Legal challenges the PSSA is facing

The dispensing fee for pharmacists

It took many years and a court battle to reach a point where the dispensing fee for pharmacists was finally published for implementation on 19 November 2010. The fee is determined by applying a four-tiered formula that has a rand component and a percentage component. The initial targeted fee achieved by the formula in 2010 was R38.00 VAT exclusive. Each year the Pricing Committee should review the fee and advise the Minister on an increase taking into account the annual inflation rates published by Statistics South Africa. The proposed reviewed fee must be published for a three-month comment period.

The first few years, the draft fee was published for comment, the Pharmacy Stakeholders Forum (PSF), of which the PSSA is a member, would submit comment, and most years, the increase was linked to inflation. The draft fee for the next year was usually published around the middle of the year, ensuring an appropriate timeline for the three months comment period and time to review the comments before publishing the final fee.

In recent years the PSF has encountered a number of problems with the dispensing fee, one being the timelines when the draft and final dispensing fees are published.

The 2019 dispensing fee

Draft fee published on 9 July 2018

Final fee published on 23 January 2019

The 2020 dispensing fee

Draft fee published on 12 July 2019 – notice was signed by the Minister of Health on 15 May 2019

Final fee published on 19 June 2020 – notice was signed by the Minister of Health on 12 December 2019 (6 months to publish signed notice)

The 2021 dispensing fee

Draft fee published on 21 August 2020 – notice was signed by the Minister of Health on 5 May 2020

Final fee published on 10 September 2021 – notice was signed by the Minister of Health on 26 January 2021 (9 months to publish signed notice)

The 2022 dispensing fee

Draft fee published on 17 December 2021 – notice was signed by the Minister of Health on 19 October 2021

Final fee still to be published.

Another challenge that the PSF is currently facing is the fact that the previous and the current Pricing Committee do not understand that by just adjusting the rand component of the four-tiered formula by inflation does not lead to an inflation percentage increase in the targeted fee.

Each year Mediscor and MediKredit assist the PSF in comparing the current fee to the proposed new fee. The formula adjustment for the 2020 fee resulted in a 1.9% weighted average increase. The formula adjustment for the 2021 fee resulted in a 0.79% weighted average increase and the proposed formula adjustment for the 2022 fee results in a 0.9–1.3% weighted average increase.

The PSF has obtained the services of an actuarial company to assist them in compiling comments to the PSF in such a way that the message about how the four-tiered formula is used to determine the fee and that the fee should increase by at least CPI comes across clearly.

Destruction of Schedule 5 and 6 substances

On 25 August 2017 the General Regulations to the Medicines and Related Substances Act (Act 101 of 1965) as published in 2003 was repealed in its totality and replaced by a whole new set of General Regulations. One of the changes in the new regulations related to the destruction of medicines.

In the 2003 regulations, it was Regulation 27 that deals with the destruction of medicines and it read as follows:

1. A medicine or scheduled substance may be destroyed as follows:

   (a) A medicine containing a Schedule 5, 6, 7 or 8 substance may only be destroyed in the presence of an inspector, an officer of the South African Police Service or any other person authorised by the Director General.

   Such inspector, person or officer, as the case may be, shall issue a certificate confirming the destruction of the medicine and in the case of an officer, the case number must be entered in the register

In the 2017 regulations, it is Regulation 44 that deals with the destruction of medicines and it reads as follows:

1. A medicine or scheduled substance shall only be destroyed by a waste treatment facility authorised to destroy medicines or pharmaceutical waste in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).
5. A Schedule 5 or 6 substance or medicine shall be destroyed in terms of subregulation (1) in the presence of
   (a) an inspector;
   (b) a pharmacist; or
   (c) any other person authorised by the Chief Executive Officer.

It is clear from Regulation 44 that pharmacists are authorised to witness the destruction of Schedule 5 and 6 substances without any need for authorisation to destroy. If one looks at Section 22A of the Medicines Act, which deals with the control of medicines, scheduled substances, medical devices and IVDs, pharmacists are authorised to manufacture, import/export, wholesale, acquire, keep and sell Schedule 5 and Schedule 6 substances. So although Section 22A is silent on destruction, one can infer that since a pharmacist is authorised to do all the other steps, a pharmacist should be authorised to destroy Schedule 5 and 6 substances as detailed in Regulation 44.

Before the new General Regulations were published in 2017, pharmacists had to obtain authorisation from the then MCC (now SAHPRA) before Schedule 5 and 6 substances could be destroyed. The implication of the changes in the 2017 regulations were not realised as pharmacists continued to apply to SAHPRA for such authorisation.

In September 2021, SAHPRA published a number of guidelines for comment with the closing date for comment being 8 October 2021. Two such guidelines were guideline 5.05 – Guideline for destruction of Schedule 5, 6, 7 and 8 medicines/substances and guideline 5.11 – Guideline for permits and authorisation requiring fee. In terms of guideline 5.05, pharmacists still have to request authorisation from SAHPRA before Schedule 5 and 6 substances can be destroyed and in terms of guideline 5.11 the fee for such an authorisation is R950 per application.

Since these guidelines contain information specific to the manufacturing and wholesale industry, the PSSA agreed that the SAAPI sector of the PSSA would submit comments on the guidelines and in the comments they raised the issue of the guidelines falling outside of Regulation 44.

To date the guideline has not officially been published on the SAHPRA website, however, in January 2022, when pharmacists requested authorisation from SAHPRA for destruction of Schedule 5 and 6 substances they were sent guideline 5.05 as published for comment and were requested to pay the R950 fee.

The Pharmacy First Working Group, comprised of stakeholders in the private pharmacy setting, all agreed that the guideline is *ultra vires* (acting beyond one's legal power or authority) since in terms of Regulation 44, such authorisation is not required. The PSSA and ICPA met with SAHPRA on behalf of the Pharmacy First Working group and explained the challenge SAHPRA is facing.

It has since been explained by SAHPRA that they require information on the quantities of Schedule 5 and 6 substances as they need to report annually to the International Narcotics Control Board (INCB) on the quantities of narcotics imported, manufactured, exported, consumed and destroyed in South Africa. The INCB works closely with the World Health Organization (WHO) and United Nations (UN).

Activities of the International Narcotics Control Board

- Administration of a system of estimates for narcotic drugs and a voluntary assessment system for psychotropic substances and monitors licit activities involving drugs through a statistical returns system, with a view to assisting governments in achieving, inter alia, a balance between supply and demand.
- Monitoring and promotion of measures taken by governments to prevent the diversion of substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances and assesses such substances to determine whether there is a need for changes in the scope of control of Tables I and II of the 1988 Convention.
- Analysis of information provided by governments, UN bodies, specialised agencies or other competent international organisations, with a view to ensuring that the provisions of the international drug control treaties are adequately carried out by governments, and recommendation of remedial measures.
- Maintenance of a permanent dialogue with governments to assist them in complying with their obligations under the international drug control treaties and, to that end, recommendations, where appropriate, on technical or financial assistance to be provided.

Based on its activities, INCB publishes an annual report, which provides a comprehensive survey of the drug control situation in various parts of the world. As an impartial body, INCB tries to identify and predict dangerous trends and suggests necessary measures to be taken. The annual report is supplemented by technical reports on narcotic drugs and psychotropic substances, giving a detailed account of estimates of annual legitimate requirements in each country as well as data, the licit production, manufacture, trade and consumption of these drugs worldwide.

South Africa is a member of the INCB and currently Zukiswa Zingela of South Africa is one of the elected Board Members. SAHPRA, therefore, has a duty to report the requested information to the INCB. The challenge is now to find a way whereby SAHPRA receives the required information in order for them to comply with the INCB requirements, without going outside of their legal authority. At the time of writing, a solution had not yet been agreed to as discussions are still taking place.