TRANSCRIPT OF "FILE ON 4"

CURRENT AFFAIRS GROUP

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TITLE: COUNTERFEIT DRUGS

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PRODUCER: Jenny Chryss

EDITOR: David Ross

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THE ATTACHED TRANSCRIPT WAS TYPED FROM A RECORDING AND NOT COPIED FROM AN ORIGINAL SCRIPT. BECAUSE OF THE RISK OF MISHEARING AND THE DIFFICULTY IN SOME CASES OF IDENTIFYING INDIVIDUAL SPEAKERS, THE BBC CANNOT VOUCH FOR ITS COMPLETE ACCURACY.

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Producer: Jenny Chryss Reporter: Allan Urry

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ACTUALITY OF SINGING

URRY: Four year old Rebecca Edwards joins in a family singsong, but earlier this year she was fighting for her life, struck down by malaria. In West Africa, where Rebecca lives, 70% of those who die from the illness are children under five. Her family, like many living in poverty, have to make fundamental choices.

GRANDMA: You have to decide to buy the medicine or to feed the family, because if you buy the medicine, the family won't take food, and if you buy the food, the child is going to die.

URRY: But the decision to buy medicine can still be deadly. Counterfeit drugs have swept across the developing world, including useless copies of life-saving medication. It's an illegal trade and a growing one, worth as much as \$45 billion worldwide. File on 4 has been to Ghana to assess the scale of the problem. We've found a country too poor to effectively regulate its own medicines market, meaning counterfeiters can thrive. And we've investigated concerns about the behaviour of a British based international pharmaceutical company following the discovery of a fake life-saving medicine for children. We've also heard criticisms of the international body, which is

URRY cont: supposed to help developing nations protect themselves from bogus or substandard medicines. The commitment of the World Health Organisation is being called into question.

SIGNATURE TUNE

ACTUALITY AT CUSTOMS

THOMPSON: These anti malaria tablets, a lot of them, and they are fake. These ones are original. It was part of a consignment intercepted by the Customs Task Force, smuggled into the country.

URRY: At a compound in Ghana's capital city, Accra, Customs Officer Jacob Thompson is sorting through the latest big seizure of counterfeit drugs, captured just a few weeks ago.

THOMPSON: These are capsules, they are imitations. First we have to look for the hologram, from there we will detect if it's original or not. When somebody starts messing with drugs, you may not know, because they contain the same packing to the original. It's getting worse. As we keep on intercepting them, they are becoming more clever. The packaging, they use different packing just to outwit our officers.

URRY: When production of these drugs is on such a scale, it's a constant battle to keep ahead of the fakers. Organised gangs copy the holograms, the labels, the batch numbers and other security measures supposed to distinguish the real product from the fakes. Some counterfeits end up on sale in local markets.

MARKET ACTUALITY

WOMAN: This is supposed to be a cosmetics shop that sells only beauty products. They are not supposed to sell any drugs product.

URRY: A woman whose family runs a pharmacy agreed to help us cast a critical eye across the stalls at this market in the centre of Accra. We found prescription-only creams containing steroids, and dozens of other pills and potions which looked suspect. And it's from places like this that counterfeit and substandard medicines spread out into the rural areas of the country, traded by the chemical sellers and drug peddlers who provide the link with those in the bush. They are mostly untrained, but it's accepted that many sell prescription drugs illegally. There's little regulation of what amounts to a black market distribution network.

ACTUALITY OF CICADAS AND COCK CROWING

URRY: In those rural areas, most people don't have access to qualified people to help them choose their medicine.

ACTUALITY OF POUNDING NOISES AND TALKING

URRY: Rebecca Edwards prepares food for her family. There are a lot of mouths to feed. Seven children, six grandchildren and one great-grandchild. The Edwards' live in the bush. They don't have running water. When the children are sick, they have to carry them a kilometre to the nearest road and then hope they can flag down a passing car for help. But although there are no doctors nearby, Rebecca can get plenty of drugs, through the peddlers and chemical sellers.

EDWARDS: We have so many that produce medicine. Some are effective and some doesn't work well, so those that doesn't work well, the prices are cheaper. And those that are effective, their prices are high. So if you are not lucky, maybe because you are not having the money to buy the costly one that will cure the child very well for you, they will have to go and buy the cheaper one just to try your luck. If you are lucky then you will get healed.

URRY: The most reliable places to buy are usually pharmacists, but there's a critical shortage of them. Most are mainly in the cities, like Chief Essiam who believes counterfeit drugs are silent killers.

ESSIAM: If it is a fake and you are taking it, it isn't a drug that is going to kill you, but it's going to allow the illness to kill you. That is why we have to be careful with what is going to who, especially children. The mother, the African mother is so busy, so we give the drug in the morning, hopes that by afternoon there has been an improvement, but the drug is fake, so actually it's snuffing out the life of the child. If a grown-up takes a drug and it's not working, he sees it. But if a baby takes it and it's not working, nobody sees it. By the time we see that it's a fake drug, the child is just about to die off.

ACTUALITY IN LABORATORY

MAN: So now we will add 15ml of water Right? Then separate it in a funnel, right? So we just have to shake a little bit for the suspension to be uniformly distributed.

URRY: Ghana has few early warning systems in place. Testing facilities are thin on the ground. The Food and Drugs Board has this laboratory in Accra. Elsewhere a handful of pharmacists rely on basic equipment they unpack from a suitcase to try to find out if a drug is a fake. Even the big name brands are not immune from the counterfeiters. It's an industry in neighbouring Nigeria, where it's been estimated that as much of 50% of what's on sale there is bogus. Dr Dora Akunilyi is the head of Nigeria's drugs regulatory agency. She's under armed guard. Her crackdown on the gangs has led to attempts on her life. But it's a battle being fought on a bigger front. She knows that Nigeria's become the distribution hub for the rest of West Africa.

AKUNILYI: It's like a syndicate. Most counterfeit drugs come into Nigeria from India and China, in collaboration with Nigerians. It is Nigerians that go to these Asian countries and tell them, 'Produce this drug, it doesn't have any taste, just compress lactose, chalk into tablets. Put olive oil in capsules, copy this drug and get something that looks exactly like this.' And they import and sell, because these are real drugs that we have been destroying in hundreds of thousands of cartons.

URRY: Do you get a sense of how many Nigerians have been involved in this trade?

AKYUNILYI: Oh, too many Nigerians are involved. Because of our legal system we have not been able to convict what I will call the masters. We have delays in court, we have adjournments, we have court orders to open factories when we've closed them. And when a judge is transferred or a judge dies, the case starts afresh.

URRY: Although Dr Akunilyi feels let down by her nation's justice system, she says she's getting good co-operation from the major drug companies, such as the UK's GlaxoSmithKline. They've been helping her tackle problems with fakes of their brands, like the anti-malarial medicine Halfan.

AKYUNILYI: They have come up to report when they want us to have them flush out the fakes out of the system. Once we place a public alert, once we send our officers and visit all markets and all shops and look at, for instance, every Halfan bottle to compare with the counterfeit. And in five to seven days we comb the whole system, come out with the fake ones, get the process ... on how to recognise a fake one. The fact the company is better off, you can make them lose a little business, but in the end they are better off for it, because when people like ... say this is the difference between fake and genuine product, the counterfeiter is in trouble.

URRY: Like other major drugs manufacturers, GSK has impressive policies on counterfeits, aiming to protect patients worldwide, by working with government ministries, investigating and prosecuting those it helps catch. But File on 4 has discovered a disturbing incident in Ghana, which calls into question how some of those policies are put into practice. In August 2002, Ghana's Food and Drugs Board made a shock discovery. They found a counterfeit anti-malarial syrup for children on sale in a chemist. It was a fake of GSK's Halfan. The next month, the head of the board, Emmanuel Agyarko, stood up at a conference in Geneva about anti-counterfeiting, and he startled delegates with a serious accusation. We've obtained a tape recording of his comments.

ACTUALITY OF TAPE RECORDING

AGYARKO [voiced over]: We called the agent of the multi-national company and its attitude was, please don't put this out in the press. Because our attitude was, we

AGYARKO cont: were going to issue a public statement, and it creates panic to the extent that they would have to call their managers from overseas to come to our office to say, if you do this you will damage our product.

URRY: Mr Agyarko, told us when the first reports of this fake paediatric medicine started to come in, he began an investigation, centred on the country's second largest city, Kumasi...

AGYARKO: We eventually located a problem with some pharmacy business in Kumasi. We took a consignment that was there, and when we did the laboratory analysis, the active was way below the pharmacopial standard. It was completely not acceptable. It was maybe half, maybe a quarter, in that region. Our first inclination was that there was fake Halfan on the market and the public must be warned.

URRY: The regulators carried out a risk assessment, which confirmed their initial reaction about going public. It was something they'd done with other counterfeits many times in the past, and fake anti malarial products for children could hardly be more serious. But before doing so, Mr Agyarko says he met GlaxoSmithKline's representative in Ghana and discussed the matter with him.

AGYARKO: He said obviously this is fake, it is not from them. They are aware that these things happen and most of it comes through Nigeria, but he thought well, looking at the sample size, it might not be very helpful, because when you issue public alerts, this is obviously a fake product. But there is the genuine product on the market, so there was a probability that it would affect the brand to the extent that people that really needed to take Halfan, which they could find the genuine one, would stay away from it, and it would cause some public health problems.

URRY: There was a difficult decision to be made. Would a public warning put people off taking the real product, either through ignorance or misunderstanding? Would that amount to a bigger risk than quietly trying to deal with the matter in what seemed an isolated outbreak? Mr Agyarko says that certainly seemed to be the drug company's position, so despite his own risk assessment, completed before the meeting with GSK's representative, he decided not to issue a public warning after all.

URRY cont: This doesn't sit easily with Mr Agyaro's opposite number in Nigeria, Dr Dora Akunilyi, who two months prior to this was investigating Nigeria's own fake child Halfan outbreak.

AKUNILYI: I don't believe it's a valid position. We don't defend companies, we are defending the people. It is very important, because when we publish the differences between fake and counterfeit products, or when we tell a lot of the public that there is a counterfeit or fake Halfan in circulation, people will be able to now screen what they are buying. If they don't know that it is in circulation, they will not even check the packets properly before they buy.

URRY: Isn't there a dilemma about making these things public, because you might frighten people off taking the legitimate product, simply because they're worried that they might not be the right thing?

AKUNILYI: Well, it is more dangerous not to alert the public. There is more danger in keeping quiet.

URRY: But if you, for example, found that there was a very isolated case of fake Halfan syrup emanating from one particular chemist and you'd thought you were on top of that problem, would you nevertheless still be issuing a warning about that?

AKUNILYI: Well we still issue a warning, even if we find it in only one shop, because Nigeria is a very big country. If you find any fake product in one shop, you can be sure it is in many villages.

URRY: Given Dr Akunilyi's reservations, could Ghana's regulators be sure they'd contained an incident at a pharmacist when chemical sellers and drug peddlers roamed the bush, largely beyond the control of the authorities? Could GlaxoSmithKline be sure they'd put forward the right argument? We wanted to interview them about that, but they declined. There does seem to have been some fundamental misunderstandings. At first the company told us that no reports of any fakes were lodged with them, even though the head of the food and drugs board, Mr Agyarko, and his deputy

URRY cont: say there were two meetings with GSK officials, one of which included people from head office in the UK. Now, GSK have told us:

READER IN STUDIO: Our representative in Ghana was at the FDB for another reason and bumped into Mr Agyarko. The fake Halfan was discussed in passing.

URRY: GSK also insisted that:

READER IN STUDIO: At no point was any pressure put on the Ghanaian authorities not to issue a public warning on fake Halfan.

URRY: A medicines research group has been pressing GlaxoSmithKline to become more active in issuing information about fake child Halfan. The group argues it's in the interests of public safety. Last year, a doctor spotted a reference to it on an obscure website which published technical information in a journal of mass spectrometry. Dr Paul Newton, from the University of Oxford's Centre for Tropical Medicine, saw that tests had been done at GSK's own medical research centre in Stevenage. Although we've spoken with Dr Newton, we've been unable to record an interview with him, because he's conducting field research in South East Asia. Instead we've been given an account of what happened by Robert Cockburn who's a writer and researcher, assisting Dr Newton and his colleagues.

COCKBURN: Paul Newton needed this information for his research work. He wanted to know if it came from his area and he should start to investigate. He was particularly concerned about the GSK analysis, because it not only showed that there was a fake of the child Halfan, which would not work, but also that the GSK research centre had discovered that there were two potentially dangerous sulpha additives in the fake. This was information that was vital to be given to health authorities, not only where the sample had come from, but in the whole area where it's suspected that the fake drugs might be moving in.

URRY: Dr Newton was told by GSK scientists they wouldn't give any information about the tests, because for them it was a sensitive area and possibly a security issue. A leading authority on malaria, Professor Nicholas White, then wrote to

URRY cont: GSK to press them for more details. Professor White is chairman of a tropical medicines research programme and sits on committees of the World Health Organisation, examining the treatment of malaria. We've obtained a copy of his letter written on the 20th June last year.

READER IN STUDIO: I would be very grateful for information as to where counterfeit Halfan has been found, and when these discoveries were made. The sulpha drugs found in the counterfeit suspensions will be dangerous to those with allergy to this class of antibiotics. Could I ask which national and international organisations information has been disseminated to?

URRY: According to Robert Cockburn, the reply received a month later was a statement of policy from the company, not an attempt to offer specific information.

COCKBURN: A reply came from a different part of GSK, just to say that it was understood there was fake Halfan in Nigeria and Sierra Leone, but no reference was made to Ghana, no reference was ever made to the analysis that had been done by GSK, no acknowledgement, and there was no information about the spreading of public warnings. Paul Newton puts it this way. He says what he found on the internet did not add up to a public warning by GSK about the dangers of the fake child Halfan syrup they had analysed. In his own words, he says, 'To put it on this obscure website, which would never be seen by the people who needed to see it, was like putting a message in a bottle about an earthquake and hoping someone would find it.'

URRY: Again, GlaxoSmithKline wouldn't be interviewed about their position, but they told us in a statement if they had been aware of the concerns of the Oxford Group that had not been addressed, they would have taken steps to meet them and provide more information. They say they are happy to extend this information now. But they do seem less keen to put information in the public arena. GSK told us:

READER IN STUDIO: As regards warning or educating the general public and in making counterfeits easier to spot we do see that as primarily the responsibility of the authorities

URRY: And that position raises bigger questions about what consumers are told about counterfeit medicines by the big pharmaceutical manufacturers. Fake Viagra and other lifestyle drugs bought in Europe or the USA get wide publicity. But there's less hard data available on the corruption of life-saving medicines for the third world. Much of that is kept within the confines of the industry, by an organisation it funds called the Pharmaceutical Security Institute. And, it's not only academics complaining about the tight grip it keeps on what it knows. The World Health Organisation has told File on 4 that the PSI won't share valuable information with them either. Dr Lembit Rago of WHO's Essential Drugs and Medicines Policy Department has been trying to persuade the PSI to open up.

RAGO: I think they are not really eager to share the concrete cases. They are quite good in talking to us in general about the problem, trying to put pressure to us also to do probably more in this area, and eager to cooperate with us, but not really providing concrete data.

URRY: But these dialogues have been going on for years,

haven't they?

RAGO: So far it has been dialogue, but not with too many

results.

URRY: Do you get a sense you're being brushed aside then?

That they're offering a sympathetic ear but in fact not doing anything about it?

RAGO: Well, we are working on this direction, but I cannot

comment more.

URRY: Dr Harvey Bale, who speaks for the large drugs companies and their Pharmaceutical Security Institute makes no apologies for manufacturers restricting certain categories of information, gathered by investigators.

BALE: Sharing information of a very sensitive nature with officials of any international institution - not just the World Health Organisation - that does not have the safeguards of confidentiality and would potentially tip-off the counterfeiters as to the arrival of police, even within a period of one hour before arrest, gives those counterfeiters enough time to get everything packed up and moved away and escape prosecution. The information is shared fully by the Pharmaceutical Security Institute companies with institutions that are vitally important to the capture of the counterfeiters.

URRY: The industry decides what it's going to share?

BALE: No. It's been decided by the World Health

Organisation that it does not have an enforcement responsibility in the field of
counterfeiting.

URRY: Well why are they trying to negotiate

BALE: It's been decided by the United Nations ...

URRY: Why are they trying to negotiate with you to get you to open up with that information then if they've decided that they don't really want it?

BALE: I think the information to them is useful as an indication, post-operations, of information that is useful to describe the problem.

URRY: WHO's broad criticism is this: look, you come and give presentations, or your industry comes and gives presentations and talks a good game, but when it comes to delivering the sort of information that they say they want, you won't do it.

BALE: If the WHO decides to give a very high priority to the counterfeiting issue, then I think the basis for collaboration and information sharing will exist, and I think the World Health Organisation is one of the institutions that carries the kind of moral leadership responsibility that could make a difference if it were to begin

BALE cont:	to raise much more of an alarm and coordinate	
various national authorities in a fight against this problem.		
URRY:	Those criticisms raise concerns about how active the	
World Health Organisation is in the fight against counterfeiting. Dr Lembit Rago, in		
charge of quality assurance at WHO's Essential Drugs and Medicines Programme, accepts		
they are compromised.		
How much information does the World Health Organisation have on counterfeiting?		
RAGO:	Reporting of counterfeit drugs is not so good as we	
would like to have it. We have a system where governments can report to us and are very		
much encouraged to report to us cases of counterfeiting. But, as I said, reporting is clearly		
under-reporting, but we have certain data.		
URRY:	But can you actually save lives as a consequence of	
the intelligence that you've been able to gather?		
D 4 GO		
RAGO:	Counterfeiting is quite sometimes country-specific or	
region-specific. We have been issuing rapid alerts to the governments, as we did in the		
case of one counterfeit drug		
LIDDV.	One cose?	
URRY:	One case?	
RAGO:	That's one case.	
14100.	That I one case.	
URRY:	How many times do these warnings go out?	
RAGO:	The warnings we can send out, having solid evidence	
and basis for taking action are really quite rare, I must admit.		
	, C	

URRY:

counterfeiting issues?

How many staff does WHO have working on

RAGO: responsible professional, but	Directly on counterfeiting issues, we have one
URRY:	One?
RAGO:	Yes, that's correct.
URRY: Only one member of staff working on what you've recognised as a really serious problem?	
RAGO: are not really probably having enoug	It is a serious problem and I can be quite open. We h resources.
	It gets worse. File on 4 has discovered serious ch is supposed to link developing countries with materials so they can make their own medicines. It door for counterfeiters.

ACTUALITY AT KINOPHARMA FACTORY

MAN: The tablets come through the machine and it is cut, automatically cut into size and it drops into the container you see here.

URRY: In Ghana, private sector manufacturers are being encouraged to buy these raw pharmaceutical ingredients, partly because it's cheaper to make drugs themselves than buy finished products from big brands. So when the World Health Organisation helped set up a system to provide information on where to get them from and how much they might cost, it looked to be a welcome step in the right direct. It's known as the Market New Service, or MNS. The Food and Drugs Board in Ghana thinks it's a great idea. Deputy Chief Executive, Ben Bushe is encouraging its use.

BUSHE: I get information from the system, and as soon as they come we pass it on to industry and we make a strong recommendation to be able to contact some of these companies for the raw materials. We have been giving them their websites, we encourage them to go to the website for updates all the time. I think it's a

BUSHE cont: good service that they can use. What I know is also that the region has its own methods of pre-qualifying some of these manufacturers, and I think it's quite a comprehensive system, so we recommend that the industry uses the system.

URRY: That's a dangerous misunderstanding of the scheme, according to its critics, who are concerned that developing countries are being conned. Mike Anisfeld, an independent consultant who advises on best practice in the pharmaceutical manufacturing industry, says MNS is misleading from the start.

ANISFELD: If you go to the Market New Service website, you'll see that the section which deals with pharmaceutical styling materials actually has the World Health Organisation logo, and it gives the impression that the whole service for pharmaceutical styling materials is endorsed by the World Health Organisation. Well then when you say to the World Health Organisation, 'What is your involvement with this?' they come up and say, 'Well, it's a good idea.' The trouble is that people in the third world are looking for cheaper sources of raw materials, assume that the World Health Organisation has approved the sources, endorsed the sources, and therefore it must be good stuff, and it isn't good stuff.

URRY: You've investigated the service itself. What have you found out?

ANISFELD: Well, in theory it's to put the producer into contact with the person who wants to buy the chemicals. The trouble is that you don't actually get to the producer, you get to a whole series of middlemen. And the middlemen – the brokers – are those who are illicit on the service, and they say if you reach them, they will give you a quotation and then you can buy the active ingredients through them.

URRY: Can the World Health Organisation actually vouch for the quality of the brokers?

ANISFELD: Oh no. They don't have any inspection force. We're not sure what it takes to become a broker, what it takes to get on the list, and why the World Health Organisation themselves are endorsing people who are just traders, we have no idea.

URRY: It's not just Mike Anisfeld who's worried. The International Federation of Pharmacists is strongly critical of the MNS scheme, according to documents seen by this programme. But Dr Lembit Rago, responsible for quality assurance at WHO's Essential Drugs and Medicines Department would only concede some weaknesses.

The International Federation of Pharmacists has said that WHO should either remove its name from the service or should provide some guarantee of quality, because countries in the developing world that respect WHO as a brand will trust what's on that list.

RAGO: I think it's a slightly simplified approach. If people would collect together all what WHO has been doing in respect of active pharmaceutical ingredients, they would find that there is very much balance in documents and guidance to the countries how to ensure the quality.

URRY: I've got here minutes of a meeting that go back to 2002 between those from WHO representing the Market New Service and the International Federation of Pharmacists, and there's a whole list of criticisms here about product quality, about pharmacopeia specifications, the internationally-recognised specifications, about good manufacturing practice, about the screening process for those on this list, all of which have been criticised by senior figures in that federation.

RAGO: You have to look on the totality. I think it has certain probably weaknesses, as many ...

URRY: Well what are those weaknesses?

RAGO: There are a lot of listings that have no comprehensive information

URRY: If that's the case, then why has WHO still got its name on, or is associated with, a list that's providing – by your own admission – substandard information?

RAGO: That's a very good question, but as often for very good questions, there is not sometimes very good answers.

URRY: Since that interview was recorded, Dr Rago has told us he's not directly in charge of the MNS service, which is the responsibility of others in his department, and that the issue of quality of medicines has never been so high up the agenda. The International Federation of Pharmacists have been asking WHO to explain the selection process for those few companies who do appear on its MNS list. File on 4's own investigations confirm that they are right to be concerned. One of them is from the same organisation heavily implicated in the chain of supply of a contaminated ingredient which killed more than eighty children.

EXTRACT FROM NEWSNIGHT

REPORTER: It took ... the best part of a year to die. Her tiny organs were simply too badly damaged to fight anymore. An American charity tried to save her, but the 18 month old child died as she waited for a kidney transplant.

URRY: In 1995 and 1996, children in Haiti were being poisoned. They were being killed by paediatric medicine, which was supposed to help control fevers. A manufacturer in Haiti had made up the medicine, having imported what he thought was pharmaceutical glycerine to use as a suspension, but it was a fake. The manufacturer had taken the product on trust and not tested it, with tragic results. The official death toll was 88 children. But almost certainly there were more fatalities in rural areas which went unreported. David Mishael is a lawyer based in Florida, who's trying to bring a case in the American law courts against some of those who were part of the chain of supply of this fake raw material.

MISHAEL: These families were beyond devastated. It's unbelievable what happened to them. I mean, you can just imagine that a lot of these mothers buy the anti-fever medicine in Haiti and their children have fevers, and the parents are actually giving the medicine to their children, and unbeknownst to them they are killing their own children. So the psychological ramifications of what happened here, these families were just ripped apart. In some instances it was their only child who died, and it's just outrageous. I could see this happening in the 1880s or something, but not now, not with all the testing abilities we have and the high technology practices that most industrialised countries have.

URRY: America's Food and Drug Administration began an investigation. It was an international emergency because no-one could be sure if there was more contaminated glycerine on the loose, waiting to be made up into medicine. Investigators discovered the product had been bought and sold around Europe by brokers and wholesalers, that some had altered paperwork to disguise the real manufacturer. That's known in the trade as obliteration - making sure your buyer doesn't go direct to the source. Although that's done to protect profits of the brokers, the opportunity it presents for abuse is all too obvious. It also made the FDA's job that much harder. But eventually they were able to follow the trail of the poisoned glycerine eastwards, to a vast conglomerate.

MISHAEL: It was sold by a trading company in China called Sinochem International Chemical Trading Company. There are almost a thousand Sinochem companies, if not more, in China. They are basically government-owned, government-created companies or entities, but ultimately this Sinochem company obtained the product either from one of its subsidiary companies or maybe it manufactured it itself. I ran an entire search of Sinochems, and in the same Yewlong Hotel in Beijing you had a different Sinochem on different floors of this hotel and in different rooms of this hotel, and who's to say who's behind door 3 and who's behind door 4, and who's to say they don't switch every other day? So it's impossible really to realise who is the real entity that was involved in this. And the only thing that we can do is look at documents and see whose name is on the document. But again, if you obliterate the original label of the manufacturer, then you never know who manufactured it. So from an evidentiary standpoint it makes it impossible to conduct a reasonable trace-back investigation.

URRY: We wanted to ask Sinochem about the glycerine it exported, but no-one got back to us after we faxed them with our request. However, the company has previously denied any involvement in the contamination of the product. No-one's been prosecuted over the deaths of children in Haiti. If America's Food and Drugs Administration couldn't penetrate the web of companies and wall of silence thrown up by the Chinese, then developing countries like Haiti stood no chance. Further enquiries made by this programme have established that Sinochem is now banned from selling drugs in Nigeria after the regulator there investigated its involvement in three separate cases of counterfeit medicines. But Sinochem's not only still trading, it's doing so through the MNS service supported by the World Health Organisation.

ACTUALITY OF COMPUTER IN OFFICE

URRY: As part of our investigation at File on 4, we subscribed to the MNS through an intermediary. If you go onto its website, as I've been doing here in our office at the BBC, you can't see which companies are being put forward to supply the world's poorest countries with vital raw materials for medicines. But with a subscription, you get a list - and here it is. Sinochem is at number 14 of 16 on that list, which is dated 24th September 2004.

At the World Health Organisation's Geneva Headquarters, Dr Lembit Rago seemed keen to avoid the issue.

What is Sinochem doing on a list with the WHO name on it?

RAGO: Well actually, if we go to the extremes, I think we can go to the even more extremes, probably all companies in the world have killed at some point somebody.

URRY: Well hang on. Just to take that point on Sinochem, why are they on the list? Because developing countries have got – hang on – lists like this to choose their raw materials.

RAGO: One thing to remember is that the quality standards all around the world are not harmonised. So what is illegal or substandard under one legislation may be perfectly legal under other legislations.

URRY: So are you suggesting that you're comfortable with the idea that a conglomerate implicated in sending a poisoned product which ended up killing children is on a WHO-approved list that goes to developing countries to allow them to buy the same sort of starting material.

RAGO: Well I think that I am not very happy with that list, but that's my personal opinion. This list has been a subject of controversy for a long time, and I think it would be probably time again, if we get new leadership, because for the time being our department is without, to re-look at the issue, because often things are connected to the leadership.

URRY: You're blaming the leadership for this mess?

RAGO: I don't blame anybody, but I think often good things happen if leadership change.

URRY: It's not the only change that's needed. The marketplace in which ingredients for medicines are traded needs international regulation and enforcement to stop poisoned products from killing children in regions vulnerable because they can't afford to apply the standards of America and Europe. Drug companies could do more to help the WHO, but the credibility of the World Health Organisation will be at stake if it doesn't properly resource and oversee its own efforts to help those regions keep the counterfeiters at bay.

SIGNATURE TUNE