Differential Pricing and Financing of Essential Drugs
A World Health Organization and World Trade Organization Secretariat Workshop
8-11 April 2001 Høsbjør, Norway

Market segmentation and price differentiation: a novel approach

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Let me start remembering you the access puzzle Jonathan Quick had shown us ("Access to essential drugs depends on: 1) rational selection and use of medicines 2) sustainable adequate financing 3) affordable prices and 4) reliable health and supply systems"), because we have to remember that what we are talking about here is how to find ways of improving access to essential drugs. Price is indeed an important element, but it is only one of many. Other key elements include healthcare infrastructure and access to healthcare services, distribution networks, information about disease and help-seeking behavior to name only a few.

Novartis has a long-lasting experience in the field of leprosy that can demonstrate what I mean. We had developed with WHO the multi-drug therapy (MDT) consisting of two of our compounds, namely rifampicin and clofazimine plus another, dapsone. But we found that the availability of this treatment in itself change little. Information was the key in this field. So in the early 80s, we launched a campaign under the motto "Leprosy is curable" and developed a calendar blister pack for MDT drugs, which contained the high dose of rifampicin – to be taken once a month – together with dose units for the two other drugs, which are taken daily. This had the advantage that patients had to go to their health centers once a month to exchange the used pack for a new one. There he or she had to take the rifampicin. This was necessary because rifampicin is a potent anti-infective agent that is effective in the treatment of many infections, including sexually transmitted diseases. It was therefore a great temptation to sell rifampicin at a good price and make a little money out of the medicine instead of taking it. Since symptoms improve rather quickly with MDT and patients have to take the treatment for six months to two years (depending on the type of leprosy they suffer from), the temptation to sell part of the medication was understandable.
We then became involved in field programs in many parts of Africa, Asia and Latin America. Recently Novartis joined the WHO effort to eradicate leprosy worldwide. We are providing the treatment for this project free of charge in order to ensure that no substandard drugs are used in the final phase of leprosy elimination. The Global Alliance for Leprosy Elimination – which brings together the governments of countries where leprosy is endemic, the WHO, NGOs, and the pharmaceutical industry – is working to implement an eradication strategy in the field. Drug donation works in this specific context, but it cannot be a general solution for other diseases and it is not enough as

the following excerpts of a report to the Global Alliance for Leprosy Elimination illustrates. It describes the strategies as

- Improving access to leprosy services by enabling all general health facilities in endemic areas to diagnose and treat leprosy
- Changing public perception of leprosy, and motivating people to check their skin for signs of the disease and to seek timely treatment
- Ensuring that all patients receive a full course of treatment and are cured
- Monitoring progress towards elimination
- Ensuring availability of free MDT drugs at health centers: “A shortage of multi-drug therapy at the health center level is a chronic problem due to poor information systems, inadequate planning, limited distribution networks, and a shortage of vehicles or fuel. This seriously impairs the prospects of cure for patients and undermines the credibility of the health services, as well as efforts to eliminate leprosy. It is crucial to plan, control, quantify and monitor carefully the supply of MDT at all levels”.

And remember: these drugs are off patent for a quarter of a century and are supplied for free!

A new area where we undertake efforts to improve access is the field of malaria. Novartis has developed a new drug in collaboration with a Chinese partner who had discovered the efficacy of the active ingredients artemether and lumefantrine. This novel treatment is especially indicated for uncomplicated malaria where drug resistance is a problem. The advantages over existing treatments are that it requires a relatively short treatment time for a cure and that no resistance has been reported to date. It is also especially indicated in children.

From the outset, Novartis was aware of the fact that in those regions where malaria is endemic there is no market in a commercial sense. Nevertheless, we decided to invest in this development because we saw an opportunity to contribute in some way to the treatment of this terrible disease and also because it opened up the possibility of a cooperative venture with a group in China, which at the time was novel and of general interest. We saw the possibility of a small market in the industrialized world for travelers who visit countries where malaria is endemic. Instead of a preventive treatment, which has to be taken weeks in advance, lasts for a long time, and is associated with possible adverse effects, the immediate use of this new medicine could cure malaria quickly in those cases where a person had become infected. The project was therefore approved and the treatment developed. Today, it is registered in many countries.
As mentioned, we recognized at once that there were two completely different markets for this product. And as a result, it was decided to market the product under two different trade names: one for the endemic countries, COARTEM®, and one for the industrialized countries, RIAMET®. This new approach allowed us from the very outset to apply different prices.
RIAMET® today is registered in Switzerland, the EU, Australia and Mexico. It will be available in Switzerland at a price of CHF 75 (US$45.00) for a 24-tablet pack for treatment in adults at ex-factory level. In many countries, this

price has to go through a costly administrative procedure and may be modified by the authorities. To this, you have to add import duties, the margins of the distribution chain, which differs from one country to another, and taxes. The price will therefore vary considerably from country to country from the very start. If you review the situation after a few years, a different development of exchange rates will have added to the price differential. In short, we cannot base our approach for the pricing of COARTEM® on one price for RIAMET® as a reference, because there are many different prices in the different countries.

With regard to COARTEM®, the product for endemic countries, we are prepared to make it available widely at a low treatment cost. In special cases this can be at cost. Before arriving at a final price, we have to consider the specific circumstances and target populations. At present, we are negotiating with the WHO and are at a stage where neither side can give any further detailed comments on the subject. But one thing we can say: we are discussing many aspects of a sustainable approach. Price is not the main topic: we have already promised to supply at cost in this agreement.
Why such a complicated approach? Why not supply free of charge or at one subsidized price all over the world?
We have to bear in mind that this product may be needed over decades. In the leprosy project, we face a completely different situation: we have an old treatment, which does not need any further investment in the development of new forms, in clinical trials or in drug monitoring. The project is about finding ways to eradicate the disease and make the drug eventually redundant. For clofazimine and dapsone there are practically no markets to which these drugs could be diverted.
In the case of COARTEM®, we have a new medicine that needs close monitoring. In all probability, we shall have to further investigate its use and dosage, monitor possible resistance, and develop other forms, etc. The launch of a new drug is not the end, but just one step in the development of the ideal treatment of a disease. If we want to have a certain guarantee that this product can remain available over time, we have to put it on a firm footing that will allow it also to survive periods when the business of our company may be less positive. At a moment of a crisis, the first step, which any company will take, is to suspend products, which are making losses. This is not a choice, but an obligation upon management to safeguard the substance of the company and the jobs, which the company offers. A long-lasting sustainable policy should therefore be commercially sound for both sides.
The beauty of the new strategy, which involves the use of two product names, is that the product used for the industrialized countries is addressing normal markets and should be able to be marketed profitably. It could under ideal conditions support the large-scale production and supply of COARTEM® at low prices to endemic countries. For the company, the product as a whole would look better and be less exposed to the pressure on products that show low profitability. But we have to accept that this is still just a strategy or a dream – neither product is yet selling at a high volume, and we are not yet able to produce on a very large scale. We first have to further invest in the project.

Conclusions:
What can we learn from these examples?

1. The leprosy case shows that, in order to make any sustainable progress, infrastructure, information, political support, changes in patient behavior and good project organization are essential prerequisites for success. The price of drug treatment is just one prerequisite among many. And it has to be adapted to the specific situation of the case.
2. Novartis has taken the risk of developing a malaria treatment because there were some other factors which made it look attractive. Every case is different. In order to channel new investments into R&D of this kind, we have to create attractive conditions.
3. The idea of having two different trademarks for different markets is appropriate to the specific circumstances surrounding malaria. It may not be feasible in other situations. Ways to avoid cross market-segment trade must be found if we want to obtain larger discounts.
4. The actual transaction prices for COARTEM® are subject to an unconditional negotiation between the interested partners. We do not see any advantage in developing a general formula, to determine differential prices, because every case and every transaction or group of transactions is different and must be freely negotiable.
5. We have seen that every case is different and that solutions can be found by a thorough professional analysis of the circumstances of the case and by fair negotiations and co-operation between the stakeholders. An important part in this process is the political will of the governments involved to give priority to the specific healthcare problem in question and to respect the basis of any investment in drug R&D, namely the intellectual property rights.
6. I am convinced that we can make progress together, if we respect each other and if at the end of the day we can quantify how many more patients have gained access to the treatments needed and the healthcare supplies provided by our common actions. We, as Novartis, are concerned to do what we can to help solve healthcare problems and to improve patients' access to treatment by collaborating in specific cases in alliances with all stakeholders in a professional spirit of mutual respect that is focused on solving the problems.

And in addition, our chairman, Daniel Vasella, has recently announced that Novartis will install a new research center dedicated to diseases prevalent in developing countries. And this research will be done "pro bono"!

Thank you for your attention!