Motivated Campaign To Kill Generic Industry

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In the backdrop of the Ranbaxy case in the US, Newsclick talks to Dr Amit Sengupta from the Jan Swasthya Abhyan on the situation in the pharmaceutical sector at large. Dr Sengupta says that a motivated campaign, supported by big US pharmaceutical industries, is being orchestrated to kill the Indian generic industry as they see it as a threat to their own markets.

Prabir Purkayastha (PP): Hello and welcome to Newsclick. Today we have with us Dr. Amit Sengupta, of Jan Swasthya Abhiyan. Amit, recently, the Ranbaxy case has made the headlines. Half a billion dollar settlement with the Federal Drug Authority and a huge campaign against the drug industry, talking about substandard drugs basically making out that drugs from India particularly from the generic industry is not safe. Is it very large settlement, is it something very unusual for drug companies, of course, Ranbaxy cannot be defended for whatever the problems might be. But is it really something which is completely exceptional, or is it something that other drug companies have also faced and this specific attack on the generic industry is only an excuse for the larger campaign against generics in the United States and elsewhere?

Amit Sengupta (AS): No, clearly there is a clear motivation behind the campaign. It's not an innocent campaign and the target is the Indian generic industry which by big pharma, the large pharmaceutical companies based in the US and Europe see generic industry from India as a threat in their own markets and if you really look at the kind of press that this story has been getting, it is clear that they are really trying to go after the Indian Generic Industry in order to demonise and de-legitimise it. And, for e.g., the *Fortune* blog, the long rambling story that *Fortune* carried, even the title, 'Dirty Medicine'. So, the image that they are trying to create is very clear: dirty country, producing dirty medicine in dirty facilities and warning US citizens against such medicines. Now, this contrast actually, if you go to the US FDA site, you will see, the US FDA site has a question and answer page there, where they talk about the generic medicines and what it says is that we test generic medicines regularly and they are not less safe than the other medicines, similar medicines in the market. This is what US FDA itself says. So we have to put whole story in a proper perspective. There have been several cases, some of them fairly recently where drug companies have been slapped with felony charges. The largest payout actually is by Pfizer. This case was in 2009 and among other things, Pfizer was also charged of bribing doctors, bribing various officials in order to illegally sell medicines that they were not supposed to. $2.3 billion. Then, Glaxo paid out 3 billion dollars, six times the Ranbaxy settlement. It was in 2012 and again on very similar charges of bribing doctors of actually getting people to write in journals, planted stories in favour of their medicines etc.

PP: Also the quality of medicines.

AS: The sort of parallel case that exists quite recent is again relates to Glaxo in 2010 when one of their plants was indicted for producing substandard medicines, in fact the charges against the Glaxo plant were much more serious than against Ranbaxy's plants. It included for e.g., charges that their bottling plant was so badly damaged, mal-functioning so badly, that there was possibility that it would mix two different kinds of medicines into the same package. So they were fined 750 million dollars for that. If you go to the US FDA site, every month they send out warning notices to companies. That's how US FDA works. Now, if you come back to the present case involving Ranbaxy, now, it is true that Ranbaxy lied. Ranbaxy lied to the regulators. It gave them false information but there is no evidence, and US FDA again has said this, that we have no reports of patients actually being harmed because they have taken medicines manufactured by Ranbaxy. So what actually Ranbaxy was finally indicted for, is in providing wrong documentation, in lying in the kind of documentation that they were putting together and in not adhering to some of the US FDA norms that you require to adhere to.

PP: Now, two issues here. One is getting permission to sell drugs in the United States and therefore satisfying regulatory requirements. So one set of issues really pertain to that. How they obtain these clearances, that was what was called as trying to game the system. The second is the quality of medicine and that is a separate issue of how it is being manufactured, what are called good manufacturing practices and all and how they were observed or not. Regarding the first, there seems to be a fair amount of evidence that Ranbaxy was indeed trying to game the system. Do you agree with that.

AS: Yes of course, Ranbaxy specially in the case of the drug Lipitor which is an anti-cholesterol drug, what Ranbaxy was trying to do was get a first mover advantage. In the US, after a patent expires, if you are the first generic to get the requisite regulatory clearance, then you have a six month exclusive marketing right kind of a situation where you are the only generic who is allowed to market. So that's what Ranbaxy was really aiming for and probably typical style in which much of Indian business is done, they tried to cut corners, produced documentation which was obviously figments that they created. Now, coming back to the quality, again the issue is that there have been various other independent agencies which have vouched for the fact that Ranbaxy's quality is not different from the quality of other drugs that are made by other companies including the WHO which has sent out a kind of an advisory on this because Ranbaxy is among one of the Indian companies that produces drugs in the WHO's pre-qualification programme. The South African Regulatory Agency recently has said the same thing. Now this is important because the way WHO uses the pre qualification programme is collaborative. WHO does not have its own mechanism. So it has drug regulatory agencies from different countries going to other countries to look at their facilities. So the South African Regulatory Agency actually had inspected Ranbaxy's facilities and it is based on that they are saying we did not find any problem in the manufacturing facilities in Ranbaxy. So that is something that is public knowledge. It is clearly not that, for e.g., the story in *Fortune* or other media stories that have come up. Its not that people did not know about this. This Dinesh Thakur who was the whistle-blower in the company. Now, he has written a long and rambling story; at one place he talks about how his son's ear infection did not clear with the Ranbaxy medicine and it cleared immediately when he switched over to a Glaxo medicine. Now, apart from everything else, I mean this is very poor evidence. Someone who is anywhere remotely connected to the sciences, should not be making such a claim. But, apart from that, it's the same Glaxo who two years has been indicted for more serious charges and he does not think about it. So it's obviously a motivated campaign that is now being mounted by and it has obviously been somehow supported by big pharma, by the northern governments in some ways and it's problematic for the Indian Generic industry to get out of this.

PP: Let's also look the other side of it. Ranbaxy was started by Bhai Mohan Singh and who really built a very good Indian generic company. It's also true that after Bhai Mohan Singh has left the helm of the company if you will, his son Parminder Singh who passed away recently and then his son, after he was heading it would have also.. Is it true that they were making money in a hurry and therefore initially deviated from what Bhai Mohan Singh's principle was, which was to really build a case for Indian generic industry and not aligning with multinationals and Parminder Singh's Ranbaxy really broke ranks with the Indian generic industry; aligned with the multinationals saying that becoming a supplier of generics to multinationals is preferable than fighting for, you know, protection for Indian patent regime that existed, as you are aware of this part of it. Do you think it's also trying to make money in hurry and therefore, also what leads to the current Ranbaxy scenario.

AS: At the end of the day all companies, and especially drug companies, because they have particularly gory history, would cut corners if they are allowed to. Unfortunately and this is true; unfortunately in India they work in a situation, in a system where regulation is weak. We have the laws in place. The issue is not that we don't have the laws in place. But the CDSO, the regulatory agency in India is understaffed, it's got very few resources and there are, of course, allegations of corruption, many of them or some of them have been substantiated in the past. I mean all that we have been talking earlier is not to say that our regulatory environment is what we needed to be. But, the two situations we are talking about are different. This was about Ranbaxy trying to sell in the US market and what they actually called adulterated in the US market. The definition of adulteration in the US is very different for regulatory

purposes. It means that if they have a doubt that the manufacturing process is flawed, even if there is insufficient documentation, they will call the drug adulterated.

PP: So, its the quality test of the drug, as much as proper documentation exists for the process...

AS: Exactly, as I was saying earlier, there is no evidence of that quality not being upto the standards. But it is the particular language that they use when manufacturing practices are not found. So the issue is not of adulteration but the fact remains that today most big companies in India, Indian as well as multinational, get a bulk of their drugs manufactured in the small scale sector. Loan licensing and by various others and a very large portion of the active ingredient is today been imported. 50% of that is coming from China. Nobody has seen those facilities or actually goes and sees those facilities. Today, the whole regulatory environment is in a big mess and it's true just not in India. The API, the active ingredient centres are few all over the world and every drug company today buys drugs from some of these, Chinese and some of the others. There is a case for much more stringent regulatory functions being adhered to by the CDSU which means much larger investment. But the point is this cuts across all companies.

PP: It is not restricted to generics alone.

AS: It's not as if Ranbaxy's drugs are bad, or Cipla's drugs are bad but Pfizer's drugs are better. If you really look at the Indian market, most of the drugs come actually from the same source. So it's really about the regulatory agency being able to assure patients which unfortunately today there are not able to do completely, that the drugs in the market are standard and safe. But, that's not really related to the Ranbaxy's case in the US market because they have a different system of regulating. They have different rules by which they regulate.

PP: Amit, do you also look upon this as an opportunity, if you will, that after Novartis, the pharmaceutical industry is sort of striking back because Novartis case where the patent case was lost in India is almost a blow to the pharmaceutical industry worldwide because it has gone across the globe this can be done and as of date nobody has yet gone to the WTO dispute settlement saying that India's patent law is actually discriminatory and it's not TRIPS compliant. So given the threat of the patent system being weakened, if you will, by the TRIPS flexibility which Indian case has shown, do you think it is a way of setting, if you will, balance right by helping, using this to actually strike at the generic industry worldwide and also introducing the fear that this kind of industry, if it comes in, then you are at risk.

AS: Oh, yes, I mean they have obviously gleefully lapped up the story. Isn't it? There is an orchestrated campaign that's been going around now. But at the end of the day, again finally Ranbaxy lied. Unfortunately what Ranbaxy did is washing off on the entire generic industry in India. And a lot of people, because these are technical details which are very difficult to understand unless and until you actually go through it. So a lot of people including people in India are buying this story. You have a PIL now in the Supreme Court saying that Ranbaxy's medicine should be banned. You have some some big hospitals in Bombay now saying that they have stopped buying medicine from Ranbaxy.

PP: Apollo yesterday.

AS: Yeah, so these are knee jerk reactions but this also shows the power of the campaign that is now taking place, that even in India, we are not talking about the US. Even in India, people are taking it so seriously and trying to take various actions on this.

PP: So, a self goal, if you will, after the Novartis case by the India generic industry, which today of course in not Indian at all. Its actually is owned by the Japanese.

AS: That's really the irony of the story that Ranbaxy is actually a Japanese company owned by Diachi and in fact, as we were talking about it earlier, Ranbaxy had taken a different route much earlier. By the 1990s, they had started aligning with big pharma. They tied up with LLA at one point. They had for a brief while some arrangement with Glaxo. Now, Diachi has taken up over majority share. It's unfortunate that Ranbaxy is being seen as a typical Indian company which it is not. But it is also true that, given the fact that the Indian market, the domestic market is not growing and that is because we invest so little in the public health system and there is a limit to which people can pay from their pockets. But the domestic industry, its manufacturing capacity has grown enormously. So, now if you look at the big companies, not just Ranbaxy, if you look at the top ten companies in India, the generic Indian companies, seventy percent of their production is actually being exported. Now, that's apart from the present controversy. It has a bearing on the trajectory of all these companies, not just Ranbaxy. Others are also going to follow suit as well because if they are going to compete and look at the export market and largely this is the US market and the European market. The two together is almost 2/3rds or more than 70% of the global market. That's the market that they are eyeing for. Then, it has repercussions regarding how much they will be bothered about the domestic market, one, and second that they will build linkages with big pharma to survive and that's what they are doing. Ranbaxy actually showed the way. But we do know that many other companies, some big Indian companies are tying up with big pharma through various licensing agreements etc. So that's a bigger issue that has implications for the survival of the Indian generic industry as we have known earlier which is a self reliant industry, which has some nationalistic goals etc. All that is actually starting to disappear now and the lines are starting to blur between what is big pharma and what is Indian generic industry.

PP: So increasingly it is becoming an inter big pharma fight rather than Indian drug industry versus the global.

AS: Yes, I wouldn’t say entirely. But there are elements of that you see now happening. So finally it's a fight between Diachi and the American big, Pfizer and others. Isn't it?

PP: It's the larger battle of generics versus branded patented medicine and trying to keep the patented medicines' brand value up; certainly it's going to harm.

AS: Yes, of course, the bottom line of the story is Indian generics are bad. That's what the story in the *Fortune* said - Dirty medicine. That's the bottom line of the story. That's what they want to hit at finally.

PP: As you said earlier, at the end of it what we stick is Ranbaxy lied and that's not good for Indian generic industry or the generic industry generally. Thank you very much. We will follow further developments in pharmaceutical industry and the health issues in the country with Dr. Sengupta and others. Thank you very much for coming Ami