Corridors overflowing with unprocessed applications

So while inroads have been made, many challenges remain. Several sources spoke of a time when the corridors on the MCC's second-floor offices in the Hallmark building in Pretoria were clogged with overflowing cardboard boxes containing thousands of applications for registration, many of them for so-called complementary medicines. At one time there were about 20 000 alternative medicine applications sitting with the MCC unprocessed and there was no plan to process them, Geffen said.

Some of this mess has now been cleared and on the surface order has been restored. Insiders said the new sense of urgency was also due to the involvement of Hogan's former special adviser Dr Nicholas Crisp, who is now overseeing the establishment of a Medicines Regulatory Authority (MRA), expected to eventually replace the MCC.

Quantifying the backlog

The extent of the current backlog is unclear. In a 2008 briefing to Parliament's portfolio committee on health, Hela said the backlog for registration in 2003 (the number of applications received but not registered in that year) was 28%. Those not registered for 2004 came to 31%, not registered for 2005 53%, not registered for 2006 80% and 98% were not registered for 2007 (see the graph on the opposite page).

It has also been reported that of the 748 applications received in 2008, only five were registered and of 2009's 281 applications, only two had been registered by January 2010.

In January the backlog was standing at nearly 3 000 medicines and it was estimated it would take two years to clear. An industry source said current delays continue for up to 40 months.

However, critical drugs are fast-tracked and registered within nine to 15 months, Hela said at the 2008 briefing.

The international average for the registration of drugs is between 20 and 22 months.

Explaining the problem

In 2008, Hela offered various reasons for the backlog, including that the MCC still had the same number of evaluators and committee members it had in 1965 in spite of an increase in the number of applications.

But the main culprit was what she called a 'tsunami' of generics. There are many duplicate applications of generics because a separate application is submitted for each different market targeted by the same product.

Very few of the dossiers in the system are New Chemical Entities (NCEs), in other words, many are simply versions of the original.

A 2008 report by Professor Ronald Green-Thompson, adviser for former health minister Dr Manto Tshabalala-Msimang, found the following: in 2003 there were 16 applications for NCEs and 508 for generics; in 2004, 27 were NCEs and 563 generics; in 2005, 18 were NCEs and 490 generics; in 2006 21 were NCEs and 801 generics; and in 2007 22 were NCEs and 765 were generics (see the graph on the opposite page).

The ARV issue

The MCC has also come under pressure from those who have an interest in seeing antiretrovirals registered. Earlier this year, HIV stakeholders called on the MCC to speed up the registration of the critical anti-HIV medication or face legal action.

The Southern African HIV Clinicians Society sent an appeal to the health minister to intervene and address the MCC registration process which they described as the single biggest obstacle to getting affordable access to medicines. They claimed that some drug dossiers had been in the MCC pipeline for years.

President of the society Dr Francois Venter warned at the time that the drugs on the list included all fixed-dose combinations, especially those that will be on the state's first-line regimen.

Alternatives: a free-for-all

In March this year, the Parliamentary Committee grilled Hela on the impunity with which those ▶

TIMELINE

THE UPS AND DOWNS OF THE MCC OVER THE DECADES

1965

▶ **The Medicines and Related Substances Control Act** is passed, establishing the Medicines Control Council.

1960s and 1970s

▶ **Every category of medicine** for treating major diseases is called up for registration.

1972

▶ **Johan Schlebusch** joins the MCC, starting as an inspector (medicine controller).

1981

▶ **Professor Peter Folb** is appointed chairperson of the MCC. He is a leading international expert on drug safety and an outstanding scientist.

1984

▶ **Schlebusch** is appointed registrar of the MCC.

1991

▶ The MCC tries for the first time to **regulate medical devices** and complementary medicines.

1994

▶ **The US Congress** passes the Dietary Supplement Health and Education Act that deregulates the supplements industry, making it easier to sell diet remedies and other dubious products alleged to improve health.

1996

▶ **Then director-general of health Dr Olive Shisana** chairs a meeting of alternative practitioners to discuss their concerns. The concern is that such a meeting falls under the MCC and not the health department. The health department is thought to have undermined the MCC's authority by hosting the meeting and rumours fly that change is in the offing.

▶ The sellers of complementary medicine seize on this time of uncertainty and **illegal medicines start pouring on to the market.**

▶ **Drug policy** is published for the first time in South Africa.

1997

▶ **The MCC convinces Shisana to change her mind** and Schlebusch moots a plan that would have brought the market under control. The plan never sees the light of day.

▶ **Wide-ranging changes to the Medicines Act** are introduced which the pharmaceutical industry opposes, resulting in years of litigation.

▶ **The MCC stands firm against Mbeki** on the false Aids medicine Virodene. The MCC suspends a clinical trial of Virodene which had proceeded without the approval of an ethics committee or the MCC.

▶ **Precious Matsoso** joins the MCC.

1998

▶ **Folb is not reappointed** when his term of office expires. Schlebusch and his deputy Christel Bruckner, who had both been with the MCC for over 20 years, are dismissed. Professor Helen Rees replaces Folb and Matsoso replaces Schlebusch. Deterioration of services is observed.

2001

▶ **A CCMA award reinstates Schlebusch and Bruckner** and the Labour Court makes it an order of the court. The department reaches a monetary settlement with Schlebusch, but continues to refuse to reinstate Bruckner in an appropriate position. She brings a contempt of court application against the department, minister and director general.

2002

▶ **The MCC publishes a notice in the Government Gazette** superseding all previous calls for registration of medicines in the same class – the previous call-up notices for herbal drugs (1973), special foods for which a claim was made (1974), products using the terms 'medicated', 'medicinal', 'medical use' etc (1978) and vitamins and minerals (1985) are superseded. This allows quacks to claim their concoctions are 'registered' with the MCC just because they had lodged an application.

2003

▶ **The court sentences Dr Manto Tshabalala-Msimang and Dr Ayanda Ntsaluba** to 15 days in prison for contempt (re the Bruckner matter), but the sentence is suspended. Bruckner is reinstated and is still there today, but is not assigned any substantive work. Professor Peter Eagles is appointed chairperson of the MCC.

2004

▶ **Matsoso leaves the MCC** and joins the World Health Organisation.

▶ **The Code of Practice for the Marketing of Medicines** is published for the first time in terms of the drug policy. This has never been finalised and leaves the door open for some of the marketing practices seen today with complementary medicines.

2005

▶ After repeated calls, **MCC registrar Dr Humphrey Zokufa** claims they are investigating the operations of German vitamin seller Matthias Rath. These claims are exposed as untrue when the Treatment Action Campaign goes to court. It turns out that there was no investigation into Rath's actions, nor into his unethical clinical trials.

▶ **Zokufa leaves the MCC** in November and becomes CEO of the Board of Healthcare Funders.

2006

▶ It emerges that the health department director general, **Thami Mseleku**, has been appointed interim registrar as a stop-gap measure to avoid any further delays in the registration of medicines.

▶ The acting head of pharmaceutical planning in the health department, **Mandisa Hela**, is later appointed registrar, a position she still holds.

2008

▶ The department of health proposes the introduction of regulations dealing with the **registration of complementary and alternative medicines** differently from scientific medicines.

▶ **The Medicines Act is revamped,** but has not yet been implemented. It provides, inter alia, for the MCC to be replaced by a new authority called the Medicines Regulation Authority which must be more independent of the health department.

▶ **Barbara Hogan is appointed health minister.** She sets up several task teams, one of which has the task of examining the legislation and problems linked to drug regulation. It is headed by Matsoso and includes several well respected experts in the field, including Folb.

• SOME OF THIS INFORMATION HAS BEEN SOURCED FROM *DEBUNKING DENIALISM* BY NATHAN GEFFEN (JACANA 2010)