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TRANSCRIPT OF "FILE ON 4" - "COUNTERFEIT MEDICINES"

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"FILE ON 4"

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ACTUALITY OF TAPE

MAN: Okay, to make it … can we provide you … just by having some of the pills … or what do you need?

URY: Secret recordings of a man under investigation for supplying bogus medicines - thousands found their way to patients in the UK.

ACTUALITY OF TAPE

POLICE: Police. Put your hands up. Hands up.

MAN: Yes sir.

URRY: He's just been jailed, having made a fortune from potentially dangerous counterfeits, including cancer and psychiatric drugs, by exploiting European trading arrangements, aimed at keeping prices down.

THOMPSON: We exist in an extremely complex distribution system. The players in that market, not least the high street pharmacists, are in a cut throat environment, which leads them to source their medicines from the cheapest source.

URRY: Has the Government's push to cut the NHS drugs bill left the door open those who threaten patient safety - the counterfeiters? Even with proper drugs, some patients say they're suffering in the drive to persuade doctors to prescribe cheaper, generic alternatives to the expensive brands. Tonight we ask, just how safe are our medicines?

SIGNATURE TUNE

ACTUALITY AT NEWS MEETING

MAN: So this morning then. Mary, bulletins? Mary, what do you think this morning?

SAUNDERS: It was nice this morning, the lead on the grandchildren followed the programme nicely. I thought there was stuff to clip all the way through. Light and shade, plenty of local stories.

URRY: Journalist Mary Saunders reports the news in Gloucestershire. At 25 she has her whole career ahead of her, but to lead a normal life she needs help with a medical condition. Mary has epilepsy. She takes medication to prevent seizures, and that's worked fine, until last December.

SAUNDERS: I just collapsed at work, essentially. No warning of it whatsoever. I was just in a meeting and speaking to a colleague and I had a major seizure. The very upsetting thing was that I hit my head quite seriously on a metal table, a desk that was near me when I fell, and actually that was the more serious injury. I had a very, very large sort of gash on the back of my head and ended up in A&E having my head stitched back together.

URRY: Mary had trusted her usual branded medicine, called Lamictal, but that day she'd been given a different version.

SAUNDERS: Because I've always got it from high street pharmacies, they tend to give patients the branded drug. Just before Christmas I got my medication from a smaller pharmacy, just because of where I was at the time and I needed to get hold of them. And I was given a drug called Lamotrigine, which is what Lamictal is, but it's the generic version of it. And on the day that I started taking the Lamotrigine, which is the generic version, I had my first major seizure in seven years.

URRY: Generic version are supposed to be the same, aren't they?

SAUNDERS: They are meant to be the same, but that turns out probably not to be the case.

URRY: After leaving hospital Mary went to see her doctor. Could the change to a generic alternative have caused her seizure? She says he thought it likely, and altered her medical records to make sure she gets the branded version from now on. Her health's been fine since, but what happened has had other serious consequences.

SAUNDERS: As soon as you have a seizure, that's it for driving for a year. At the time I lived a good half an hour drive away from work in quite a rural village. I work quite anti-social hours, shift work starting very early in the morning sometimes and public transport just wasn't an option. So straightaway I had to give up my driving licence. I've had to move house. Obviously losing your car and having to move house are huge upheavals just to happen overnight.

URRY: And it seems Mary's not alone.

CRAWFORD: Every time an anti-epileptic drug, generics become available, we get a flurry of phone calls to my specialist nurse or myself saying, "I've had my first seizure for x number of years and I've been given a different set of tablets."

URRY: Dr Pam Crawford is a consultant neurologist, who specialises in the treatment of epilepsy. She believes switching from brands to generics can cause problems, because of small variations.

CRAWFORD: When a drug's developed it's branded, it's made by a certain manufacturer and they have a patent, and when that patent goes then a lot of other manufacturers develop preparations that are the same, but they're not quite the same. The blood levels can be plus or minus 20%. Now with most things that doesn't matter, but with something like epilepsy it can do because we titrate blood levels really quite carefully, really quite small dose increments, and you can imagine if your blood levels drop slightly this may allow a seizure to break through. We can't predict who's likely to have difficulties. Some people get increased side effects. We found overall about 10% of people had problems.

URRY: Given that there's nearly half a million people suffering epilepsy in this country, isn't there, that is quite a few.

CRAWFORD: There is. And 60% will be seizure-free on drug treatment, and you can imagine how disastrous it is if you have the first seizure for many years because you've been given a slightly different form of your drug. And people can die during seizures. Quite a lot of my patients have fractures each year as a result of seizures and other injuries.

URRY: But the Government wants to bring down the cost of the NHS drugs bill, which currently stands at £11 billion. Primary Care Trusts are encouraging prescribers to choose more generics because they are cheaper. Some GPs are becoming concerned.

ACTUALITY WITH COMPUTER

FELLOWS: Now you will notice that this is a dummy patient. I'll get into the medication screen. Let's assume I want to give him a drug for epilepsy and I want to prescribe it by brand. The Government interferes with what is being put onto these clinical computers. And if I prescribe a drug called Epilim …

URRY: Which is a branded drug, is it?

FELLOWS: Which is a branded drug. You will see it comes up there, top of the picking list, as Sodium Valproate. Right?

URRY: What's that?

FELLOWS: That's a generic.

URRY: Supposedly the same thing?

FELLOWS: Supposedly the same thing, but it's not, because the substrate, which makes it a slow release drug, is different.

URRY: Dr Peter Fellows is a senior partner in a small practice in the Gloucestershire town of Lydney. He's also a former chairman of a clinical and prescribing sub committee of the BMA.

FELLOWS: We already prescribe more generics than anywhere else in the whole of Europe, so we support that, but the Government isn't satisfied and they are pushing it more and more. It should be a clinical decision and there are many instances where generics are not sensible - for example, in slow release drugs, compound drugs and drugs for conditions such as epilepsy and diabetes..

URRY: But GPs would be expected to know that, wouldn't they? So what is forcing GPs to prescribe those things?

FELLOWS: The Government basically. They are paying GPs, in a sense, bribing them to increase their generic prescribing rates through what they call a quality and outcomes framework of the new GP contract, and through pressure from the Primary Care Trusts with prescribing incentive schemes and so on, so we are leant on. We have a PCT prescribing advisor comes here who will try and pressurise us to prescribe more and more generics - and quite honestly it's a nonsense.

URRY: These incentive schemes vary across the country, but for Gloucestershire Primary Care Trust, Dr Mike Roberts argues that those who prescribe are not being forced to make a choice to save money.

ROBERTS: Certainly in Gloucestershire the advice has been given out as guidance. There is no sanction, there is no financial pressure on GPs as such.

URRY: But there's incentivising, isn't there?

ROBERTS: There is incentivising to a small degree. We have, for example, in Gloucestershire a prescribing incentive scheme which rewards GP practices, it doesn't reward individual GPs, for reaching certain targets. Generic prescribing is only one of about five targets.

URRY: But it's illegal, isn't it, to give financial incentives to a doctor to prescribe a particular drug?

ROBERTS: But they're not financial incentives to prescribe a particular drug. Again it's …

URRY: Well what are they then?

ROBERTS: What you're talking about is getting to what is nationally agreed that about 80% generic prescribing is good. The sensible thing to do is to look at the clinical aspect of the drugs, but not necessarily to prescribe the most expensive one if there is a generic equivalent. The savings are actually quite astonishing for certain of the drugs.

URRY: But what about patient groups like epileptics who get very serious problems when there are even small changes to their drug regime?

ROBERTS: The British National Formulary suggests that those patients are prescribed branded drugs.

URRY: So how come when we speak to some epileptics they're being given generic alternatives? This isn't uncommon.

ROBERTS: The advice nationally and from the PCT is that those patients should not be changed to generic drugs. And if that pattern is there, it's wrong, because that is going against advice.

URRY: The organisation which represents British companies manufacturing prescription medicines, the ABPI, says it too has serious concerns about the effects of incentives.

FISHER: It puts doctors in a very difficult position where they have to consider not only what's right for the patient, which is perfectly proper, but also whether or not the prescription they're about to write will give them a payment or not.

URRY: David Fisher is the ABPI's commercial director. The association has taken the unusual step of bringing a case in the European courts, seeking a ruling about the health service offering financial incentives to doctors to influence prescribing. Mr. Fisher says they've spent months in discussion with the Department of Health trying to resolve the issue, but without success. He insists that legal action was the last resort.

FISHER: Prescribing incentives in general are a good thing. We would fully support prescribing incentive schemes that drive high quality prescribing. But the law on this is very clear.

URRY: But if it's so clear, why is it taking so long to resolve in the courts?

FISHER: Well, the Department of Health's position on this is frankly that the law does not apply to them. They are not a commercial organisation. However, we believe that the law is unequivocal on this point.

URRY: But isn't there another agenda here? I mean, you don't really speak for patients, do you? You speak for the industry and it looks, certainly on a superficial reading, as though what you're trying to say is, well hang on, you need to buy our expensive branded products and not move in to the generic arena any further than you already have.

FISHER: No, far from it. Generally speaking, the standard of generic medicines has improved and is of a good standard in the UK. The industry's concern is to ensure that patients who are started on one medicine and switched to another do not encounter problems because of that.

URRY: The ABPI says it expects the European courts to rule later this year. But the drive for cheaper medicines has opened the door to a much more serious threat to patients - counterfeit drugs.

ACTUALITY IN MHRA DRUGS STORE

LEE-FROST: We're in the basement of a Government building in central London and this is the central evidence store for the MHRA – this is where we keep all of the seized medicines.

URRY: The Medicines and Healthcare products Regulatory Agency, or MHRA, is Britain's regulator. Few outside the Agency have been to this secret storeroom, packed with tons of illicit pharmaceuticals.
It does have a faintly pharmaceutical whiff to it.

LEE-FROST: Not surprisingly. There is about £10 million worth of seized stuff in here, some of which is genuine, some of which is counterfeit.

URRY: Much of what's here relates to the illegal trade in so-called lifestyle drugs for erectile dysfunction, hair loss and weight control, sold through internet sites. 50 % per cent of online pharmacies are thought to be selling bogus drugs. Buying from the Internet is one thing, but millions of patients rely on the safety of medicines prescribed by doctors and dispensed by pharmacies, and now that authorised and regulated

URRY cont: supply chain is the target for criminals. Last July, Shabbir Hussain, who ran an import/export business from North London was jailed for four years for smuggling. His real line of work was getting fake lifestyle drugs from Pakistan and selling them on websites. But the MHRA's Head of Operations, Danny Lee-Frost, says that when they raided his home in Cricklewood, officers noticed some mainstream prescription pills among the chaos that Hussain called his drugs store.

LEE-FROST: He showed us to this shed, a glorified wendy house, a huge thing at the bottom of the garden, and once we got through the front doors in there, it was an Aladdin's cave. There were boxes piled everywhere. The state it was in, it was dreadful, it was all over the place. Not just in this outhouse, but once we got back into the property itself, there were bin bags full of stuff all in the kitchen. If there was an empty space available, then this stuff was stuffed in there. It was all over the place.

URRY: This was prescription only medicine, was it?

LEE-FROST: All prescription-only medicine.

URRY: Any lifesaving medicines?

LEE-FROST: Yes. There was some there.

URRY: Quantities of a lifesaving treatment for strokes and heart conditions were seized. The MHRA also discovered that just days before the raid, Hussain had applied to them for a licence to become an authorized wholesaler. He was trying to go legitimate. By law only those who are licensed are allowed to trade and distribute medicines. Even so, Hussain got his fake drugs into the system of supply to high street chemists, trading first with a small dealer in the North West, who then sold the stock to a bigger supplier.

LEE-FROST: They ended up as far as a quite large wholesaler in central England. Licensed, big company. They didn't like it. It had some discrepancies about it, about the product. They then got in touch with us.

URRY: What does the Hussain case tell you about the targeting then of the regulated supply chain?

LEE-FROST: They will always be looking for the big deal, where they can shift half a million pounds worth of product on one pallet. We're seeing people that have been involved in the internet one trying then to get legitimate to shift these large amounts, which is where there are vast profits to be made.

URRY: This time the fake drugs were discovered before they reached patients. But there were much bigger players than Hussain at work, and even though he was caught, others involved in a separate major international fraud were able to trick the system, with devastating consequences.

EXTRACT FROM 'TODAY'

PRESENTER: It's seven o'clock on Saturday 2nd June. Good morning. This is Today ….

NEWSREADER: A criminal investigation has been launched after a counterfeit prostate cancer drug was offered to a wholesaler. The batch of the hormone treatment Casodex has been recalled, but it's not clear whether it's been given to patients through other suppliers and pharmacies.

URRY: June 2007, and the most serious medical drugs alert Britain has ever seen was underway. Just how serious hasn't emerged until now. Three lifesaving medicines - Casodex for prostate cancer; Plavix, used to treat strokes and heart conditions; and Zyprexa, to control schizophrenia - had to be removed from pharmacy shelves and warehouses across the UK. The MHRA took the unprecedented step of triggering four emergency recalls in the space of a few days. Head of enforcement, Mick Deats, says it put the industry on its highest alert.

DEATS: A Class 1 recall is carried out where there is life threatening or possibility of serious adverse reactions in patients. So a class 1 recall will be conducted when we've got some evidence to suggest that we're dealing with a counterfeit

DEATS cont: medicine and it's got to patient level. It's not something that's done lightly. In fact, that was the first time Class 1 recalls were ever carried out in the UK. And in that case, healthcare professionals are communicated with, press releases go out, rapid alerts go out to other relevant agencies in this country and other countries to warn them and to ask for immediate action in removing that batch of that product from the shelves.

URRY: A UK wholesaler had spotted discrepancies in packaging of stock bought from elsewhere in Europe. Buying and selling pharmaceuticals around the EU is known as parallel trade. Both branded and generic drug prices vary from country to country, and British traders and pharmacies are on the lookout for the best deals. But, according to Graham Satchwell, a former industry investigator, this time reputable companies in the UK supply chain were duped.

SATCHWELL: All three medicines would have been medicines that pretended to be medicines that were destined for other European markets, so there's be for instance, as in the case of the Plavix they'd be in a French language pack. Very often, of course, medicines in other parts of Europe are cheaper than they are in the UK, so there's an opportunity for UK businessmen to buy cheaper products from elsewhere in Europe, repackage them into English language packs and sell them into the UK distribution chain. So this would have been a typical sort of transaction.

URRY: Nothing illegal about that, had it not have been counterfeit drugs?

SATCHWELL: Nothing illegal about it at all. In fact, the Government encourages the National Health Service to buy drugs that have been moved in this way, because they tend to be a penny or two cheaper than those intended for market by the manufacturer. Something like 20% to 25% of the drugs consumed through the National Health Service have been in the past parallel traded. The figures for this month I couldn't tell you, but certainly those have been the figures in the last few years. The other effect of being a free market is the fact these goods are traded around the country, around Europe like any other commercial product and that creates very convoluted long and complex distribution chains, which means that to check on a drug's authenticity is a very difficult thing to do.

URRY: There are many hundreds of parallel traders in the UK. What the counterfeiters are trying to do is to trick some into placing regular orders for expensive medicines. In such a trading environment, cheap deals can be tempting. Dozens of UK companies are thought to have been involved in the importation and distribution of the fakes. Many wouldn't have known what was really going on. Because of that, the fakes ended up being sold on to pharmacies, from where they were dispensed to patients with life threatening conditions. The problem is, no-one knows who.

ANNIE: I remember taking off in my pyjamas in my car in the middle of the night and going up to a remote spot, remote reservoir to walk into it, because the lady in the lake was calling to me, because I was so ill with hallucinations and paranoia and delusions that I went to join her in the lake.

URRY: In late summer 2007, by the time the fuss over the drug alerts had died down, Annie - not her real name - was suicidal. She was diagnosed as schizophrenic in 1996. But her treatment had been a success. For seven years Annie had been taking the branded drug, Zyprexa, and until the summer of 2007, she was much improved. She enjoyed good support from her consultant and a community psychiatric nurse in Greater Manchester, where she lives with her family. So much so that she started to retrain for a new career.

ANNIE: For three years, working on placements, travelling to uni on the train, looking after my family, keeping the house clean and studying, I kept it together really well.

URRY: And you were functioning throughout that, were you?

ANNIE: Oh absolutely, yeah. I mean I had other people around me and at uni I did have to be occupational health screened, just to make sure that I was fit to practice, and that was the General Social Care Council vetted me very closely, and I was deemed fit to do the course. Even my course leader didn't even know that I had this illness, because I'd not posed any problems to them.

URRY: In early May of 2007, shortly before the big drugs alert, Annie picked up a supply of her Zyprexa medication from her regular chemists, a branch of the Co-op pharmacy. Annie keeps a diary, which also helps her manage her condition, and had noted it wasn't long before she started feeling unwell.

ANNIE: I put in my diary two entries in June. I put in that I was unwell, that I increased the Zyprexa to 20mg and that I had to contact my consultant and my CPN because I was feeling very ill at the time. In the past I'd very rarely approached the care services, because I've always felt like I should deal with my own problems. In September 07 I had to go into hospital because I was so ill that I had to be sectioned under Section 3 of the Mental Health Act for six months.

URRY: Sectioned, paranoid and suicidal, Annie had suffered a profound relapse, far more serious than anything she'd experienced in the seven years she'd been taking the drug. Her diary shows she was taking her medication regularly. At the time she thought it could have been down to the stress of changing careers. While that can't be ruled out, today she's not so sure. Now, back on Zyprexa,she says she's been fine since. Drugs seized by the MHRA had only between 50% to 80% of the active ingredient in them, so could low strength counterfeits around in the supply system at that time have caused her relapse? Annie will never know, because no-one can tell her if she got one of the batches which were fake. Although warnings were sent at the time to chemists, PCTs, strategic health authorities and the industry which provides the drugs, we've discovered that no-one took charge systematically of telling the people who mattered the most - the patients. Mick Deats, who speaks for the MHRA, which issued the alerts, concedes there's been a problem.

DEATS: It's very difficult. Every effort made to contact patients and individuals and track down to the pharmacy and get the message out to those who could have taken these medicines, but quite often you won't get anything come back as the result of a recall.

URRY: So the end user actually, the patient, the important people in this, they don't actually all get told?

DEATS: Well they'll get told through press releases, you know, the press heavily cover the recall issues, and the reason press releases are put out at the time is to get the message out to patients.

URRY: But people are taking anti-psychotic drugs and may have been taking them and they're not effective are likely to become more disturbed, aren't they, and they are unlikely to pick up on press releases?

DEATS: That's possibly the case. I mean it's an interesting point you make there, because getting this message out to patients is very important.

URRY: But isn't that where the system breaks down from what you're describing, because pharmacists don't seem to be able to keep track - once it leaves them - of who got what?

DEATS: Well, they'll know how much they've prescribed and they would be able to research who they've been prescribed it from, but that can be quite a big job and they might not have a record of the actual batch that went out to them, which is why it's important we get it out in press releases.

URRY: Why wouldn't they have a record of the batch that went out to them?

DEATS: You'd have to ask the Royal Pharmaceutical Society the question about pharmacies, we don't regulate pharmacies, but you've got to think of the turnover, you know, and the amount of patients that they're dealing with and how difficult it would be for them to recall the batch on every occasion.

URRY: So we asked the Royal Pharmaceutical Society of Great Britain, the governing body for pharmacies, who keeps track of what. They told File on 4 that from the wholesaler down to their chemist shops, no-one is legally obliged to record batch numbers, currently the only way which would allow an audit through the supply chain. Worse than that, they said chemists don't keep records of which patients are dispensed

URRY cont: drugs from which batch. When the emergency happened, it was left to the individual chemists themselves to try to get in touch with their regular patients and warn them. So how well did that work? Annie, the woman who suffered a relapse of her schizophrenia, says she's been going to the same chemist in her town for many years, and yet she received no notification of any warning about Zyprexa.

ANNIE: I would have hoped that they would have had a database that they could have just accessed and then they could have informed everybody. I've had no messages, no phone calls or letters, and they've got my name and address. I rang the chemist up. They said they'd look into it, and when I rang up this time, in January this year, the second time I spoke to them they were quite concerned that I was asking questions, and they said there was no way of tracing the drugs that I had after two years.

URRY: When you put all the facts together that you've now seen, as you've done a bit of your own investigation into this, what conclusion do you come to?

ANNIE: Well thankfully I'm all right now, but how many people out there who did have the counterfeit drugs and who weren't informed have gone on to kill themselves? That's what I'd like to know.

URRY: We contacted the Co-op, the third largest high street chain in the UK, to see if they could tell us if Annie's local branch had been in receipt of fake psychiatric drugs. They didn't answer the question though, instead offering a bland statement.

READER IN STUDIO: The Co-operative Pharmacy branches implemented the recall in line with MHRA and company guidelines.

URRY: The inability of the system to reach out to the end users of these drugs is all the more serious because of the volumes which made their way through the supply chain, according to Mick Deats of the MHRA.

DEATS: We think about seventy thousand packs were in, of which we seized forty thousand. Thirty-two thousand got down to pharmacy level and some got to patients, and a recall was then conducted where some of those were recovered.

URRY: How many were recovered?

DEATS: It ran into the thousands that came back. But nevertheless a significant amount of medicine got out down to patient level, and that's why a Class 1 recall had to be conducted to try and retrieve or quarantine or seize as much of it as we possibly could.

URRY: So what has happened to the other thirty thousand that are unaccounted for?

DEATS: They would have been consumed by patients.

URRY: Thirty thousand packs?

DEATS: Yep, yep.

URRY: Do you know for sure that you've got it all off the shelves of the people that you regulate?

DEATS: You can never tell whether you've got it all. And don't forget we're not dealing with manufacturers, lawful manufacturers here who know how much their batch contains and has very strict records of how much is contained in one batch of medicines. You're dealing with criminals that are producing counterfeit medicines in another part of the world and they'll run off as many of a batch as you like. So if you recover several thousand from one batch, you can never be sure you've got it all

URRY: That does raise the rather worrying prospect that although you've got an audit trail for seventy thousand, that it could be part of a much larger consignment or consignments.

DEATS: Well, as I've said to you, this case is under investigation so we'll be looking for the audit trail of how the goods reached the UK. In the previous months the individuals that we're investigating were involved in other medicines that reached the market.

URRY: Two years on, the MHRA won't say what they've found out about the criminal enterprise behind the counterfeits. But File on 4 can reveal the man who's been a key figure in penetrating the European drugs market, from where Britain buys big quantities of medicines. He was even caught selling bogus drugs elsewhere with the same batch numbers as those recalled in the UK.

ACTUALITY AT ICE MEETING

MYERS: Good morning, Chairman Bachurst and distinguished members of the committee, it is my privilege to testify before you here today…

URRY: Julie Myers, Assistant Secretary of Homeland Security for US Immigration and Customs Enforcement, or ICE, giving testimony to a Senate hearing last July.

MYERS: In 2007, ICE learned of an individual who was exploiting our trade system with potentially lethal results. The pharmaceutical industry alerted ICE that Kevin Xu, a citizen of the People's Republic of China and owner of Orient Pacific International, was allegedly involved in the distribution of counterfeit, live-saving drugs. An investigation followed …

URRY: Three weeks ago, Kevin Xu was jailed for six and a half years for distributing counterfeit and misbranded pharmaceuticals, but it was a judge in Texas, not the British authorities, who put him behind bars. Xu was hoping to break into the lucrative American market, but ICE agents had run an undercover operation following tip-offs from the pharmaceutical industry, and they trapped him before he could succeed. Director of ICE's Office of Investigations, Marcy Foreman, says he was a major operator.

FOREMAN: Well, he was a very large distributor of these counterfeit pharmaceuticals and he could provide any type of medication that we so desired.

URRY: Any type?

FOREMAN: Any type.

URRY: That includes the lifesaving ones, does it?

FOREMAN: That absolutely includes the lifesaving medications.

URRY: Were you able to find out where his source was? Where he was getting them from?

FOREMAN: We're still working with various authorities to identify the source of where he's getting these medications from. Mr Xu was a very sophisticated international businessman and he had a vast knowledge of the import/export requirements. The bottom line is that his motivation was simply about the money and ultimate greed

URRY: And is he getting these counterfeits made at a factory somewhere then?

FOREMAN: That's what we believe, that these counterfeits are being made at some type of factory

URRY: Do you know what part of the world that might be in?

FOREMAN: We're still exploring. We suspect that it might be in China and we're working with the Chinese officials, and also ICE has an attaché office in China, and we're working with other foreign governments and law enforcement to actually pinpoint that.

URRY: They may not have traced the source, but what has emerged from the ICE operation was that Kevin Xu was already well established in Europe long before his arrest, and was running a lucrative criminal business. We've obtained copies of the secret recordings taped by undercover ICE agents, posing as potential US buyers of his counterfeit drugs, in which Kevin Xu makes that clear.

ACTUALITY WITH VIDEO

URRY: I'm watching the surveillance video now and the screen originally is split into four here. We can see Kevin Xu accompanied by an undercover agent coming into the building and then the picture changes to show us a little office where clearly they've set up recording equipment and cameras. I'm just going to skip through the tape now to just after half an hour, when there is a significant exchange, with Xu really revealing the size of his operations in Europe and a bit about what he's been up to.

EXTRACT FROM TAPE

XU: We've been doing it for six years, in the European market for six years.

AGENT: Six years?

XU: Six years. We have a partner in a European country. He's very, very huge man. He's a Swiss man, he's very, very rich. This man is …

AGENT: And he's in Europe?

XU: In Switzerland.

AGENT: Oh, Switzerland.

URRY: He's just talking about the business he's established and the partner that he's got there helping him.

AGENT: And he's had no problems with the importations?

XU: No, no, no.

URRY: And also responding to questions about how much product he's able to shift around and move around.

AGENT: Is he bringing that much in?

XU: Transport, transport, transport. So many transports! (laughs)

URRY: They're winding up the meeting now. They're talking about going out for dinner and how nice it's going to be to do business with each other, but then coming into the shot on the left hand side:

OFFICER: Police! Hands up, stand up. Put your hands up.

URRY: Someone we haven't seen up to now, and he is the arresting officer.

OFFICER: Put your hands up, stand up.

URRY: Perhaps Xu was exaggerating to impress those he thought were potential US buyers, but ICE's Marcy Foreman says he certainly knew how to exploit trading regimes within the EU to get his products onto the market.

FOREMAN: Basically in the United States we would place an order and he would just use the traditional mails or courier systems to get him into the United States, hoping that it would bypass the Customs inspection. In Europe it was a little more sophisticated. He actually smuggled goods and trans-shipped them from China into another country, and then he had them packaged into chemical drums and disguised and covered with chemicals and then the drums would be labelled as chemicals and then they would be shipped to various ports throughout Europe.

URRY: And he was already well established within Europe, wasn't he, by the time you got onto him and by the time you started to investigate him?

FOREMAN: Yes, unfortunately he had been operating in Europe for approximately two years before we became aware of what he was doing.

URRY: Have you any idea how many drugs he got into the European Union in those two years?

FOREMAN: We're still researching that and we're working that angle with our foreign counterparts to determine that.

URRY: In fact, ICE began investigating Kevin Xu in November 2006, six months before the emergency recall of cancer, schizophrenia and heart drugs in the UK. File on 4 has also spoken with two dealers who say they unintentionally imported fake Plavix, one of the three recalled drugs, months before the alerts were triggered. Xu's European operations appear to have carried on unhindered and by May 2007, thirty thousand packs of potentially dangerous counterfeits had been taken by British patients with life threatening conditions. No-one knows who they are, and because of that, no-one knows whether anyone died as a result or what effect it's had on people's treatment. For the MHRA, Mick Deats argues they responded quickly once counterfeits were discovered. But wasn't all that a bit too late, given that their American counterparts and the pharmaceutical industry were already on to a major player in this international fraud.
Are you satisfied that your agency did all it could really before these drugs actually found their way down to patients?

DEATS: Yes, this case was referred to us in early May 2007. Within two hours of the case being referred, product was being quarantined by officers from this agency to stop it getting out to the public.

URRY: There's this Chinese national, Kevin Xu, isn't there, said to be a key player in this illegal enterprise? When did you first become aware of him?

DEATS: Again that's not something we're going to discuss with you in case it impacts on the future hearing that we've got coming up.

URRY: But he's in jail in America, isn't he?

DEATS: Correct.

URRY: That's all a matter of public record really.

DEATS: Well then you'll be able to research that with the American authorities.

URRY: Which we've done up to a point. One of the things they've told us is that he was operating in Europe for two years prior to his arrest.

DEATS: That may be the case, but I'm not going to be able to comment on Kevin Xu's conviction in the States, not because I don't want to tell you about it, but because I don't want to jeopardise the current investigation …

URRY: I understand that, but I'm wondering why it took law enforcement in America to catch this guy when he'd been trading in Europe for two years?

DEATS: I'm not going to be able to give you any details about UK involvement with that case, but it will be completely disclosed to our lawyers and they'll be making decisions whether they need to use any of that in evidence against any potential trial here in the UK.

URRY: But after nearly two years no-one in the UK has been charged. The MHRA say they've learned lessons about weaknesses in regulation, practice and EU directives following this and other cases they've investigated. Those lessons will need quick implementation, because just at the end of last year, the European Commission announced the seizure of 34 million illegal medicines in targeted swoops by Customs officers of 27 member states, and that was in just a two month period. The Commission told File on 4 that they are still analysing the data, but that they were

URRY cont: concerned by the percentage of bogus lifesaving medicines recovered during those operations.

DEATS: This is a massive, massive supply chain and you're never going to make a supply chain of that size absolutely watertight, but we can do our best to try and learn from the lessons that we've seen over all the previous cases to try and encourage changes to legislation to make it tougher, make the environment more difficult for the counterfeiters to operate. It's extremely rare to see counterfeit medicine in the regulated supply chain. It's a tiny tiny fraction of a proportion.

URRY: That's not much consolation to the thirty thousand packs that were taken by patients that you've identified though, is it?

DEATS: Absolutely not, and that's why this case has been taken so seriously will, we hope, lead to changes in the law in Europe and in the UK and we'll take the offenders to court.

SIGNATURE TUNE