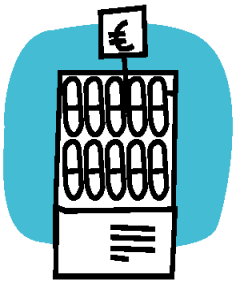
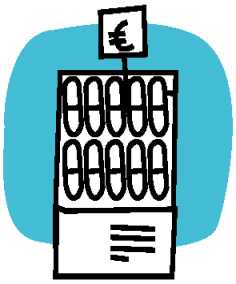
Unit 3: Are medicines an economic good like any other ?



5. Generic drugs in France (1): Government efforts for a market with price competition

Hello, I am Etienne Nouguez head of research at the Center for the Sociology of Organizations. Today, I will talk about generic drugs. Generic drugs are a hot topic at the moment with some people lauding them as true drugs capable of treating patients just as well but at a lower cost and others criticizing them as being subpar drugs that sacrifice health to bring down costs. I will cover generic drugs in general but, in terms of price competition and the conditions that allow this competition to play a role or not. I will specifically look at France, as this is what I know best and it is interesting in this way. This video will be in two parts. Firstly, I will talk about the quality and price of the drugs and secondly, I will talk about doctors, pharmacists and patients and how French authorities tried to increase support for generics. So, to begin with let's talk about the quality and price of generic drugs. This is a crucial notion to develop price competition. Especially in health care, if two goods are not deemed equivalent by health care professionals or by patients price competition does not even come into the picture. If the drugs are not the same a competitive price alone won't make a difference. Therefore, when French authorities wanted to introduce generics in the middle of the 1990s their first task was to give generics a legal definition in order to show that they were equivalent to the original drugs drawing the attention of those concerned to the price only. The legal definition of generic drugs. The legal definition has three conditions which you probably already know: one, the generic drug must have the same active substance both qualitatively and quantitatively. Two, the generic drug must have the same pharmaceutical form bearing in mind all immediate-release forms are considered one and the same: a tablet can replace a powder or a capsule. Three, the generic drug must be bioequivalent. This means the generic drug must travel through the body in the same way as the brand-name drug within a certain bioequivalence margin which I will go back to shortly. Public authorities decided that if the generic drug shared these characteristics with the brand-name drug they could easily be substituted with no risks to health. Public authorities allowed pharmaceutical companies a certain amount of liberty. Generic drugs could have a different name a different appearance a different size or a different color. Excipients with known effects often cited by both doctors and patients are the other inactive ingredients used in the drug which can differ between an original and a generic. Bioavailability, i.e. how the body can use the drug can be a little different for the generic drugs but is judged as having no problematic therapeutic effects as regards pharmacology. Strategies from originator pharmaceutical companies. The companies that produce the originator drugs have tried to use this definition of generic drugs to avoid competition from generics and have employed several strategies to do so. The first was to increase the number of patents which complicates and slows down the copying process from generic manufacturers. They patent the active substance manufacturing processes, pharmaceutical forms etc. Generic drugmakers thus struggle to copy some drugs. A classic example is the double-scored oblong Lexomil tablet which was protected for a long time. Generic drugmakers were forced to offer a round tablet that was more difficult to cut which made it harder for pharmacists to substitute it. The second strategy from originator companies involved developing innovative new forms e.g. by slightly changing the active substance the dose, or the pharmaceutical form such as with a modified or prolonged release. They thus avoided a definition of the drug similar to others which avoided generic competition as these new drugs could not easily have generic copies.



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The final strategy was to walk a bit of a razor's edge by encouraging support for this innovation from doctors and criticizing generics. A number of pharmaceutical companies – such as Sanofi-Aventis, for Plavix – were charged by the Competition Authority for having criticized their generic competition to doctors. Reponses from public authorities to these strategies from pharmaceutical companies Public authorities faced with such underhanded strategies chose to broaden their definition of equivalency by considering that all derivatives of an active substance so isomers, salts, esters, and combinations of active substances could be considered as equivalent to generic drugs unless they had a true therapeutic difference in which case they would be different. Modified or prolonged-release forms are also considered equivalent to generics unless they provide better medical treatment. Public authorities therefore extended the idea of equivalence to encourage competition between generic and brand-name drugs. However, they simultaneously reduced other aspects of equivalence in order to take into account public health issues that could be linked to too much substitution. We can give two examples. Patients over 75 years of age can often have cognitive problems which can make finding their treatment hard. Pharmacists were therefore asked to use the same generic brand for them in order to avoid confusion and therefore iatrogenic risks. The second example of reduced equivalence is for drugs with a narrow therapeutic index as the difference between the effective and toxic dose is small. Health authorities therefore reduced bioequivalence margins and asked doctors and pharmacists to be careful when substituting them and to monitor the patient's therapeutic status. Passing from price competition to a regulated market Let's go back to the idea of prices. I will be brief as I will discuss it more in the next part. We must remember that in France – and we will cover this more later – drug prices are regulated. This is also true for generic drugs. What happens in France is that public authorities like the Economic Committee for Health Products gave the generic a reduced price compared to the brand-name drug. They then gradually lowered this reduction further. Initially, the price difference between generic and brand-name was 20% so the generic was 20% less but since 2012, the generic has been 60% less. They gradually reduced the price of both generic drugs and the brand-name drugs which were competing with them and they put in place a convergence of prices in drug classes where there are a lot of generics but where some drugs still cannot be substituted by generics. What we see is that public authorities particularly this economic committee mimicked price competition in a free market while maintaining price regulation. To conclude this first part, there are two things to take away. The first is that France has a market governed by price competition which is entirely organized by the State which plays both with drug equivalence to encourage comparisons and with prices to simulate price competition. The second important point is to understand that competition between drugmakers does not only concern prices but also drug quality. Originator companies wanted to show that their drugs were different from generics which could justify higher prices.