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DRUGS SHORTAGES: PROFITS BEFORE PATIENTS

A 52' & 90' investigative documentary
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NOTE OF INTENT

Are we living in the final hours of universal access to medicines?

During the last ten years, drug shortages have been on the rise. 1,200 treatments and vaccines were missing from French pharmacies and hospitals last year, thirty times more than in 2008, according to the French National Agency for the Safety of Medicines (ANSM). In Austria, the morning-after pill is regularly missing from city pharmacies, as are analgesics, anticoagulants and preparations for diabetics. In Germany, Europe's largest drug market, 271 drugs were unavailable in 2019 (compared to 42 in 2013) and 94% of pharmacists failed to obtain antibiotics, corticosteroids, anti-cancer drugs, treatments for hypertension, heart disease, etc. from their wholesalers. Alkeran's vials, used against bone marrow cancer, disappeared from the country for months. And Caelix, used in chemotherapy to treat breast cancer, remained unavailable for a year and a half worldwide.

Thus, a reality that was thought to be reserved for poor countries or planned economies is now affecting rich countries: drugs out of stock for an indefinite period of time. Yet access to medicines in sufficient quantity, with assured quality and at affordable prices is guaranteed by the United Nations.

How is such a crisis possible in Europe and North America, homes to the world's largest pharmaceutical groups, which design and market the main medicines? Why is it that an industry with an annual turnover of USD 1 000 billion, half the size of the automotive sector, is unable to meet global demand?

To understand this phenomenon, which seems to defy the ordinary laws of supply and demand, we will explore the unfamiliar and misunderstood economics of medicine to tell the story.

Our main areas of investigation will include aspects that are still poorly documented: the irruption of Bangladesh as a production site; the implementation of patient sorting in French and German hospitals (even before the coronavirus episode); the search for alternative solutions to bypass Big Pharma in the United States; the domestic relocation of strategic drugs with the example of the French Armed Forces Pharmacy.

We will unveil the manufacturers' industrial strategies. These shortages are first of all the result of a globalization of pharmaceutical manufacturing that emerged twenty years ago, when the giants of the industry decided to offshore part of their production lines to Asia. In order to reduce costs, 60 to 80% of raw material manufacturing left the old industrial countries, the main consumers of medicines, in favour of emerging countries with lower costs and more flexible standards. This is the case for the active ingredients' production of generic drugs.

Some very common molecules now come from a single plant. A defect in production

tools (hygiene, non-compliance with standards, etc.), a shortage of raw materials or insufficient production capacity are the cause of two-thirds of the world's medical or pharmaceutical products' shortages.

What is less well known is that Bangladesh is becoming the new source of supply for pharmaceutical companies, where industrial hygiene standards are less restrictive and production costs are lower.

The shortages are also the result of a purely financial logic. The economic model of the laboratories is based on temporary monopolies of new drugs. Once the patent has fallen into the public domain, they do not hesitate to stop production definitively, with no consideration for public health.

In their place, they willingly substitute new molecules at prohibitively high prices, several tens or even hundreds of thousands of euros for the latest anti-cancer treatments. Thus, this form of voluntary, organized shortage, which never affects the latest innovations, allows laboratories to impose on public authorities the replacement of inexpensive and unprofitable drugs by more beneficial molecules... especially for their shareholders.

How long will our healthcare systems be able to keep up with such fees? Some countries, such as the United Kingdom, are refusing to pay for treatments that are a burden on their public finances. In France, a treatment for hepatitis C, which appeared in 2014, has been reserved for the sickest patients because it is too expensive: 46,000€. The same product was sold in India at 550€.

Health is a field torn between contradictory positions, the health of citizens and the profitability of pharmaceutical companies.

It is the subject of a perpetual tug of war between the States and the manufacturers, who negotiate the tariffs over the counter, country by country. For example, drugs whose price is regulated in France are sold cheaper in some of our neighbouring countries. With the support of Jaume Vidal, from the NGO Health Action International in Amsterdam, we will show that labs and distributors give priority to countries where their sales are most profitable...

What is scandalous about these drug shortages is that it takes patients, who are-tax payers, hostage while they are the main financiers of the pharmaceutical industries: without public money, without State intervention, via public research, or the Research Tax Credits which very generously finances the private sector, the legal protection of innovation, partial or total reimbursement by our compulsory social protection systems, many innovations would not see the light of day. In this sense, medicines are also public goods that should not be subject only to the laws of the market.

THE INVESTIGATION

1. Medicines, a strategic geopolitical asset / Covid-19, a litmus test

By spreading like wildfire across the globe, Covid-19 showed that everyone, rich and poor alike, was vulnerable to a shortage in medicines... Except perhaps for the world's pharmacies: China and India.

The pandemic has highlighted the dependence on Asia for the manufacture of active ingredients – the most important elements in drugs, the molecules that actually cure us. The problem only worsens when Chinese factories are shut down or when protectionist measures are enacted to serve the local populations first.

We will remind the viewers that, in March, India banned the export of essential active ingredients such as paracetamol, for fear of running out. France acted in much the same way for the drug that was the most talked-about during the pandemic: hydroxychloroquine, one of the few entirely manufactured by Sanofi in Europe. Medicine is becoming a strategic product at the heart of geopolitical relations.

The graphics will be adjusted to the Covid-19 pandemic's current status during the editing phase. An all the more essential adjustment that our documentary may well come out around the same time as a vaccine for this coronavirus...

2. Paracetamol: dependence on Asia, the result of a deliberate choice by the pharmaceutical industry

Paracetamol is the world's best-selling drug. We will take viewers on a behind-the-scenes look at the manufacture and distribution of this popular drug. We will show that the pharmaceutical industry has deliberately chosen to relocate the essential stages of its production in order to cut corners. We will reveal that on a box of paracetamol bought for 2 euros in a pharmacy, the cost of the active ingredient, which makes us so dependent on foreign countries, is between 2 and 8 cents!

We will interview the former employees of the factory that produced the active ingredient in the drug until 2008 in France. We will follow the director of Seqens, the biggest producer of fine chemicals in France and fifth in the world – a pivotal sector for pharmaceuticals, which produces paracetamol in China. He will take us on a tour of his factories in the Middle Kingdom. He will explain the conditions necessary to bring back this phase of paracetamol production, which is harmful to the environment.

In 2017, China tightened its regulations to limit soil pollution. Thousands of fine chemical plants have closed, leading to consecutive shortages of drugs around the world. We will interview the CEO of Sanofi, which is supposed to relocate the manufacture of Doliprane (its brand name) to France, whereas today, the laboratory is limited to transforming the powder into tablets and then packing them.

3. Prices and shortages: quality at stake

China does not want to stop at simply being a supplier of raw materials and active ingredients. It intends to become a major global pharmaceutical power by exporting ready-to-use medicines. They have already started with some antibiotics, such as penicillin. Chinese companies invested in production by offering very low manufacturing

costs in the 2000s to attract American and European companies, to the point of achieving a dominant position on the market by eliminating all foreign competition. These “cartels” of companies then agreed to raise prices.

Chinese factories do not give priority to quality and production safety. Between the refusal to let certain factories undergo safety inspections, dubious production conditions and deliberately hidden documents... Can we trust the quality of medicines imported from China? Recent scandals suggest that we in fact cannot: the 2008 Chinese heparin adulteration, or more recently the 2018 valsartan (a heart medication) problems, have led to product recalls and thus to supply tensions.

4. Big Pharma's neglect of unprofitable life-saving drugs

The documentary will focus on different families of drugs whose production shutdowns have disastrous consequences, to varying degrees, on patients. Resuscitation products were desperately needed during the Covid-19 crisis. Without them, surgery under anesthesia was not possible either. Our camera followed the boss of Intas, India's leading producer of generics – copies of the drugs. He manufactures one of these anesthetics, Midazolam. He will explain to us why his low-cost products are preferred and will show us the manufacturing process in India.

Anti-cancer drugs are also among the vital medicines most affected by supply shortages. Not the new treatments, which are sold at premium prices, but the old ones, which are no longer protected by a patent and are therefore cheaper, with the arrival of competition from generics. As a matter of fact, the brand new products are never in short supply, but those that the pharmaceutical industry is abandoning because it considers them insufficiently profitable are hit the hardest.

A tragedy for bladder cancer patients like René: Sanofi has stopped production of BCG Medac and the small German laboratory Medac does not have sufficient capacity to take over and meet the needs of all patients. So much so that a point system has been put in place to sort out who will receive their drugs first...

5. Those who fight against shortages and for patients

In Mexico, a lawyer sued the state because her clients – more than 60 parents of children suffering from cancer – found themselves without any treatment because their hospitals had shortages. The activist thus obtained these crucial medicines for them, forcing the administration to better organize itself to secure their supply chains.

But it is difficult to fight these shortages in court... In the United States, a lawyer has been fighting for many years for 17 patients suffering from a serious and rare disease: Fabry disease. The only existing drug, Fabrazyme, was in short supply until 2012; it was manufactured in a single American factory, and it had a contamination accident. He therefore filed a class action suit against the US Food and Drug Administration (FDA) and the laboratory. The case has still not been to court, but it has already led the Obama administration to issue executive orders for the FDA to list drug shortages.

6. Patients, the first victims of shortages

Non-vital but essential everyday remedies are also neglected by the major laboratories. Hormonal pills, mainly taken by women, are regularly out of stock. Their ultra-sensitive

dosage makes it difficult to find the right treatment. Women sometimes take years to find the right medication to treat their thyroid problems, or those related to menopause.

They might literally find themselves without a plan B overnight, when the laboratory stops production or does not make up for the stock shortages. Catherine found out the hard way, she has literally toured Belgium to try to stock up on Orgametril, produced by the American company MSD, the only drug that soothes her constant headaches.

Contraceptive pills with the fewest side effects are also out of stock in French or Dutch pharmacies. In the Netherlands, it is a never-ending struggle to find the morning-after pill, an emergency remedy by definition!

In the United States, Pfizer has abandoned the abortion drug market, under pressure from pro-life lobbies. The Scandinavian laboratory Nordic Pharma is the only one to market them in France, for example. This monopoly situation increases the risk of stock shortages.

7. European neighboring countries in competition with each other

Since February in Romania, finding Euthyrox – the German name for the old Levothyrox formula, produced by the German Merck – is damn near impossible. As this is the European state with the lowest drug prices, it is the last served.

Firstly, because in the event of supply tensions, pharmaceutical companies favor countries where they can sell them at a higher price, but also because there is a parallel market for medicines there. Wholesalers buy the remedies from Romanian pharmacies and divert them to resell them in Germany in order to make more profit.

Romanians are used to coping however they can and those who can afford it try to obtain medicines from abroad or from the black market. Except that with the closure of the borders during the Covid-19 crisis, thousands of patients were left without this essential treatment taken by 5% of the population.

This competition between countries is linked to the system for setting drug prices, which is the result of a balance of power between governments and pharmaceutical companies. Those who put their profits before the interests of patients do not hesitate to blackmail. The South African laboratory Aspen, for example, has threatened to stop supplying the Italian market with anti-cancer drugs if prices were not raised. And it paid off: it obtained a price increase of between 300% and 1,500% of the initial price... before being sanctioned by the courts.

8. The challenge of relocation

Pharmaceutical giants like Sanofi have only gotten stronger from this health crisis. States are outbidding each other with public subsidies to encourage them to produce on their soil. At the same time, alternative solutions are emerging to thwart the market logic that takes precedence over public health.

Such as the one initiated in the United States: 1,200 American hospitals have joined together in a non-profit foundation, Civica RX, to set up their own pharmaceutical plant near Salt Lake City and thus become self-sufficient in their supply of old drugs that are in high demand but little produced because they are less lucrative, such as heparin. Following the Covid-19 crisis, Civica RX joined forces with Phlow, a company picked by the Trump administration to produce active ingredients and drugs on American soil.

These innovative solutions do not yet make it possible to break away from the very first step in the drug production process: industrial chemistry, to produce the raw materials essential to the development of the core substances in drugs.

What if the solution were to be found in Canada? A nonprofit institute hosted by the University of Alberta's Faculty of Pharmacy is developing a local production network for drug raw materials, including two used in resuscitation to keep Covid-19 patients alive: Propofol and Cisatracurium. But not every country has the petrochemical resources and expertise to become self-sufficient at absolutely every step of the production chain...

CHARACTERS & LOCATIONS

In order to offer different perspectives, we will select key figures in the drug manufacturing chain, lawyers and activists who are fighting alongside victims against shortages, and pharmaceutical industry “penitents” who are putting in place concrete alternatives. Potential candidates:

➤ Executives in Asian pharmaceutical giants

Like **Binish and Nimish Chudgar**. The two brothers run the Indian leader on the generics market. It produces Midazolam, an anesthetic; and hydroxychloroquine, from the active ingredient phase to packaging. Intas exports them to hospital pharmacies all over the world. Originally, the family ran a painting business... until the third sibling, Urmish, became seriously ill with cancer. Faced with the exorbitant cost of chemotherapy, the Chudgars started manufacturing cheap drugs.

Having become one of the world leaders in the sector, they set up a European subsidiary to supply the Old Continent. After recovering, Urmish became an oncologist. The scientist of the bunch now advises his two brothers on the anti-cancer drugs that are necessary but often under supply pressure. When their patents expire and Big Pharma abandons them, Intas swoops in to take over. The Chudgar family, now one of the country's wealthiest, is ready to open the doors of its factories based in Gujarat, in the heart of pharmaceutical India.

➤ Directors of active ingredients plants

Like **Robert Monti, general manager at Seqens**, the 5th largest fine chemistry company in the world (with a turnover of 1 billion euros), which now produces its paracetamol in China. The company had to deal with the offshoring plans implemented by Rhodia and dictated by the cost saving demands of its main customer, Sanofi. Robert Monti lets us film his plants in China, Germany and France. He will explain how we can bring this – highly polluting – phase of paracetamol production back to Europe... And he will not shy away from criticizing his customers (“Big Pharma”) and the conditions under which certain active ingredients are produced in China, such as heparin, which has caused uproar about the quality of the “made in China” drugs he also produces.

➤ Big Pharma representatives

Olivier Bogillot, CEO of Sanofi France, involved in our examples of Paracetamol and BCG Medac (bladder cancer). Today, the company is taking up the argument of the threat of a loss of sovereignty in the face of over-dependence on the Middle Kingdom; even though it had a decisive hand in this state of affairs. And it is taking advantage of this opportunity to ask for financial aid from the State to repatriate the production of raw materials to Europe. Sanofi took the opportunity to announce the creation of a subsidiary to bring together its European businesses dealing in active ingredients. A company, grouping together six European plants already supplying Sanofi, should be created by 2022. It would thus become the world's second largest producer of raw materials for medicines. In reality, Sanofi seems to be reacting to China's announcement that new health standards will be implemented from 2021 onwards – to limit the exposure of workers and people living near drug factories to chemical risks.

➤ **Patients' lawyers**

Like **Allen Black, patent attorney in Pittsburgh**, Pennsylvania. He first worked for laboratories; he started out in molecular immunology and then moved on to specialist in patent law. But when a neighbor experienced a drug shortage and asked for help, he realized the magnitude of the problem and took up patient advocacy. He had two landmark cases: concerning Vitamin A Injection (aquasol), he filed a lawsuit against Hospira to force the company to continue production, which was dismissed by the Supreme Court. He is also involved in a pending class action lawsuit against the Genzyme lab and the FDA over a shortage of Fabrazyme.

Or the **Mexican lawyer Andrea Rocha**. She founded the association Yo te defiendo, which represents the parents of more than 60 children suffering from cancer and deprived of access to medicines. She initiated a priority preliminary ruling on constitutionality that forced the state to give them access to medicines. Patients from all over the country, mainly women and children, have been the main victims of the shortage, which began in 2017 and flared up a few months ago. They have taken to the streets to seek medical care in Mexico City, and in the states of Veracruz, Chihuahua and Puebla in early 2020.

➤ **Leaders of institutions and organizations seeking alternatives**

Like **Martin Van Trieste, a “defector” from pharmaceutical giant Amgen**. He runs Civica RX, a non-profit organization created to circumvent Big Pharma's commercial stranglehold. In Lehi, Utah, he started manufacturing generics for American hospitals.

➤ **Activists working for Big Pharma transparency and access to medicines for all**

Like **Jaume Vidal**, senior policy adviser at **Health Action International in Amsterdam**. His NGO analyses the causal links between drug prices and access to treatment around the world. A specialist in shortages, he deciphers the financial and communication strategies – sometimes including blackmail – of pharmaceutical companies like Sanofi, “responsible for shortages that take patients hostage while managing to obtain public subsidies”.

And like the American **Rosemary Gibson**. Health policy advisor at the Hastings Center, a bioethics research institute, she also authored China Rx, a survey that reveals her country's dependence on China and the associated diplomatic risks. She is regularly consulted by the administration and the Senate on this issue. Since the Covid-19 crisis, she has been a board member at Phlow, a small company that defines itself as a “public benefit corporation”, tasked by the Trump administration with manufacturing the first stages of essential Covid-19 drugs on American soil.

Secondary characters, patients suffering from long-term conditions (cancer, etc.), leaders of patient advocacy associations, doctors or hospital pharmacists will be filmed in the various countries where we will conduct our investigation.

DIRECTOR'S NOTE

"Drugs: Profits before Patients" is an investigative documentary with a powerful narrative force because the theme of the documentary has two opposing poles:

- The big laboratories that follow the laws of the market. Their goal is to make the most of the sale of their drugs.
- The patients, for whom the laws of survival apply. Their quest is to obtain their treatment, the guarantee of their survival.

I will therefore include the documentary in this archetypal story of a confrontation between two forces. The object of the conflict is the medicine, an elixir from which each side tries to profit, financial profit or health profit. One of the narrative engines of the film and its rhythm is the back and forth between these two inextricably linked realities.

The investigation will progress in clearly identified thematic blocks embodied by dramatic human situations. For each theme, I will start from a human case and I will go back up the thread of the political, industrial or financial mechanics that prevent its treatment. Each of the major themes will thus become an episode in the global battle between the two forces involved.

Example starting point: an American patient deprived of Bacitrium, treatment of urinary tract infections. The release will come from the decision of hospitals to manufacture this drug themselves via their own non-profit laboratory, Civica RX, where 18 drugs - previously in short supply - are currently being produced.

This narrative process places the spectator each time in a logic of conflict, in which at least one of the main actors is clearly identified (the patient). The human aspect is essential in this film. Obviously, secondary conflicts arise from this initial situation:

- City or hospital pharmacists cannot fulfil their role: to deliver the treatments
- Doctors are still trying to accomplish their mission: to heal.
- Foundations and NGOs struggle with laboratory interests
- Laboratories are caught in a vice between their search for profit, the time of research, and the time of marketing...

The characters will be portrayed in a distinctive way according to their role. At the beginning of each block, I will work with the DOP on similar framing: the patient exposes his challenge, his pathology, the type of medicine that could save him and what prevents him from getting it. Eventually, the patient doesn't speak live, but we hear his or her own voice in off-screen on himself / herself. The shots will be tightly framed, to evoke powerlessness and the blocking situation.

I will present the secondary characters in the action, whether they work for their own

interests or for those of the patient. The camera will then become mobile, fluid, favouring connections in movement, to visually restore the idea of the chain of causality that we are going back up, which is the hallmark of the investigation.

Meaningful visual elements will mark out the documentary and explain the different logics at work. The drug trade tells us about a world where a vital product is sometimes manufactured in a third world country or emerging to be sold in a developed country. However, these manufacturing and marketing locations are changing, according to market opportunities.

Likewise, intercontinental flows of medicines will connect distant points on the planet.

Data visualization will allow us to make these flows visible and to underline their arbitrary nature, sometimes contrary to human interests. We will thus be able to see the modern health routes unfolding, constantly reconfiguring themselves on the world map and going back up the circuits in a lively way: commercial circuits, from the end consumer to the factory that shapes the active ingredients; financial circuits, which tell the story of mergers and acquisitions, the savings made by relocation; legal circuits, which make it possible to bypass national jurisdictions.

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