million) project for strengthening traditional health systems for malaria control and prevention in the WHO African region.

Other potential herbal antimalarial medicines in three member states are also being evaluated. These evaluations are expected to reach the level of comparative clinical trials shortly.

Contrapuntally, a press release from Medinfo expresses some doubt about the success of such a venture:

A report by Médecins Sans Frontières (MSF), cited in an article that appears in a recent *British Medical Journal* (*BMJ*), states that traditional antimalaria drugs such as chloroquine and sulfadoxine-pyrimethamine are virtually useless due to the high degree of resistance developed by malaria-causing *Plasmodium* sp. in many parts of Africa. Indeed, the WHO guidelines on malaria treatment recommend that these drugs be replaced with artemisinin-based combination treatments.

However, the practical implementation of these guidelines is proving challenging, given the higher associated costs. Not only do artemisinin-based medicines cost US$1.50-2.40 per treatment compared with US$0.10 for chloroquine, but also a significant investment of funds is required to institute a change in treatment regimen. This said, MSF believes that an initial large injection of funds is required, after which the needs would be reduced as a result of the improved control over malaria leading to an overall decline in costs.

MSF estimates that providing artemisinin-based treatments in those African countries where it offers the most effective option would cost between US$100 and US$200 million. Not only is this an amount that international donors would be able to fund with relative ease, but also it would be an investment with significant return in terms of controlling malaria.

While no large-scale, prospective economic evaluation has been done, the efficacy of artemisinin-combination antimalarials is being monitored by organisations such as SAA-Netcare Travel Clinics. Says SAA-Netcare Travel Clinics medical director, Dr Andrew Jamieson, 'We have found artemisinin-based treatments extremely effective in several regions where the *Plasmodium falciparum* is responsible for the majority of malaria cases. In southern Africa it is resistant to traditional treatments. Our research in this area is ongoing, with a view to providing quantitative evidence that supports the WHO's guidelines while motivating a change of course for donor funds. Above all, we acknowledge the critical role that funding plays and will continue to play in rolling back the scourge of malaria and thereby facilitating economic development on the continent. As such, we are keen to ensure that these funds are invested wisely.'

MANAGED CARE

MANAGED CARE - ETHICAL ISSUES

Part I of a three-part series to be published in the July, August and September 2003 issues of the *SAMJ*.

Introduction

Health care is far more than just treating an illness. Since many treatment methods include an element of risk and harmful side-effects, morality is always a factor. There is often a need to justify the cause of these adverse features. Health care providers and patients should also concern themselves not only with what is good medical care, but also what constitutes good ethical care. There is often conflict between these clinical and moral goals since clinical practice is dissimilar to clinical ethics.

Decisions regarding health care are complex. Many medical interventions involve moral as well as medical deliberations and ethical concerns further complicate the decision-making process. The complexity arises from three main sources:

- both the doctor and the patient are involved in making decisions and there may be disagreement about what is considered proper medical treatment
- the patient's ability to make decisions might be lost or limited
- health care decisions often involve important moral issues and good clinical decisions are not always good moral decisions.

Almost all health care decisions have two objectives, namely deciding what will be good health care for the patient on the one hand and what will be morally good for the patient and the providers of health care services on the other. Deciding what is good health care for the patient is often very difficult. Some will argue that good patient care is treating to cure disease and preserve life, but although true in many cases – it is not always the case. In certain cases good care might consist of declining or discontinuing treatment because the interventions cause more harm than any possible benefits they could provide. In this case the objective becomes comfort and not cure – a recognition of medicine's inherent limitations.

Managed care introduces business considerations in the traditional doctor-patient relationship. In the USAmany large managed care companies are traded on the stock exchange. The business press regularly reports their profits along with the compensation of the chief executive and chief financial officers,

which can amount to millions of dollars annually. In colloquial terms, they are referred to as the 'darlings' of Wall Street. This has raised much controversy in the USAespecially from the provider community. Questions raised include whether these organisations are truly interested in the patients' well-being and whether practitioners will be pressurised to ensure huge profits for the managed care companies at the end of the day.

Ethics in managed care has become business ethics. Business's ethical obligations are integrity and honesty. Medicine's ethical obligations include, in addition: altruism, compassion, beneficence, non-malfeasance, and respect for patient autonomy and justice.

Doctor-patient relationship

Trust forms the central element in almost all the ethical obligations that doctors have towards their patients. Many of these are embodied in the Hippocratic Oath and include the obligation to keep a patient's private information confidential, to avoid mischief and sexual misconduct and to give no harmful or death causing agent.

The cornerstone of the doctor-patient relationship is laid in the trust that the doctors are dedicated first and foremost to serving the needs of their patients. Patients can expect that doctors will come to their aid even if it means putting the doctor's own health at risk and they can trust that doctors will do everything in their power to help their patients. It is this trust that enables patients to communicate private information and to place their health and indeed their lives in the hands of their doctors. Without the commitment that doctors will place patients' interests first and will act as agents for their patients, there is no assurance that the patients' health and well-being will be protected.

Herein arises a dilemma in managed care, since these systems restrict both patient and provider choice and could limit the clinical autonomy of providers. Managed care tools that are used to influence provider behaviour include:

- case management to coordinate expensive medical care
- financial incentives to encourage doctors to make medical decisions that conserve resources
- gatekeepers to control specialty referrals
- administrative rules or protocols.

The common element is control by managed care organisations and limitation of choices traditionally made exclusively within the doctor-patient relationship.

Conflicting duties cause a moral dilemma. Patients may not be aware that their doctors' self-interests conflict with their own. Conflict may also arise when doctors profit from patients' consumption of services, e.g. referrals to hospitals where they are shareholders. These conflicts are however not unique to managed care.

According to the American Medical Association managed health care involves at least two conflicting loyalties for the doctor, namely:

- Doctors are expected to balance the interests of their patients with the interests of other patients. For example, when a specific test is ordered the doctor should consider whether or not to save this specific slot for another patient of the funder or to rather conserve the resources. This refers to the ethical debate concerning the allocation of resources.
- A managed care plan can place the needs of the patients in conflict with the financial interests of their doctors. They could, for instance, encourage the doctors to make cost-conscious treatment decisions through the use of financial incentives. For example, bonuses could be paid to them with the amount of the bonus increasing as the plan's expenditures for patient care decreases. When a doctor decides to order a test he might recognise that it could have an adverse impact on his/her income. In an effort to control utilisation, managed care plans might even withhold diagnostic procedures or treatment modalities from patients.

Since managed care programmes have an inherent incentive to compromise the quality of care in the pursuit of cost-containment, it demands that doctors be both patient and organisational advocates. The doctor's fundamental obligation however remains to serve as patient advocate. By creating conflicting loyalties for doctors, some managed care techniques can undermine this primary obligation.

Specific areas within the managed care environment merit specific attention since they impact significantly on the doctor-patient relationship. These include freedom of choice, confidentiality and financial incentives. These will be discussed in Part II of this series on managed care.

Part II of this series will be published in next month's issue of the *SAMJ*.

Excerpted with permission from the Managed Care section of the Practice Management Programme of the Foundation for Professional Development of SAMA. For information on the FPD courses contact Annaline Maasdorp, tel(012) 481-2034; email: annalinem@samedical.org.

The Generic Times

JUNE 2003

OFFICIAL NEWSPAPER OF HEXAL PHARMA SA. WITH NEWS YOU CAN USE AS A HEALTHCARE PROFESSIONAL.

Vol. 1 No. 1

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FIRST GENERIC FLUCONAZOLE IN SOUTH AFRICA:

Hexal Pharma SA launch S4 FLUZOL™

Product details:
Hexal Pharma SA is proud to announce the launch of FLUZOL™ (fluconazole) capsules and infusion. The capsule formulation range includes 50mg (14's), 150mg (1's and 4's) as well as a 200mg pack of 30's.

FLUZOL™ (fluconazole) is the first generic equivalent available in South Africa, to the originator.

Hexal Pharma SA has positioned all strengths and formulation variants of FLUZOL™ (fluconazole) to retail at a price of 50% more cost effective versus the originator.

FLUZOL™ (fluconazole) represents the latest addition to Hexal Pharma's constantly expanding range of quality German generics. Your local Hexal representative will furnish you with more product related details. If you require further information, please contact Nic Strelzer on 700 6501 or e-mail: nstrelzer@hexal.co.za.

After all, is it not time someone ruled out the high cost of fluconazole!

The AIDS issue.
While FLUZOL™ is not an anti-retroviral drug, it has proven highly effective in treating two serious fungal opportunistic infections associated with the disease; namely cryptococcal meningitis and oesophageal candidiasis. Cryptococcal meningitis is a life-threatening infection of the membranes that surround the brain and spinal cord, occurring in 10% of AIDS patients.

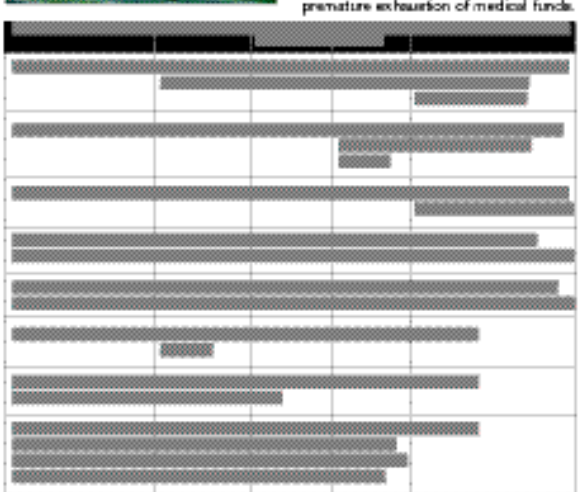
Oesophageal candidiasis is a fungal infection of the oesophagus, reported in 20-40% of all patients with HIV/AIDS.

Other indications:
Vaginal Candidiasis, Systemic Candidiasis, Cryptococcal Meningitis, Oropharyngeal Candidiasis, Oesophageal Candidiasis, Candida Balanitis, prevention of Candidiasis, Dermal infections - Tinea cruris, pedis, corporis, tinea unguium.

The Doctors responsibility
As you know, a General Practitioner needs to take a holistic approach to his patients' health care needs, not only caring for acute or chronic medical challenges, but also to effectively manage the patients medical savings account.

Very often a family may have limited "out-of-hospital" benefits which may not last the entire year. Indeed it has become a common occurrence that families tend to run out of benefits during the second quarter of the year.

FLUZOL™ and the substantial product line-up of Hexal Pharma (SA) enables you to offer your patient's quality German generics. On top of this, the cost saving to your patient may be as much as 40% as compared to originator products. By scripting or dispensing Hexal brands you will ultimately enable these medical benefits to last during the year & prevent premature exhaustion of medical funds.



Medicines from Hexal are a healthy choice.
Hexal medicines are characterised by high quality, and are ideally suited to doctors' needs. During the constant development of the medicines, attention is paid to special details, such as designing tablets with practical advantages eg. unique scoring/notching and user-friendly dosage forms ie. effervescents.

QUALITY GERMAN GENERICS

Hexal Pharma SA is part of the global pharmaceutical giant, Hexal AG of Germany, which specialises in the development, production and marketing of modern generics.

The company also has a focus on innovative pharmaceutical preparations.

Today only 16 years after being founded, Hexal is a leading international generics group, with subsidiaries in more than 35 countries, more than 4 500 highly qualified employees worldwide, and global sales of more than euro 800-million.

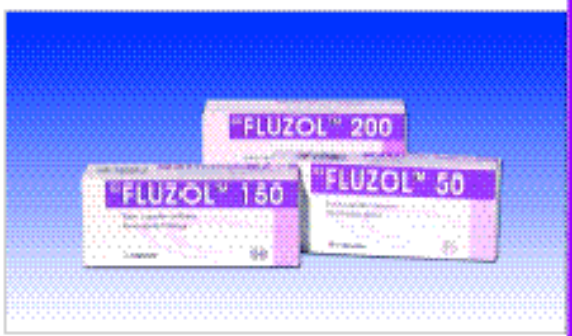
Quality and efficiency in all we do, treating people with respect, caring for the ill - these are and remain the principles of our thoughts and actions, and they are the cornerstones of our success.

Good medicine for doctors and patients

Hexal invests about 15% of total sales in research - which means that both the patient and the doctor benefit.

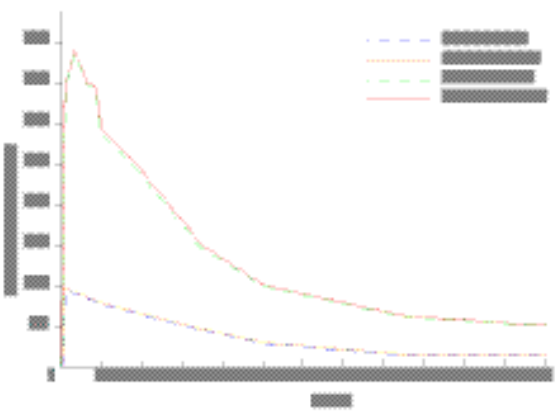
The doctor benefits by prescribing state-of-the-art treatment. The patient benefits from a wide range of high quality generics and pharmaceutical specialities. With its wide product-range, Hexal is represented in all therapeutic areas.

The main focus of the product portfolio is on cardiovascular drugs, analgesics and gastro-intestinal preparations. In the OTC sector, Hexal's ADC 200™ and Lorano™ have been the most successful to date. Hexal AG already has a wide spectrum of genetic engineering and biopharmaceutical methods.



FLUZOL™ 50mg capsules
FLUZOL™ 150mg capsules
FLUZOL™ 200mg capsules

Fluconazole Mean Concentration - Time profile for FLUZOL™ 50mg/200mg capsules Vs the originator



Conclusion:

1. As can be seen from the graph, both FLUZOL™ 50mg and 200mg capsules closely mimic the plasma concentration of the originator product.
2. FLUZOL™ 50mg and 200mg capsules thus compares most favourably to the reference product in terms of bioavailability.
3. This highlights Hexal's quest for excellence from formulation through to pharmacokinetics!

Ruling out the high cost of fluconazole!