NEGOTIATING THE NEW MEDICINES REGULATORY FRAMEWORK: SOME BASIC FACTS AND OBSERVATIONS

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After many years, the controversial provisions of the Medicines and Related Substances Control Amendment Act, 90 of 1997, are finally coming into full force. The brakes were first put on Act 90/1997 in early 1998, when the Pharmaceutical Manufacturers' Association (PMA) and most of its members took government to court. In that application, which was finally abandoned in April 2001 following civil society intervention and international outrage, the PMA had sought to prevent the law from coming into force.

It took a further 2 years before most of the law, by now slightly amended by the Medicines and Related Substances Amendment Act, 59 of 2002, came into force. On 2 May 2003, most provisions of Act 90/1997 came into effect, as did the General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (101 of 1965), as amended.[1] These general regulations fleshed out much of the detail in respect of the legislative provisions in question.

There were a number of reasons why the full regulatory framework did not come into effect last year. First, Act 59/2002 expressly delayed the coming into effect of certain provisions of the law until 2 May 2004. Second, a further set of regulations dealing with medicine prices could not be drafted until the Pricing Committee had made recommendations to the Minister in this regard, and the committee could only be established once certain provisions of Act 90/1997 had come into effect. The Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances thus only came into effect on 2 May 2004.[2]

While all the relevant laws and regulations have finally been promulgated, the complete package of regulatory reform is still not fully operational. While certain aspects of the pricing regulations came into force immediately upon promulgation, others will take from 1 to 3 months to become operational. In addition, the provisions of the legislative framework dealing with dispensing health practitioners will only come into effect on 2 June 2004 (in terms of an order of the Pretoria High Court of 1 June 2004 in case No. 1908/2004).

MEDICINE PRICING REGULATIONS

PROHIBITION OF INCENTIVE SCHEMES

Since 2 May 2004, it has been unlawful to supply medicines 'according to a bonus system, rebate system or any other incentive scheme'. Sampling has also been prohibited. This means, for example, that 'bulk purchase' discounts are now a thing of the past. Nevertheless, discounted stock purchased before 2 May 2004 will remain in the supply chain for some time. As there is nothing in the law preventing these discounts from being passed on to consumers, medicine prices should not have been affected by the regulations in the short term.

This article focuses on some of the key issues that are of relevance to members of the Southern African HIV Clinicians Society and their patients. It is not intended as a comprehensive guide to the new regulatory framework.

SINGLE EXIT PRICE

Linked to the prohibition of discounts is the single exit price (SEP), a price set by the manufacturer or importer of a medicine for 'the lowest unit of the medicine . . . within a pack multiplied by the number of units in the pack'. The SEP includes the ex-manufacturer/importer price, a 'logistics fee' (a distributor and/or wholesaler fee) and VAT. The only additional cost to consumers will be the dispensing fee.

The SEP, which must be displayed on the medicine package or container in which the medicine is sold, is the same for all in the private and not-for-profit sectors. Simply put,

manufacturers and importers may not sell medicines to anyone other than the State at prices higher or lower than the relevant SEP.

The pricing regulations set out two mechanisms in terms of which the manufacturer or importer of a medicine must determine a particular medicine's SEP:

- The first mechanism, which has been effective since 2 June 2004, removes the 'cost' of incentive schemes such as bonuses, rebates and discounts. This effectively averages prices out without making any significant dent in the manufacturer's bottom line.
- The second mechanism is somewhat more complex. It involves the development – by the Director-General of Health (DG) – of a 'methodology for conforming with international benchmarks'. This is to ensure that medicine prices in South Africa are in line with those in other countries where medicine prices are regulated.

Manufacturers and importers will have 3 months to adjust their SEPs once the DG has published the 'methodology'. This process may very well result in a significant reduction in medicine prices, particularly if comparisons are made with developing countries like India. But until this happens – and it is unclear when this will be – the first mechanism must continue to be used.

This means that in the short term, the *average* price of medicines sold in the private sector should not change significantly as a result of the new law. Prices for those who buy medicines from large pharmacies in major cities may go up, whereas prices for those who buy from small pharmacies outside of the major metropoles and cities may drop. This is because the discounts and rebates offered in the past to some resulted in higher prices for others. But on average, however, prices should drop slightly because the SEPs are based on figures from last year.

DISPENSING FEES

The new law on dispensing fees only comes into effect on 2 August 2004. Until then, pharmacists and dispensing doctors can continue to sell medicines as they have done for some time. From 2 August 2004, however, dispensers may no longer charge a mark-up, but will be entitled to charge the following dispensing fees (exclusive of VAT):

- Pharmacists:
  For each Schedule 1 and 2 medicine without a prescription - 16% of the SEP up to a maximum of R16
  For each Schedule 3, 4, 5, 6, 7 and 8 medicine (and Schedule 1 and 2 medicine with a prescription) – 26% of the SEP up to a maximum of R26.
- Dispensing doctors:
  For all medicines regardless of scheduling, 16% of the SEP with a maximum of R16.

Pharmacists are unhappy with the new dispensing fees. The Pharmaceutical Society of South Africa (PSSA) believes that the fees are 'inadequate to ensure the survival of pharmacy'. It argues on the basis of an independent audited actuarial assessment that the fees 'will not be sufficient to ensure that the Department [of Health] achieves its objective of improving accessibility to pharmaceutical services', directly resulting in the 'unavoidable closure' of many pharmacies.

The PSSA and others have instituted legal action against the Department. In essence, the PSSA argues that the regulations should be amended to ensure the survival of existing pharmacies and the ability of pharmacies to 'extend pharmaceutical services into under-serviced areas', while at the same time reducing the costs of medicines. It is unclear at this point whether the PSSA's concerns will be addressed in an out-ot-court settlement, or if the constitutionality of the new dispensing fees will be tested in court.

DISPENSING DOCTOR LICENCES

WHY REGULATE DISPENSING BY DOCTORS?

While most dispensing doctors play a crucial role in ensuring that people access essential medicines, the right to dispense has in many cases been abused. This has been possible because the linkage of prescribing and dispensing creates perverse incentives, with the prescribing doctor having a direct financial interest in what he or she dispenses. This is not so when doctors prescribe and pharmacists dispense, as is the ordinary practice.

There is therefore a clear need to separate prescribing and dispensing wherever possible, only permitting the practice where it can be shown that the service is indeed required. This approach is endorsed by the World Health Organisation and practised in many countries internationally.

WHAT DOES THE NEW LAW SAY?

As a result of Acts 90/1997 and 59/2002, doctors (and other health professionals such as dentists and nurses registered under the Health Professions Act) now have to apply for and be granted licences before they can dispense medicines. There are in essence five requirements that must be satisfied before a licence can be issued:

- Completing and submitting the application in the prescribed form to the DG.
- Paying the application and licence fees.
- Successfully completing a supplementary course determined by the South African Pharmacy Council.
- Publishing an advertisement in a newspaper circulating in the area where the service is to be provided (for the

purpose of soliciting written representations, either in support of or in opposition to the granting of the dispensing licence).

- Demonstrating the need for the particular dispensing service to be provided.

The first three requirements are not particularly onerous. The requirement to place a newspaper advert may involve some cost and may potentially delay or prevent the granting of the licence. It is unclear how objections will be handled by the Department of Health.

Most problematic is the requirement to demonstrate need. In specifying the geographical area to be serviced, applicants must supply information not only on its population size, but also 'the disease patterns and health status of the population'. Further, the 'names and addresses of other similar existing services in the catchment area of the proposed new service' must also be supplied, including those of pharmacies, hospitals and clinics. It remains to be seen how the Department of Health will deal with those applications that do not provide such information because it is too difficult or expensive to obtain, if it can be obtained at all.

WHEN DOES THE NEW LAW COME INTO EFFECT?

The constitutionality of the new law – which was scheduled to come into effect on 2 May 2004 – is currently being considered by the Pretoria High Court. Brought by the Affordable Medicine Trust, the National Convention on Dispensing and Dr Norman Mabasa, the legal challenge to the law was argued on 31 May and 1 June 2004. In terms of an order of court made on the second day, the coming into effect of the new law on dispensing health practitioners has been postponed until 2 July 2004, on the understanding that the court will have made a ruling on the issue by that date.

REFERENCES

1. *Government Gazette* No. 24727, 10 April 2003.
2. *Government Gazette* No. 26304, 30 April 2004.