

**Pricing and Reimbursement of Pharmaceuticals in
Macedonia**

**CONSULTANT REPORT: THE PHARMACEUTICAL SECTOR:
DEVELOPING A METHODOLOGY FOR DRUG REFERENCE
PRICING**

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1. EXECUTIVE SUMMARY

The following measures are proposed

- Implementing an internal reference price system, based on groups with the same active ingredient, pharmaceutical form and strength and reimburse all products with active ingredients that are on the positive list up to the reference price. .
 - The reference price should be based on historical prices as achieved in the last tender process.
 - Implementing in addition an international reference price system based on groups with identical active ingredients for all prescription only medicines - reimbursed and non-reimbursed - on the market.
 - Continuing the tender system for some items like vaccines and drugs that are used in national health programmes.
 - Combining the purchasing activities of several hospitals to create more bargaining powers
 - Improving the availability of drug utilisation data.
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2. INTRODUCTION

The Macedonian healthcare system is in transition from a centrally planned system towards a market-driven system. In recent years a large number of reforms have been implemented with many more to come.

Important areas for reform are the reimbursement of pharmaceutical care and the way prices are set for medicines. It is felt that the current process is inefficient and does not always lead to acceptable outcomes in terms of patient choice and price levels achieved.

Therefore the Macedonian government is interested in a set of policy options focusing on reference pricing as a way to control prices and reimbursement and consequently costs of drugs while at the same time creating more freedom of choice for patients in the reimbursed products they can choose from. Also, these policy issues should be compatible with EU-law as Macedonia is expected to join the EU in the near future.

The Macedonian government has commissioned Arie Rietveld for this work, which is sponsored by the World Bank in the context of the Health Sector Management Project. As indicated in the TOR, Arie Rietveld, pharmaceutical pricing and reimbursement expert, has researched the Macedonian situation with respect to the prices of medicines and has formulated recommendations on how to control prices.

In-depth discussions were held with:

- Prof Dr Vlado Dimov, Minister of Health
- Mr Romil Sandzakovski, Director Drug Bureau
- Prof Dr Nicola Panovski, Director of HIF
- Prof Lidija Petrusevska Tozi, President of the Pharmaceutical Chamber
- Prof Svetlana Kulevanova, Pharmaceutical University
- Dr Zora Uzunoska, Project Coordinator

In addition discussions have taken place with representatives of local pharmaceutical companies and representatives of several hospitals.

The mission would like to express their gratitude to the people mentioned above and all others who so kindly shared their knowledge and experience and who set aside the time in their busy schedules.

The report aims to provide concrete recommendations for reforms with respect to the price control of pharmaceuticals. These recommendations have been made as concrete as is possible under the current circumstances and within the available timeframe.

3. SITUATION APPRAISAL

3.1 Importation, production and distribution

Pharmaceutical products may only be sold on the Macedonian market if they have been given marketing approval by the Drug Bureau. If products are locally produced or imported from countries other than the EU, US, Canada, Japan or Australia, a more thorough approval process is applied by the authorities.

There are 4 local producers in Macedonia, all of which are said to produce according to GMP-standards. Prices of domestically produced products, mainly generics, are very low and it is estimated that their share of reimbursed products produced is around 60%. However, expressed in value their market share is estimated to be around 20-30% confirming that local production is much lower priced than imported products. Local producers export part of their production to neighbouring countries. The largest producer, Alkaloid, says to export about 60% (volume) of its production.

The remainder of the pharmaceuticals on the Macedonian market is imported, predominantly from surrounding Eastern European countries and the EU.

There are no import hurdles for pharmaceuticals other than a flat rate fee and a 5% customs tax. Smuggling of goods, including pharmaceuticals, to avoid custom and other taxes was mentioned as a problem.

Importation takes place via wholesalers and the subsidiaries of foreign companies. A license from the Drug Bureau is required both for wholesaling and importation of pharmaceuticals.

By law all drugs have to be sold through wholesalers, including medicines sold to hospitals. There are about 75 pharmaceutical wholesalers in Macedonia of which only about 20 are active and/or allowed to wholesale. Some wholesalers are sole importer of unique drugs and as such can exert considerable market power as is evident

from high unmotivated price increases that appear to have taken place in the past.

Wholesale margins are not regulated and the Drug Bureau is currently thinking of implementing a digressive wholesale margin system with, depending on the price of the product, 3 tiers: 5, 7 and 9%.

The process of privatisation of pharmacies is rapidly underway with the majority of pharmacies now being privately owned. There are about 700 pharmacies in Macedonia on a population of 2 million (less than 3,000 inhabitants per pharmacy). As with wholesalers, a licence is needed from the Drug Bureau in order to be allowed to run a pharmacy. Only community pharmacies are allowed to dispense pharmaceuticals to the public. Hospitals are not allowed to dispense to out-patients.

The current pharmacy mark-up for products on the positive list is set at 13% which will change to a flat rate fee of Denar 20 per dispensed prescription. For non-reimbursed products the pharmacy margin is not regulated but believed to be around 10 to 25%, depending on the price of the product.

Through an unintended loophole in the drug legislation third parties like wholesalers and manufacturers are able to own and run pharmacies which has led to forward integration and consequently increased competition at the retail end as these chains are able to offer products cheaper than the traditional pharmacies. Currently there are 4 combined wholesaler-pharmacy chains with an estimated market share of 30% (in volume, probably 40% in value). Within the different stakeholder groups it is felt that this competition is unfair as it leads to the disappearance of small, family-owned pharmacies and as such should be prevented. Consequently, there are plans to close this loophole.

For prescription only medicines (POM) a doctor's prescription is mandatory in order for the pharmacist to dispense. However, many patients obtain their medicines without a prescription. Also, as the pharmacist is not obliged to take the prescription in, patients often manage to have the same prescription filled several times at different pharmacies. Control of pharmacies is lacking in this respect.

Medical treatment, including prescribing and use of medicines, is reported to be irrational. In response, the Ministry of Health has encouraged the development of treatment protocols that are also used as

a basis for decisions regarding which active substances to include on the positive list.

Pharmaceutical companies are not limited in their promotional activities other than they are not allowed to promote their products to the general public. A draft medicines law exists that deals with many of the regulatory issues described above but after numerous revisions this draft has not been submitted to the Parliament yet.

3.2 Financing of Pharmaceutical Care

3.2.1 Health Insurance Fund

There exists a national Health Insurance Fund (HIF) that covers about 90% of the population. Premiums for the insurance scheme are paid for by the employers and through direct contributions from the government for certain special healthcare programmes.

In order to be financed through this system, the active ingredients need to be on the positive list, a reimbursement list managed by the HIF. The list is based on the Essential Drug List of the WHO, structured according to the ATC classification system and contains some 400 active ingredients (about 700 individual products) that can be dispensed to the patient reimbursed. The list consists of 2 parts that respectively apply to inpatient and outpatient sectors. The list contains also a number of products (HIV products, some oncological drugs) that have not been formally registered in Macedonia, due to the Macedonian market being unattractive for companies because of its small size. These products are imported with a special license of the Ministry of Health.

If the active ingredient of a pharmaceutical product is not on the list, it will not be reimbursed unless in individual cases with special permission from the HIF. Per listed active ingredient, only the product selected through the tendering process (see below) will be reimbursed. All other, similar products will not be funded unless there are shortages. These shortages seem to occur frequently with pharmacies running out of the reimbursed products at the end of the month, sometimes even earlier. Patients can then buy the same but non-reimbursed product and claim the costs from the HIF. The HIF only reimburses the cost up to the price of the reimbursed, tendered product. As the price of reimbursed, tendered

products often is less than third of the price of the non-reimbursed product, patient co-payments can be very high in these cases.

For individual patients prescribing physicians can make a motivated request to the HIF for the funding of non-reimbursed, often high-priced products. This usually happens after the treatment has been given and results in a positive decision in about 50% of the cases

The positive list is updated every 6 months by a Committee of pharmaceutical/clinical experts and is, after endorsement by the HIF governing board, approved and signed by the Minister of Health.

In order for medicines to be sponsored by the HIF a prescription is needed. The reimbursed prescriptions have to be written by private doctors that have a contract with the HIF. Contracts with these doctors contain clauses on certain performance criteria (*e.g.* maximum number of referrals to specialists, maximum number of prescriptions per year per patient). There are also publicly employed doctors that seem to have more freedom in their prescription behaviour with respect to reimbursed medicines.

In order to be reimbursed, prescriptions need to be filled through pharmacies that have a contract with the HIF (about 120 pharmacies have this contract, which number will have increased to around 300 by the middle of this year). In exceptional cases (*e.g.* when a medicine is out of stock) drugs can be obtained reimbursed from a pharmacy without a contract and the bill is sent by the patient to the HIF.

The HIF reimburses pharmacies for medicines actually dispensed to the patient, although it is acknowledged that control is not optimal and payment usually late.

According to the HIF, the products on the positive list account in volume for the majority of the dispensed products in Macedonia, the remainder being non-reimbursed drugs. According to the HIF the total funds for healthcare amount to Euro 250 million of which Euro 20 million are costs for pharmaceuticals in primary healthcare.

However, according to the pharmaceutical companies and wholesalers non-reimbursed products make up about 60% of the value of dispensed drugs. They claim that the Macedonian retail market for pharmaceuticals excluding oncologicals and insulines is worth around Euro 100 million.

There exists a tiered co-payment system on pharmaceuticals with a ceiling of 20%. Certain patients (*e.g.* those with low incomes or suffering from certain chronic diseases) are exempted from paying co-payments. Patients do not pay for products dispensed in the context of the positive list as payments are made directly by the HIF to the providers of care.

The medicines on the positive list are cheap, usually generic and are by some perceived as being of lower quality than similar products in neighbouring markets (*e.g.* Slovenia) although there appears to be no concrete evidence for these suspicions. This perception is enforced by the fact that many of the active substances on the positive list are produced by local manufacturers (60% in volume, 20-30% in value) whose products are for some reason often seen as being of lower quality than foreign products, despite the fact that these medicines have been granted marketing approval and should thus be considered to be of sufficient quality.

Payments by the HIF are reported to be late with delays of 6 months creating financing problems for the debtors. One of the wholesalers interviewed said that the risks associated with these payment delays were the reason for them only to bid for a limited number of products on the positive list.

3.3 Price Setting of Medicines

Medicines on the positive list are procured by the HIF through a system of international tendering. Procurement is done under general public procurement guidelines, specifying items like the number of companies to invite etc. The HIF also procures the drugs on the positive list that are used in hospitals. Hospitals tender also individually for the pharmaceutical products they use but that are not on the positive list. These appear to be only a small percentage of total drugs used in hospitals. The tendering by hospitals themselves seems to happen for un-registered drugs, in emergencies and in those cases that the HIF tendering process does not generate enough bidders. The hospitals need permission from the HIF to buy drugs themselves.

Medicines that are supplied in the framework of the national health programmes (*e.g.* vaccines) are also acquired through international tendering in which case price negotiations take place. The tendering is

handled by the HIF together with the Procurement Office in the Ministry of Finance and takes place once per year.

Prices of tendered reimbursed products are at wholesale selling level including VAT (18%) and are published in the official gazette. To reach the final pharmacy selling price a pharmacy mark-up of 13% is added, soon to be replaced by a flat fee of Dinar 20 per prescription.

Once a tender agreement has been reached with a company, the HIF asks pharmacists how much of the product they will need on a monthly basis. An equal number of stamps are then sent to the wholesaler to be put on the packages. Only packages with the official stamp on it are reimbursed to the pharmacy by the HIF. As mentioned earlier in paragraph 3.2.1., the HIF operates a system of strict volume control and pharmacies regularly run out of packages with stamps, leading to patients having to buy much higher priced other –non-reimbursed- products.

The stamp (banderol) system is not used for positive drugs used in hospitals. For hospitals annually quantities are agreed and consequently the hospitals order monthly the drugs they think they will need from wholesalers. If they need more, they will order so at the tendered prices.

There appear to be a number of issues associated with the tendering procedure:

- (1) From start to finish it may take as much as half a year or longer, especially for products that have no or only a few competitors, which is considered too long and too time-consuming;
 - (2) There are suspicions that the tendering procedure sometimes has been rigged by companies colluding to increase the price (*e.g.* the company with the lowest price pulling out after agreement has been reached leaving the contract to a company with a higher-priced product);
 - (3) Tendering proves to be difficult for products that are unique and for which no or hardly any competition exists (*e.g.* oncological products, ARV drugs). In these cases no bids are made or, as the tendering rules require at least two bidders, the HIF has to repeat the tendering process, then ask permission from the Minister of Finance to deal with only one bidder and, finally, negotiate with the bidder on the price and quantity. The
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HIF considers this as unnecessarily complicated and time-consuming.

It is believed that the prices paid for these unique products are often too high and that prices can be more than 30% lower in neighbouring countries. The oncological products have been given as an example: apparently Serbia with 8 million inhabitants is spending Euro 10 million on cancer drugs while Macedonia, with only 2 million inhabitants, is spending Euro 14 million;

(4) There have been complaints that the Drug Bureau has been pressured to grant a marketing approval in a very short time frame to products produced outside the listed countries (EU, US, Canada, Japan and Australia) because these particular products had the lowest price. The fear was that quality and thus safety could be compromised. For this reason, it has now been stipulated that only products already registered in Macedonia will be allowed to participate in tenders;

(5) Although tenders are international and published through the appropriate channels, products need to have marketing approval in Macedonia and the bidding company needs to be registered in Macedonia. In effect, this means that the big pharmaceutical companies leave the bidding to local wholesalers who have freedom in setting their mark-ups. This leads to much higher prices than necessary;

(6) For primary care drugs, ultimately the HIF guarantees only to buy 20% of the tendered requested quantity, for hospital products this is 80%. In combination with the small size of the market, the registration requirement and the payment delays, foreign companies find it often not very attractive to make a bid in the tendering process.

Despite these issues, all stakeholders agree that the tendering process has been extremely successful in securing lower prices for those drugs for which there exists sufficient competition. In fact, so successful that some doubt if the products procured at these low prices have the same quality as similar products on the market in neighbouring countries like

Slovenia, Greece and Croatia. Tendered prices in Macedonia can be as low as 5-10% of the prices in surrounding markets. It has been suggested that, as quality testing only takes place at the time of registration, subsequent batches may have lower quality. However, there seems to be no concrete evidence for this suggestion.

In 2005 through tendering an average price decrease of 45% (30% for community products and 6% for hospital products) as compared to the previous year has been achieved and further price decreases are expected for the upcoming tendering round this year. However, some question this and feel that tendering has outlived its usefulness as for many products it may prove impossible to achieve lower prices in the coming tendering rounds than already achieved.

The prices and margins of all other medicines, including those that have lost the bidding process or that are not on the positive list, are not regulated and producers, importers, wholesalers and dispensing pharmacists can set the prices freely. This has led to a situation in which prices of similar or identical drugs can differ considerably between pharmacies. This situation is seen by many as undesirable as it leads to confusion and complaints from patients. Consequently there is support for controlling also the prices of non-reimbursed drugs.

4. CONSIDERATIONS FROM A PRICING AND REIMBURSEMENT PERSPECTIVE

For a number of years now the pharmaceutical sector in Macedonia has been transforming from a centrally plan-driven situation into a more market-driven sector. Privatisation of hospitals and pharmacies is progressing and a national health insurance system has been implemented.

Although clearly there are growing pains, it is the impression of the author that the cost containment and patient access policies of the Macedonian authorities on the whole are rational, coherent and fundamentally sound.

Having said that there are a number of areas where improvements should be made.

1. Although very effective for products for which ample competition exists (mainly generics), the current tendering system does not seem to perform well for products with limited competition, leading to unnecessary delays in the procurement process and very limited success in achieving lower prices
2. The tendering process may have been sometimes sabotaged by companies colluding to achieve higher price levels. This seems to happen with those products for which no or very limited competition exists. If proven real, these anticompetitive behaviours need to be fought tooth and nail as they are very damaging to the effectiveness of the system and the reputation of the HIF
3. Also, some of the conditions applied in the tendering process seem to hinder a positive outcome or lead to unnecessary delays. Examples of these are only guaranteeing to buy 20% of the negotiated amount of primary care products and the requirement for having to repeat the tender if there is only one supplier for a unique product
4. The achieved prices in the tendering process are very low, in fact so low that one can doubt whether some bidders are able to make a profit on their products at these price levels. What seems to happen in practice is that, since many pharmacists run out of stock of products on the reimbursed list once the stock of stamped packages are sold, they sell un-reimbursed stock of the same brand instead to the patient at much higher (sometimes 3-5 times higher) prices. Thus companies are able to compensate for their low tendered prices by co-payments of the patients, which make the low tendered prices possible.
5. There exists no structural international price benchmarking system for the prices of tendered products with no or limited competition. This means that the HIF, when accepting a bid from a company, does not have knowledge on how the offered price compares to other markets and whether Macedonia is paying a too high a price. Also, as the wholesaler is free in setting his mark-up, there is room for price manipulation.
6. In the current system, for out-patients only one reimbursed product per listed active ingredient is available and all other products with

the same active ingredient are automatically not reimbursed. Although admirable in its simplicity, this does not give the prescribing physician or the patient any room for choice nor makes it the situation easy if the only reimbursed product is out of stock.

7. There are no price controls for drugs that are not reimbursed leading to different prices for similar/identical drugs across pharmacies. Although one could argue that this is not a real problem as essential medicines are available through the positive list system, this situation leads to in-transparency and uncertainty with respect to the prices of non-reimbursed products. Also, it could lead to certain non-reimbursed products not being accessible to patients because of their high prices.
 8. In this context it appears that Macedonian doctors and patients are requesting more choice in the currently very lean package of products that are reimbursed. From this perspective it is rational to create a healthy basis for potential future extensions of the reimbursement package by ensuring that price levels are in line with surrounding countries
 9. There are no margin controls for pharmacists leading to different prices for similar/identical non-reimbursed drugs across pharmacies. Again, this leads to in-transparency and potentially high prices.
 10. Hospitals negotiate on an individual basis with companies on products with active ingredients that are not on the positive list. The quantities for which these negotiations take place are relatively small and hospitals may not be able to achieve the best results in terms of price.
 11. The control of what happens at the pharmacy end of the distribution chain seems to be lacking. For any system to work properly, it is pivotal that the authorities ensure that in all cases a doctor's prescription is present when dispensing POM. Also, this prescription should only be used once and should therefore be taken in by the pharmacist.
 12. Payments by the HIF to pharmacists and companies should not dramatically exceed the term as specified in the contracts. Currently payment terms are too long which increases the financial risk of
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wholesalers and pharmacists. This seems to prevent some companies to bid for their products in the HIF tenders.

13. There appears to be a general lack of drug utilisation data. Reliable and up-to-date data on drug utilisation are pivotal in developing effective cost containment policies.

5. SUGGESTIONS FOR CHANGE

5.1.1 Admit New Drugs Selectively To the Positive List

The cost increase in pharmaceutical expenditures in western-industrialised countries can be attributed largely (70 to 80%) to new, higher-priced products coming to the market. It is advised to be very restrictive in extending this positive list since a too liberal policy could lead to high increases in expenditures. A limited positive list, provided developed on the basis of sound, rational criteria, will not lead to a loss of quality of available pharmacotherapy.

But as time progresses, the Macedonian pharmaceutical market will resemble more and more the markets in surrounding countries. Perceptions of what quality care is will be more and more influenced by the situation in these other countries.

One of the likely consequences will be a greater number of drugs on the Macedonian market. This will put pressure on the positive list as most drugs on the market will not be reimbursed and thus not accessible to many patients. This situation, if not properly managed, may result in a rapid increase in the number of reimbursed medicines and thus in the pharmaceutical costs for the HIF.

It is understood that a new positive list has been developed which contains considerably more drugs than the current one. More than 150 active ingredients have been added to this list, thus increasing the number of reimbursed active ingredients by almost 50%. These additions could lead to high incremental costs for the HIF.

Before endorsing the new list, Macedonia should therefore make a careful analysis of the cost consequences and the public health/medical necessity of these additions. As to the latter, it is advised to ask support from WHO Regional Office in Copenhagen to perform a screening of the new list, using their network of experts. The WHO has a long history in doing this screenings and is widely seen as very knowledgeable in this area.

5.1.2 Implement An Internal Reference Price System (also known as Reimbursement Limit System)

The current positive list in combination with the tendering system leads to a very restrictive reimbursement situation in which there is very limited choice for doctors and patients. Of course, one could take the position that the positive list guarantees adequate pharmaceutical access for patients as long as companies are willing to supply the HIF at these low prices and safeguards are present in case of out-of-stock situations.

However, the price pressure on products through the tendering system seems to find relieve, because of the free pricing environment, through much higher prices for the non-reimbursed products and products without the HIF stamp. Also, the tendering process does not work very well for unique products with no or limited competition in the absence of incentives for companies to offer these products at low prices. Finally, price levels in Macedonia are dramatically lower than in surrounding countries leading to the question of how sustainable these current price levels will be in the coming years.

It is expected that the current absence of choice for doctors and patients will be less and less acceptable and that pressure will continue to build up to create more choice in the available reimbursed products. This pressure will also come from industry which views the current tendering process as too restrictive.

In order to deal with these pressures, the number of reimbursed products needs to be increased while at the same time safeguards must be created that this will not lead to unaffordable cost increases for HIF.

Increasing the number of products to choose from can be done by implementing an internal reference price system.

In internal reference price systems (in order to avoid confusion with international reference price systems in the remainder of the text I will use the term 'reimbursement limit system') the patient only pays a co-payment if he/she chooses for a more expensive product. This puts a ceiling to the costs for health insurance while at the same time exerting a downward pressure on prices.

Reimbursement limit systems are based on the element of choice and are thus only a real option when more products containing the same active ingredient are on the market.

Although there is the option of creating reimbursement limit systems based on therapeutic substitution, it is felt that a reimbursement limit system that clusters products with different active ingredients is not (yet) needed for Macedonia as there are only a limited number of active ingredients on the positive list.

Moreover, clustering on the basis of therapeutic effects of drugs (leading to clusters containing different active ingredients) is complicated as a set of criteria needs to be developed in order to make this clustering possible. Last but not least, a scientific and managerial infrastructure needs to be built in order to operate a reimbursement limit system based on therapeutic substitution which will take considerable time to develop (the estimated time needed is 2 years).

For the reasons above it is advised to opt for a reimbursement limit system based on groups with the same active ingredient, pharmaceutical form and strength.

Instead of the current system that leads to only one product being reimbursed per ATC 5 code, this reimbursement limit system would grant reimbursement to all available registered products with the same active ingredient, strength and pharmaceutical form in a given ATC code up to a defined price level. This would lead to a system in which reference prices are set per ATC level 5 thus following the way the positive list is built.

For example: a cluster would contain ranitidine tablet 150mg brand X, ranitidine tablet 150 mg brand Y, ranitidine tablet 150mg brand Y and so on and so forth.

The reference price could be calculated on the basis of historical prices as achieved in the last tender process.

The major differences with the current system would be that no tendering would take place and that similar products of other companies would be reimbursed up to the level of the reference price.

The reimbursement limit system described above will be effective in dealing with multi-source products, but much less so in dealing with

products that are unique and for which no or limited competition exists as it will be difficult to create clusters for these products. Also, the prices that have been achieved through tendering for these products seem to be much higher than the prices for similar products in surrounding countries. Using the tender prices as reference prices would lead to too high price levels.

For these products a different methodology is required, not based on prices of competitive products but on the prices of these products in other markets: international reference pricing.

5.1.3 International Reference Pricing

Many countries that operate reimbursement limit systems also operate international reference price systems in order to cope with the fact that for some products there may not be sufficient competing products on the pharmaceutical market to make a reimbursement limit system work.

The advantages of using comparative pricing methods for setting prices are that prices are set in an objective and transparent manner according to the EU legislative requirements. Also, it is a relatively simple, practical and proven methodology for setting prices.

In Europe most countries use some form of international price referencing, most notably Greece, Portugal, the Netherlands, Denmark and most of the accession countries. International price referencing is also widely used outside Europe in for instance Japan and Canada.

The number of reference countries should be manageable as not to make the system too complicated to manage. Also, including many reference countries would not necessarily generate better results.

In the case of Macedonia it is recommended to use 3-4 reference countries in order to minimise chances that no maximum price can be calculated if products are not on the market in the reference countries.

The reference countries should be as much as possible comparable to Macedonia with respect to the available drugs on the market, GDP per capita and healthcare systems.

As to the selection of countries, it is suggested to use low-priced markets where prices of pharmaceuticals are published in a public price list.

Some former East Bloc countries (Albania, Slovenia, Czech Republic, Bulgaria, Croatia and Greece) may qualify. The official or universally accepted price lists in these markets should be used to establish the appropriate prices as international databases on prices are usually not accurate enough nor particularly up-to-date. It is recommended to contact the Ministries of Health in the selected reference countries to identify the official price lists for pharmaceuticals.

If the product is available in only one market at launch in Macedonia, it is advised not to approve the price of the product and thus delay market access until the product has been launched in at least one other reference country.

Prices should be revised periodically and a twice yearly revision seems appropriate. Companies should not be allowed to increase prices on other grounds than price increases in the reference countries as it will otherwise invite many fruitless negotiations that can only result in price increases.

5.1.4 Define Comparable Products As Containing The Same Active Ingredient

When defining the products of which the prices will be used for international comparisons, it is recommended not to limit price comparisons to identical products (*e.g.* identical brand name) but instead to focus on products containing the same active ingredient. Thus the likelihood of finding comparable products for price comparisons will be increased and advantage can be taken of the fact that there may be lower priced generic products on the market in the reference countries.

Comparable products can also be products that contain a slightly different quantity of the active ingredient *e.g.* 110 mg instead of 100 mg. In that case simple arithmetic will lead to the comparable price:

$$110/100 * \text{price} = \text{comparator price}$$

To increase the likelihood of finding comparable products for the price calculations, one could specify in the regulation that, for the purpose of the law, certain pharmaceutical forms are seen as similar *e.g.* one could stipulate in the law that transdermal formulations are similar to oral formulations, thus making it possible to use orals as price comparators for transdermal products.

5.1.5 Compare Products On A Unit Level

Products may be on the market in different pack sizes in the reference countries which can make comparisons difficult. It is therefore recommended to express prices in price per unit. Units can vary according the presentation form of drugs:

- price per tablet
- price per inhalation
- price per millilitre
- price per vial
- price per gram

As unit prices of individual drugs may vary according to pack sizes, it is recommended to use for the calculations only the pack size with the lowest price per unit.

5.1.6 Use Manufacturer Selling Price Or Wholesale Selling Prices

The use of prices at MSP or WSP level exclusive of VAT will simplify making price comparisons as especially remuneration systems for pharmacists can differ from country to country (*e.g.* flat rate dispensing fee versus a margin on products dispensed). If the price lists used include the pharmacist margins in the prices, it is usually possible to calculate the list prices back to the wholesale prices. The same is true for calculating WSP back to MSP.

The choice between using the MSP or the WSP will be largely determined by the existing situation: if Macedonia decides to regulate the margin of the wholesaler it makes sense to compare at MSP level and add the wholesaler mark-up later on. If wholesale margins are not regulated it is best to use the WSP levels. In that case the need to regulate wholesale margins disappears as the margin of the wholesaler is included in the regulated WSP price.

5.1.7 Use Only Lowest Prices In The Reference Countries

Similar products may be on the market in the reference countries under different brand names at different prices. There are broadly two ways dealing with this: one way is to calculate per reference country an average price per unit for all different brands. The other way is to simply take only the lowest priced product as comparator product in one of the reference countries. For example: if a product is available at the lowest price in Greece, then the Greek price would become the reference price in Macedonia.

In view of the budget situation, for Macedonian the latter option is advised as it is simple, effective and will lead to low prices.

5.1.8 Maximum Prices or Fixed Prices?

Ideally the calculated Macedonian prices should be considered as maximum prices: selling and/or promoting products for a higher price than the maximum price is forbidden but a lower price is allowed. In this way, the price control system may take advantage of any competition that exists between wholesalers and between pharmacies. However, there are concerns in Macedonia with respect to the forward integration of some producers/wholesalers and it is feared by the Drug Bureau and others that setting maximum prices would allow these parties to continue gaining ground on the traditional pharmacists.

Although there are no real pricing & reimbursement reasons for not allowing this forward integration, in this case it is recognised that there may be other reasons for preventing producers and wholesalers running pharmacies (*e.g.* social and political).

Setting fixed prices instead of maximum prices would not diminish the efficacy of the reference price system but would prevent integrated wholesale-pharmacy chains to compete on price. Thus the position of the traditional pharmacies would be protected.

However, should a system of fixed prices be chosen, it is essential to make it illegal for producers, importers, and wholesalers to offer discounts on the fixed prices to community pharmacies. Consequently it should be made illegal for community pharmacies to request, negotiate and/or accept discounts. Discounts in this context are all services to

which a monetary value can be attached (e.g. interest-free loans, free goods, etc etc).

5.1.9 The Prices Should be Made Publicly Known

The set prices should be communicated to the companies, pharmacists, hospitals and prescribing doctors. Also, it is advised to inform the public so that it knows what the prices are. Every pharmacist could be required to have an up-to-date price list hanging in the pharmacy that people can see when buying their medicines.

Requiring the companies to put the price of the medicine on the package is only advisable if prices are stable over a longer period of time (2 years) as fluctuating prices would make it necessary for companies to adjust their packaging frequently thus generating additional costs for them.

5.1.10 Selection Of Medicines Of Which The Prices Should Be Controlled

As a general principle, only the prices of drugs of which society (government) feels they should be accessible for patients should be regulated.

Most countries that operate price controls (and in Europe this means virtually all countries with the exception of Germany and possibly the UK) either control the prices of all POM or limit the direct control of prices to those products that are reimbursed. With the exception of Greece prices of non-reimbursed OTC drugs are not controlled.

It is therefore a matter of choice how far one wants to extend the price controls. The rule of thumb is to control what needs to be controlled and to refrain from this kind of interventions whenever possible.

In the case of Macedonia the positive list is very limited which means that most drugs are not reimbursed, including some that may be considered as being better than the reimbursed drugs. In the current free pricing situation prices for these drugs vary across pharmacies and in some cases could be too high priced to be accessible to patients.

It is therefore recommended to control the prices of all registered POM on the market, reimbursed and non-reimbursed. It is recommended to

exclude OTC medicines as these are indicated for minor and self-limiting diseases and use is by choice rather than necessity.

5.1.11 Continue Tendering For Specific (Groups Of) Drugs

It is recommend continuing the tender system for undifferentiated items like vaccines and drugs that are used in national health programmes. These drugs are used in short periods of time in high quantities and by tendering Macedonia can profit from lower prices that can be achieved on the world market.

Some minor adjustments could be made to the tendering procedures in order to increase the efficiency of the process. Some suggestions: make it easier to conclude the tendering process when there is only one bidder as can happen with unique drugs; guarantee the bidder a higher percentage of sales than is now the case thus making it more attractive to bid; consider contracts that run for more than a year.

5.1.12 Organisation Of Reimbursement Limit System And International Reference Price System

Building and running a reimbursement system and an international reference price system is complicated and requires considerable pharmaceutical expertise. For this reason in virtually all markets, the responsibility for running these systems lies with the Ministry of Health which is usually also the body that is responsible for deciding which medicines should be reimbursed.

One could give the responsibility for running both systems to the Drug Bureau within the MOH, this being the department responsible for the development of pharmaceutical policies.

Alternatively, one could envisage giving the task to the HIF as both systems are, at least to an important degree, linked to the positive list. However, running the positive list system is not the only responsibility of the HIF and, considering the fact that running a reimbursement limit system and an international reference price system are activities of a very technical nature that require considerable pharmaceutical expertise, on balance it seems appropriate to give this responsibility to the Drug Bureau.

5.1.13 Compatibility Of Reimbursement Limit Systems and International Reference Pricing With European Union Law

According to EU-law, national measures should not form an impediment to cross-border trade between the member states. This applies to both measures that have the intention to prevent cross-border trade and to measures that, although not aimed as such at preventing cross border trade, still de facto create impediments.

More specific rules for pharmaceuticals are laid down in Directive 89/105/EU ('the Transparency Directive') that gives rules for governments on the way they deal with reimbursing drugs and setting prices of drugs. In essence Directive 89/105/EU says that governmental and semi-governmental decisions on the pricing and reimbursement of pharmaceuticals have to be objective, transparent and taken within a reasonable timeframe. In practice this means that similar decisions have to be taken in similar conditions for similar cases, that companies need to be able to see how decisions have been reached and, finally, that companies are entitled to decisions being taken within 3 months of application for a price and/or reimbursement (unless the company does not supply the necessary information to base a decision on in which case the procedure is stopped and will start again once the requested information has been received).

The reimbursement limit system and the international reference price system are in principle compatible with EU legislation.

The Reimbursement Limit System

1. The reimbursement limit system works in the same way for any product that is reimbursed. Once the positive list committee has decided by to put a certain active ingredient on the list, all products with this active ingredient, provided they are registered in Macedonia, will be reimbursed. The rule applies to all in the same way and is therefore objective.
2. As the rules will be laid down in a law or regulation all stakeholders can see how clustering takes place, which criteria are used, how the reimbursement limit (reference price) is set and at what intervals the system is reviewed. The system is therefore transparent.

3. Decisions on applications for reimbursement are taken within 3 months unless more information is needed. This is conform the times mentioned in the Transparency Directive.
4. The Reimbursement Limit System does not make a difference between locally produced products and imported ones and creates as such no impediments to cross-border trade.

The International Reference Price System

1. The International Reference Price System works in the same way for all products that fall under the scope of the regulation. Once marketing approval has been granted, a price will be set for all pharmaceuticals excluding OTC drugs. The rule applies to all products in the same way.
2. All stakeholders can see which countries are used as reference countries, which products are used for setting the reference price, how the reference price has been set and at which intervals the reference price will be reviewed. The system is therefore transparent.
3. For non-OTC products that have marketing authorisation the need for reference price revisions will be investigated every 6 months and a decision will be taken within 3 months of the investigation. This is compliant with EU legislation.
4. The International Reference Price System does not make a difference between locally produced products and imported ones and creates as such no impediments to cross-border trade.

The conclusions above on the compatibility of the proposed measures with EU legislation need to be seen as preliminary, since the way and exact form of implementation (*e.g.* appeal procedures) can influence the compatibility with EU law. It is therefore recommended to seek legal advice before actually implementing the measures.

5.2 Increase The Effectiveness Of Hospital Negotiating Power

Currently hospitals negotiate with suppliers independently and are thus not able to create the negotiation power they could have if they would combine purchasing activities. If several hospitals would combine purchasing activities and form purchasing groups, it is likely that they would be able to negotiate better deals on pharmaceuticals and other supplies. This is done in many countries (*e.g.* France, the US) and can result in a more rational use of medicines through a joint assessment of the actual drug needs as well as lower costs through the negotiation of lower prices and/or higher discounts.

It is therefore recommended that the national authorities in the form of the HIF investigate how to stimulate the joint buying of medicines and other supplies by hospitals.

5.3 Increase The Availability Of Reliable Up-to-date Data To Monitor Market Developments

Cost containment policies as well as price control measures can only be implemented effectively when the responsible authorities have an effective monitoring system that tracks relevant developments in the market.

Most countries have set up extensive systems to track drug utilisation and costs. The biggest hurdle in building these systems is to get them up-to-date as too often data trickle in months or sometimes even more than a year after the drugs has been dispensed to the patient. The data should therefore be collected and sent timely to the HIF to be analysed and used as guidance for possible actions.

Essential in this respect is that periodically data are collected per distribution channel on:

- prices of (imported) medicines
- volume of sales
- number of prescriptions

This is a limited data set but will nevertheless enable the authorities to make relevant analyses without running into the problems associated

with the collection of (too) many variables. The data could be collected via sampling techniques. The data collected by the HIF could also provide valuable insights although a preliminary investigation has revealed that the administration seems not to be based on a computerised system. Data should be available in electronic form to enable an effective –timely- use of the data.

It is recommended to make an assessment of the actual availability of data, the degree to which the administration of the HIF can be made accessible to make timely analysis, and the degree of computerisation. On the basis of this assessment concrete recommendations can be developed to build a computerised system for data collection on pharmaceutical expenditures.

6. ACTION PLAN

The action plan focuses on implementation of the reference price system and the reimbursement limit system.

The following actions need to be taken:

1. Request assistance from WHO to screen new positive list on medical necessity and assess cost impact of additions
2. Reach broad (political) agreement on which measures will be taken:
 - a. International Reference Price System
 - b. Reimbursement Limit System
 - c. Future of tendering system
 - d. Joint purchasing by hospitals
3. Reach broad (political) agreement on which organisation will be responsible for
 - a. Setting prices in the international reference price system
 - b. Setting reimbursement limits in the reimbursement limit system
 - c. Controlling the adherence of stakeholders to the regulations (international price referencing system)
4. Agreement on the methodologies to be used
 - a. International Price Referencing:
 - i. Selection of reference countries
 - ii. Scope of measure (POM , OTC excluded or not)
 - iii. Set prices or maximum prices?
 - iv. Method for setting prices
 - v. Contact Department (Ministry?) of Justice to check appropriate punitive measures to be included in legislation

- b. Reimbursement Limit System:
 - i. Method for setting reimbursement limit
- 5. Development of appropriate legislation
 - a. Regulation on (maximum) prices
 - b. Regulation on reimbursement limits
 - c. In case of set prices instead of maximum prices: a regulation that forbids giving discounts to pharmacists
- 6. Contacting the responsible ministries in the reference countries for selecting the appropriate official price lists
- 7. Obtain legal advice on EU compatibility of final legislative proposals
- 8. Development of a communication plan to inform stakeholders (producers/importers/wholesalers/doctors/pharmacists/patients) of the upcoming changes

As the above actions require careful planning and execution, Macedonia should not rush into far-reaching changes of the reimbursement system without thorough preparation. The implementation of international price referencing is less critical and can be done at any moment without endangering the available funds for financing pharmaceutical care

With reference to the reimbursement system, the current tendering system should only be abolished -for multi-source products- when all stakeholders are certain that the new measures are ready for implementation and that all their effects are understood and foreseen.

In this context, and like with any major policy change, an option to consider is to keep the current tendering system for a limited time in order to be able to prepare properly for the implementation of the reference price system, instead of rushing and potentially creating (financial) problems that may prove difficult to solve.

In this respect, there is a strong link between the revised positive list and implementation of the reimbursement limit system. Assuming that many new additions are patent protected or without generic equivalents on the

Macedonian market, it will become much more difficult to implement a reimbursement limit system based on the clustering of active ingredients.

Provided the Macedonian authorities are ready to implement the reimbursement limit system, it is advised to stick to the current positive list and not to implement the new list so that the new system will only have to deal with the existing products on the market.

Although of course all steps mentioned above are important, the crucial activities are the development of the appropriate legislation (laying out the methodology properly) and the administrative procedures to manage the system (payment streams to pharmacists). These have to be developed in parallel as to make a timely and smooth implementation possible.

Provided there is a robust piece of legislation and the appropriate payment mechanisms have been created, the implementation of the reimbursement limit system could be done rapidly. The system could be up and running in 3-6 months time.

Appendix 1

Draft Law on the Prices of Medicinal Products

Preamble

Medicinal products are largely financed by society and the burden of the prices of medicinal products will thus be carried by society. In the interest of the public it is necessary that medicinal products are accessible and affordable to the entire population. To achieve this, it is necessary to regulate the prices of medicinal products.

Article 1.

1. In this law and all legislation based on it, the following shall have the meaning and definitions hereby assigned to them:

- a. Our Minister: the responsible Minister (to be decided, advised to be the Minister of Health);
 - b. medicinal product: any substance or combinations of substances as defined in § 2 of the (draft?) Law on Medicinal Products;
 - c. comparable medicinal product: a medicinal product with identical active ingredients, of identical or almost identical strength and in identical pharmaceutical form as an other medicinal product;
 - d. registered medicinal product: a medicinal product that has been granted a product licence issued by the Drug Bureau in accordance to the Law on Medicinal Products;
 - e. manufacturer: a legal person in the country holding a licence from the Drug Bureau to manufacture medicinal products in accordance with article xx of the Law on Medicinal Products;
 - f. wholesaler: a legal person in the country holding a licence from the Drug Bureau to wholesale trade in medicinal products in accordance with article xx of the Law on Medicinal Products;
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- g. importer: a legal person in the country holding a licence from the Drug Bureau to import medicinal products in accordance with article xx of the Law on Medicinal Products:
- h. (maximum) price: the (maximum) price of a medicinal product as determined by article 2 of this law.

2. By decree, Our Minister can decide that certain pharmaceutical forms for the purpose of this law are identical pharmaceutical forms.

Article 2

1. A (maximum) price shall be established for every registered medicinal product. The maximum price is expressed in a price per quantity product.
2. By decree, generally accepted price lists in the countries Croatia, Bulgaria and Greece shall form the basis for setting a (maximum) price.
3. The price lists used shall have been published not longer than 6 months before the date of establishing the (maximum) prices.
4. For establishing the (maximum) price, the lowest price of a comparable medicinal product is taken per country in local currency as published in the price list, using the price that is charged to hospitals and persons or institutions that are allowed to dispense or sell medicinal products to the public.
5. If a price list in a country does not contain the price for a comparable medicinal product that is charged to hospitals and persons or institutions that are allowed to dispense or sell to the public, the published price is adjusted on the basis of the regulations in force in that country to obtain the price as mentioned under 4 of this article.
6. If a price list contains prices for more than one package size of a comparable medicinal product, only the price of the package with the lowest price per unit of product will be taken into account.
7. If necessary, a published price of a comparable medicinal product is adjusted to reflect the quantity of a medicinal product that will be used in the calculations of the (maximum) price as mentioned under 1 of this article.
8. The price for a comparable medicinal product in a reference country will be recalculated in Dinar, using the exchange rate of the date of publication of the price list.

9. The (maximum) price is determined using the lowest of the prices as calculated under 8 of this article.
10. A (maximum) price is only set if the medicinal product appears in at least one of the price lists in the countries listed under 2 of this article.
11. For those medicinal products for which no comparable medicinal products exist in the price lists, Our Minister can set additional rules.

Article 3

At least every 6 months Our Minister will investigate the need for adjusting the decree as mentioned in article 2, under 1. If considered necessary, Our Minister will adjust the decree within 90 days after the beginning of the investigation.

Article 4

It is forbidden to promote, sell or deliver a medicinal product at a higher price than the (maximum) price to hospitals and persons or institutions that are allowed to dispense or sell medicinal products to the public according to the (draft) Law on Medicinal Products.

Article 5

It is forbidden for persons and institutions that are allowed to dispense or sell medicinal products to the public according to the (draft) Law on Medicinal Products to sell or dispense a medicinal product at a higher price than the (maximum) price to the public.

Article 6

1. Manufacturers, importers and wholesalers and persons and institutions that are allowed to sell or dispense to the public shall provide, upon request of Our Minister, a detailed administration showing per transaction to whom, at what price and in what package size the medicinal product has been sold.
2. The administration under 1 of this article shall be kept for a minimum period of 5 years following the year subject to this administration.

Article 6

DRAFT

Violations of this Act, regulations and decree's based upon this Act shall be subject to penalties as specified in regulation to this act.

A suggestion for a text:

“Our Minister can impose violators of article 4 and 5 a fine of x Dinar per violation.”

Explanation of the (draft) Law on the Prices of Medicinal Products

Introduction

The (draft) Law on the Maximum Prices of Medicinal Products establishes (maximum) prices for medicinal products, based on the prices of comparable products in 3 other countries.

The most important goal of policies in the field of healthcare is maintaining and improving the health status of the Macedonian population. In order to achieve this goal, a system of health insurance has been created that ensures that everybody in need of healthcare has access to appropriate healthcare.

As the healthcare services are financed collectively by means of employer and employee contributions as well as government subsidies, government plays an important role in allocating financial resources that are by nature scarce.

In most healthcare sectors, therefore, government has created controls of prices and tariffs.

The regulation

For establishing maximum prices of drugs, the prices of comparable drugs with the same active substance are taken into account. The law is applied to all registered medicinal products on the market. Maximum prices are set for all medicinal products on the market in Macedonia.

The regulation maximises the prices of medicinal products as these are sold to hospitals and persons or institutions that are allowed to dispense or sell medicinal products to the public. In most cases this will be pharmacies and hospitals.

The (draft) law sets (maximises) the prices of medicinal products at the lowest prices of comparable products in the countries that are referenced in this law. Price lists that are generally accepted in the reference countries are used.

The selection of the reference countries is based on comparability with Macedonia with respect to prevalence of diseases and level of quality of healthcare. Furthermore, there exist similarities with respect to the medicinal products that are marketed in the reference countries and Macedonia.

It is forbidden for manufacturers, importers and wholesalers to charge higher prices than the established (maximum) prices to hospitals and persons or institutions that are allowed to dispense or sell medicinal products to the public.

It should be made clear that the (draft) Law on the Maximum Prices of Medicinal Products only controls the wholesale prices of medicinal products, and that additional regulations are necessary to stimulate that prescribing physicians, pharmacists and patients respectively prescribe, dispense and use medicinal products in the most rational way.

It is intended that the implementation of the (draft) law will be accompanied by the introduction of a reimbursement limit system that will contribute to the rational prescribing and use of medicinal products and other measures to the same effect.

Explanation by article

Article 1

Article 1 gives the necessary definitions of the terms used in the (draft) law. These definitions are based on the definitions and relevant articles in the (draft) Law on Medicinal Products.

Section 2 of this article gives the responsible Minister the possibility to consider certain pharmaceutical forms as identical. This may be necessary as sometimes minor variations exist between countries in the pharmaceutical forms of marketed medicinal products. This would otherwise prohibit considering these medicinal products as comparable and could thus prevent the setting of a maximum price.

Article 2

Article 2 gives the method of calculating the (maximum) price. In order for the setting of the (maximum) prices to be as objective and transparent as possible, it is necessary to describe in detail the method of price setting, the selection of the reference countries and price list.

Prices are set for all registered medicinal products on the market. An exception could be made for OTC drugs. It is not recommended to create more exceptions as this will make the (draft) law unnecessarily complicated and could result in substantial loss of efficacy.

The method of setting the (maximum) price is the same for both imported and locally manufactured medicinal products. The (maximum) prices incorporate any margins or mark-ups for manufacturers, importers and wholesalers. Therefore in principle there is no need anymore for legislation on wholesale margins and other mark-ups for importers and manufacturers.

By using the lowest of the prices in the reference countries, as stipulated in section 4, it is virtually guaranteed that the resulting (maximum) prices are low. (If this is considered to be too drastic, an option is to set (maximum) prices on the basis of averaging the prices found in the reference countries.

Section 5 of this article states that, should the price lists in the reference countries contain another price than the wholesale selling price (the price that is charged to the pharmacist or hospital), these price will be recalculated to represent the wholesale selling price using the available national regulations in the reference country.

Decisions have to be taken with respect to the number of reference countries, the selection of reference countries and the selection of the appropriate price lists.

Section 11 states that, in case there are no comparable products in one of the selected price lists, the responsible minister can develop rules for this situation. It is, however, expected that this situation will occur very seldom.

Article 3

Article 3 lays out the obligation of the responsible Minister to investigate the need for a revision of the (maximum) prices every 6 months. The text gives the possibility of more frequent revisions which could be desirable in certain situations like the existence of high inflation.

The term of 90 days is in accordance with Directive 89/105/EEC (the “Transparency Directive”).

Article 4

Article 4 forbids basically all commercial dealing with medicinal products at a price higher than the established (maximum) price.

Article 5

DRAFT

Article 5 gives rules for manufacturers, importers, wholesalers and pharmacists for keeping an administration so that the responsible Minister can investigate any suspicions on violation of this law.

Article 6

Article 6 details the punishment should a manufacturer, importer, wholesaler or pharmacist violate this law by charging a higher price than the established (maximum) price. It should be noted that this punishment is per violation. This means that every time a product is sold at a price higher than the established (maximum) price the violator will be punished. Assuming there will be a fine, this means in practice that, as the product is usually sold to many pharmacies or patients, the resulting overall fine can be substantial.

Appendix 2

Regulation on the Reimbursement and the Setting of Reimbursement limits for Medicinal Products

Article 1.

1. In this law and all legislation based on it, the following shall have the meaning and definitions hereby assigned to them:

- i. Our Minister: the Minister of Health;
- j. medicinal product: any substance or combinations of substances as defined in § 2 of the (draft) Law on Medicinal Products;
- k. registered medicinal product: a medicinal product that has been granted a product licence issued by the Medicines Agency in accordance to the draft Law on Medicinal Products;
- l. Anatomic Therapeutic Chemical Classification: the classification of medicinal products, established under the responsibility of the WHO Collaborating Centre for Drug Statistics Methodology;

Article 2

Only registered medicinal products will be reimbursed that have been designated by Our Minister.

Article 3

For every reimbursed medicinal product, an assessment will be made to decide if this medicinal product is interchangeable with other reimbursed medicinal products. For all medicinal products that are considered interchangeable, a reimbursement limit will be established.

Article 4

1. A reimbursed medicinal product will be considered interchangeable if it:
 - a. contains identical active ingredients;
 - b. has an identical pharmaceutical form;
 - c. has the same or similar strength
2. The Anatomical Therapeutic Chemical Classification level 5 will be used to determine whether medicinal products contain identical active ingredients; in absence of an ATC-code the product marketing licence will be used.
3. (Option: The oral, oromucosal and transcutaneous administration forms are considered as identical pharmaceutical forms;)
4. Combination products will be considered interchangeable with other medicinal products, not being combination products, if
 - a. the active ingredients are present in medicinal products that are reimbursed; and
 - b. the products referred to under a. have the same pharmaceutical form.

Article 5

1. The reimbursement limit is expressed in a price per quantity product. The reimbursement limit is equal to(to be decided) ;
2. For combination products, considered interchangeable with other medicinal products, not being combination products, the reimbursement limit will be equal to the sum of the reimbursement limits of the individual active ingredients.

Article 6

1. For insured persons a co-payment shall exist that is equal to the difference between the reimbursement limit and the price of the actual dispensed product in those cases that the actual dispensed product is priced higher than the reimbursement limit;
2. The co-payment will be paid to the dispensing pharmacy.

Article 7

Our Minister will investigate at least every 6 months the need for adjusting the groups of interchangeable medicinal products and the reimbursement limits. If considered necessary, Our Minister will adjust the groups and the reimbursement limits within 90 days after the beginning of the investigation.

Article 8

For those products considered not interchangeable, the reimbursement limit will be set at the level of the (maximum) price.

General explanation

This draft regulation focuses on the setting of reimbursement limits. The proposed system consists of three layers:

1. the first layer is the setting (maximising) of the prices of medicinal products that are on the market by the (draft) Law on the Maximum Prices for Medicinal Products (appendix 1);
2. the second layer consists of limiting the number of drugs that are reimbursed (the positive list);
3. the third layer is the reimbursement limit system which maximises the reimbursement within a group of interchangeable medicines to the cheapest drug available.

Explanation by article

Article 1.

Article 1 gives the relevant definitions. In this article it is assumed that the Minister of Health will be responsible for the setting of reimbursement limits.

Article 2

Article 2 would be the appropriate place for setting out the criteria for inclusion of drugs on the positive list. Additional articles could deal with the organisational aspects like the composition of the positive list committee, the procedures for decision making and alike.

Article 3

The text speaks for itself. There will only be reimbursement limits for those drugs that are reimbursed.

Article 4

From the criteria for inter-changeability of drugs it follows that groups will consist of branded products that have lost their patent protection and generic versions of these products. It may also happen that products with the same active ingredients and the same pharmaceutical form are co-marketed under different brand names.

The WHO publishes the ATC codes for drugs. Level 5 is on the active ingredient level which means that, if products have the same ATC-code, they necessarily contain the same active ingredient. If occasionally no ATC-code has been established, the text of the product's marketing licence, issued by the Drug Bureau, will be used.

Patient convenience should not play a major role in reimbursement decisions (unless it really makes a difference from a clinical benefit point of view).

If certain pharmaceutical forms are considered to be different from existing ones, it will sometimes be impossible to create groups of interchangeable medicines. However, if the oral, oromucosal and transcutaneous administration forms are considered as identical pharmaceutical forms, the chances on not being able to create groups and thus reimbursement limits would be reduced considerably. This has been given as an option and is not essential for making the reimbursement limit system work.

Article 5

This article deals with the actual reimbursement limit. The limit could be set in a variety of ways and needs to be decided upon.

Article 6

The co-payment is equal to the difference between the reimbursement limit and the price of the actual dispensed product thus stimulating patients to opt for the cheaper drug without co-payment.

The system guarantees that there will always be drugs available without co-payment so that adequate drugs will remain accessible to patients and the quality of healthcare is not negatively influenced.

From fear of loss of market share, those companies with products priced higher than the reimbursement limit will be stimulated to lower the price of their product to the level of the reimbursement limit.

The co-payment will be paid to the dispensing pharmacy that will only be reimbursed for the costs of the dispensed drugs up to the reimbursement limit.

Article 7

At least every 6 months the need for adjusting the groups of interchangeable medicinal products and the reimbursement limits will be investigated. Only then can new products be added to the system.

The term of 90 days for adjusting the groups and the reimbursement limits is in accordance with Directive 89/105/EEC.

Article 8

If products are still under patent protection, it is not possible to form groups of interchangeable drugs. In these cases the reimbursement limit can be set at the level of the (maximum) price (one could also of course reimburse a percentage of the costs of these drugs e.g. 80%).