and dispensers. Prescribers and dispensers should not solicit such inducements. In order to avoid over-promotion, the main part of the remuneration of medical representatives should not be directly related to the volume of sales they generate.

6.9. The foreign companies exporting their products to Nepal should either open their office in Nepal or the importer is made responsible on their behalf. Name of the chief of the marketing of domestic as well as foreign companies must be provided to the DDA and any change of person should be notified as soon as possible.

### *7. Free Samples of Medicine for Promotional Purposes*

7.1 Free samples of legally available medicine may be provided in modest quantities to prescribers, generally on request. Free samples normally should be labelled as "Physician's Sample" and price should not be printed on it. Record of distribution of such samples should be maintained.

### *8. Symposia and Other Scientific Meetings*

8.1. The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings for healthcare professionals organised or sponsored by a pharmaceutical industry should be to inform healthcare professionals about products and/or to provide scientific or educational information. Their educational value may be enhanced if they are organized by scientific or professional bodies.

8.2. The fact of sponsorship by a pharmaceutical manufacturer or distributor should clearly be stated in advance, at the meeting and in any proceedings of the meeting. The proceedings should accurately reflect the presentations and discussions. Entertainment or other hospitality, and any gifts offered to members of the medical and allied professions, should be secondary to the main purpose of the meeting and should be kept to a modest level.

8.3. No stand-alone entertainment or other leisure or social activities should be provided or paid for by the industry or distributor.

### *9. Sponsorship*

9.1 The pharmaceutical industry may sponsor healthcare professionals to attend symposia and other scientific meetings provided such sponsorship is in accordance with the following requirements:

9.1.1 Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;

9.1.2 No payments are made to compensate healthcare professionals for time spent in attending the symposium; and

9.1.3 Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend or promote any pharmaceutical product.

9.2 Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

9.3 Payments of reasonable fees and reimbursement of out-of-pocket expenses, including travel and accommodation, may be provided to healthcare professionals who are providing genuine services as speakers or presenters on the basis of a written contract with the company at the symposium or meeting.

9.4 Payments in cash or cash equivalents (such as gift certificate) must not be offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (including, but not limited to, music CDs, DVDs, electronic items etc) must not be provided or offered.

9.5 Any support provided to individual health practitioner or organization should be transparent.

9.6 Promotional aids or reminder items may be provided or offered to healthcare professionals and appropriate administrative staff, provided the gift is of minimal value and relevant to the practice of the healthcare professional.

9.7 Items of medical utility may be offered or provided free of charge provided that such items are beneficial to the provision of medical services and for patient care.

#### *10. Post-Marketing Scientific Studies, Surveillance and Dissemination of Information*

10.1 Post-marketing scientific studies for approved medicine are important to ensure their rational use. Approval for such research should be obtained from Nepal Health Research Council (NHRC) and/or Department of Drug Administration (DDA) where necessary and relevant scientific and ethical committees confirm the validity of the research. Inter-country and regional cooperation in such studies may be useful. Substantiated information on such studies should be reported to the appropriate national health authorities.

10.2 Post-marketing scientific studies and surveillance should not be misused as a disguised form of promotion.

10.3 Substantiated information on hazards associated with medicine or adverse drug reactions (ADR) should be reported to the DDA as a priority.

#### *11. Packaging and Labelling*

11.1 Appropriate information being important to ensure the rational use of medicine, all packaging and labelling material should provide information consistent with Drug Act and regulations and standards set by Department of Drug Administration. Any wording and illustration on the package and label should conform to the principles of ethical criteria enunciated in this guideline.

#### *12. Information for Patients: Package Inserts, Leaflets and Booklets*

12.1 Adequate information on the use of medicine should be made available to patients. Such information should be provided by physicians or pharmacists or health professionals whenever possible. When package inserts or leaflets are required by regulations, manufacturers or distributors should ensure that they reflect only the information that has been approved by DDA. If package inserts or leaflets are used for promotional purposes, they should comply with the ethical criteria enunciated in this guideline. The wording of the package inserts or leaflets, if prepared specifically for patients, should be in lay language on condition that the medical and scientific content is properly reflected.

12.2 In addition to approved package inserts and leaflets wherever available, the preparation and distribution of booklets and other informational material for patients and consumers should be encouraged as appropriate. Such material should also comply with the ethical criteria enunciated in this guideline.

#### *13. Promotion at Hospital Pharmacies*

13.1 Drug and Therapeutics Committee (DTC) or similar committee of the hospital should develop code for promotion of medicine by the pharmaceutical industries at the hospital. Pharmaceutical industries and medical representatives should abide by the code.

#### *14. Implementation of the Guideline*

This Guideline will be implemented from 1 Shravan, 2064 (17 July, 2007). DDA will monitor the implementation of this Guideline. DDA may develop procedures, processes and Standard Operating Procedures for monitoring the implementation.



**Annex 2. NCDA demands**

1. The Guidelines on Ethical Promotion of Medicine 2007 should be abrogated.
2. The recent price hike in medicines should be abolished immediately.
3. For registration and renewal of drugs store recommendation of NCDA should be made mandatory.
4. The amended clause in the Drug Act which states that the Letter of Permission and Recommendation if not renewed within the three months time automatically gets cancelled should be abrogated. Likewise, new clauses that have been added in the Drug Act should be amended.
5. The DDA has increased the amount for renewal from 500 percent to 2000 percent such an increment should be revoked.
6. Orientation training that was stopped must be started again.
7. The restriction put on the registration of new WHO-GMP certified pharmaceutical production company must be rescinded immediately.
8. Organizations rendering public services that have been vandalized should be compensated immediately.
9. Value added tax that should not be levied on medical and surgical items and only custom duty should be charged.
10. Any medical entrepreneur who has taken the orientation training should be allowed to do business (open up a drug store) in any part of Nepal and restriction put on this must be revoked.
11. Company inspections that are being carried out for foreign companies that have already been registered here in Nepal and whose products are already in the market should be stopped immediately.
12. A team from DDA should make a provision to visit places to renew certificates of entrepreneurs in places where they do not have their branch offices.

### **Annex 3: from <http://www.dda.gov.np/> The DDA**

#### **Background**

Government of Nepal has promulgated the Drug Act 1978, to prohibit the misuse or abuse of drugs and allied pharmaceutical materials as well as the false or misleading information relating to efficacy and use of drugs and to regulate and control the production, marketing, distribution, export-import, storage and utilization of those drugs which are not safe for the use of the people, efficacious and of standard quality.

To implement and fulfill the aim of Drug Act 1978 and various regulations under it Government of Nepal established Department of Drug Administration (DDA) in 1979.

In accordance with the objectives of the National Health Policy 1991, to improve and manage by establishing co-ordination among governmental, non-governmental and private organizations involved in the activities related to drug production, import, export, storage, supply, sales, distribution, quality assessment, regulatory control, rational use and information flow, the National Drug Policy 1995 has been implemented. Achieving the aim and objectives of National drug Policy is another important area for DDA.

Under the Drug Act 1978, the following rules and regulation and codes have been implemented as supporting tools for the active enforcement of Drug Act 1978.

Regulation on Constitution of Drug Consultative Council and Drug Advisory Committee, 2037

Drug Registration Regulation, 2038

Interrogation and Inspection Regulation, 2040

Codes on Drug Manufacturing, 2041

Drug Standard Regulation, 2043

Drug Donation guidelines have been implemented for the quality assurance of donated drugs.

#### **Objectives**

The objectives of DDA is to regulate all functions relating drug like misuse and abuse of drugs and its raw materials, to stop false and misleading advertisement and make available safe, efficacious and quality drug to the general public by controlling the production, marketing, distribution, sale, export-import, storage and use of drugs.

#### **Strategies**

Selection of essential drug to promote rational use of drugs

Establishment of regional offices at all five regions for effective decentralization

Strengthening of National Medicine Laboratory as an Independent National Drug Control Laboratory

Drug Registration on scientific facts

Promotion of rational drug use

Development of an efficient drug information system to disseminate the relevant information

Encouragement to promote and establish pharmaceutical industries to achieve self-reliance in the production of essential drugs

Effective inspection to ensure the quality of marketed products

Prevent misuse of antibiotic to combat antimicrobial resistance

Strengthen national industry to comply with WHO-GMP