



NEWS

SURGE IN DEMAND LEADS TO SHORTAGE OF ARTEMISININ-BASED COMBINATION THERAPY FOR MALARIA

Sharply increased demand for artemether-lumefantrine, an artemisinin-based combination therapy (ACT) used to treat malaria, is likely to result in a shortage from now until at least March 2005. ACTs are currently the most effective medicines available to treat falciparum malaria – the deadliest form of the disease.

Since 2001, the World Health Organization (WHO) has recommended that countries where malaria is resistant to conventional treatments such as chloroquine should switch to ACTs. The WHO currently recommends four ACTs: artemether-lumefantrine, artesunate-mefloquine, artesunate-amodiaquine, and artesunate-sulfadoxine/pyrimethamine.

Since 2001, 40 countries (20 of them in Africa) have officially adopted these medicines for the treatment of malaria. Eighteen countries adopted them in 2004 alone. Fourteen countries have opted for artemether-lumefantrine as their first-line malaria treatment.

In 2001 the WHO concluded an agreement with Novartis Pharma AG, under which Novartis provides its co-formulated artemether-lumefantrine product (Coartem) to the WHO at cost for supply to the public sector of malaria-endemic developing countries.

Coartem is currently the only ACT that has been prequalified by the WHO. This means that the WHO has arranged for the product dossier and the manufacturing process to be evaluated, and that as a result of this evaluation, the drug was found to be acceptable in principle for procurement by UN agencies.

Orders for artemether-lumefantrine have increased rapidly since 2001, when the WHO requested 220 000 treatment courses for the public sector. In 2004, a demand of 10 million treatment courses was forecast. For 2005, the WHO projects a demand for 60 million treatment courses.

Novartis has informed the WHO that owing to insufficient supply of the key ingredient artemether from its Chinese suppliers, there is currently a shortage of the drug. As a result, the WHO will not be able to procure the quantities of artemether-lumefantrine required during the coming months.

The WHO is recommending that all countries facing shortages increase procurement of their second-line antimalarial treatment, which is generally quinine. Quinine is still effective against falciparum malaria, but it is difficult to use because treatment takes longer.

The WHO will offer technical assistance to any country facing interrupted supply of artemether-lumefantrine. It will also

provide each country that has placed an order for artemether-lumefantrine with details of expected quantities available and delivery schedules.

As a result of the supply shortage, the WHO will establish a system to prioritise between requests for Coartem, based on a number of specific criteria (in addition to the existing eligibility criteria), and will issue an update on the artemether-lumefantrine supply situation by the end of November 2004.

MEDICINES FOR MALARIA VENTURE AND GLAXOSMITHKLINE COLLABORATE TO FIGHT MALARIA

Project team selects a pyridone drug candidate for preclinical development

Medicines for Malaria Venture (MMV) have announced that they have signed an agreement with GlaxoSmithKline (GSK) to develop GW844520X, a member of the novel class of pyridone compounds that has shown promising antimalarial activities. Pyridones work by inhibiting the energy processes of the micro-organism that causes malaria.

GW844520X is the first drug candidate to emerge from one of four projects in the GSK-MMV 'mini-portfolio' research collaboration. This collaboration is investigating a number of new compounds that could be developed as potential antimalarials.

GW844520X is currently undergoing a detailed preclinical safety assessment. If successful, phase I clinical trials where the safety, tolerability and pharmacokinetics in humans are studied could begin early in 2005.

NEW WHO REPORT CALLS FOR A NEW AND INNOVATIVE APPROACH TO HEALTH SYSTEMS RESEARCH

Urgent need for research to bridge the 'know-do' gap

Health systems research has the potential to produce dramatic improvements in health worldwide and to meet some of the major development challenges in the new millennium. Effective research could prevent half of the world's deaths with simple and cost-effective interventions, the World Health Organization (WHO) says in a new World Report on global health research.

The WHO World Report on Knowledge for Better Health: Strengthening Health Systems highlights aspects of health research that, if managed more effectively, could produce even more benefits for public health in future. It sets out the



strategies needed to reduce global disparities in health by strengthening health systems.

Inequities in health are among the major development challenges in the new millennium and malfunctioning health systems are at the heart of the problem. Moreover, the culture and practice of health research should reach beyond academic institutions and laboratories to involve health service providers, policy makers, the public and civil society.

The Report also argues that science must help to improve public health systems and should not be confined to producing drugs, diagnostics, vaccines and medical devices. Biomedical discoveries cannot improve people's health without research to find out how to apply them within different health systems and diverse political and social contexts, thus ensuring that they reach those who need them the most.

Dr Lee Jong-wook, WHO Director-General, says 'There is a gap between today's scientific advances and their application – between what we know and what is actually being done. Health systems are under severe pressure and there is an urgent need to generate knowledge for strengthening and improving them'.

Based on a wide-ranging consultative process and on previous reviews of global health research, the report advocates that health equity can only be achieved through better management of health research and increased investment in health systems research. The latter suffers from a poor image and has been under-funded compared with biomedical research, despite widespread recognition of its importance. The field attracts less than one-tenth of 1% of total health expenditure in low-income countries.

The lack of attention given to this field is also reflected in that only 0.7% of scientific articles published globally in the year 2000 were in the area of health systems research.

'Health systems should nurture a stronger culture of learning and problem-solving to tackle the major health challenges of our times', said Tim Evans, Assistant Director-General, WHO. 'This could be achieved by understanding how elements within a health system interact with each other and by finding innovative ways to solve complex problems.'

LANDMARK REPORT COULD INFLUENCE THE FUTURE OF MEDICINES IN EUROPE AND THE WORLD

The World Health Organization (WHO) released a groundbreaking report which recommends ways in which pharmaceutical research and innovation can best address health needs and emerging threats in Europe and the world.

The report identifies a priority list of medicines for Europe and the rest of the world, taking into account Europe's ageing

population, the increasing burden of non-communicable illnesses in developing countries and diseases which persist in spite of the availability of effective treatments. It looks at the gaps in research and innovation for these medicines and provides specific policy recommendations on creating incentives and closing those gaps.

Priority conditions identified by the report are:

- Future public health threats: infections due to antibacterial resistance, pandemic influenza.
- Diseases for which better formulations are required: cardiovascular disease (secondary prevention), diabetes, postpartum haemorrhage, paediatric HIV/AIDS, depression in the elderly and adolescents.
- Diseases for which biomarkers are absent: Alzheimer disease, osteoarthritis.
- Diseases for which basic and applied research is required: cancer, acute stroke.
- Neglected diseases or areas: tuberculosis, malaria and other tropical infectious diseases such as trypanosomiasis, leishmaniasis and Buruli ulcer, HIV vaccine.
- Diseases for which prevention is particularly effective: chronic obstructive pulmonary disease including smoking cessation.
- Alcohol use disorders: alcoholic liver diseases and alcohol dependency.

Innovative solutions

The report suggests that efforts to shorten the medicine development process without compromising patient safety would greatly assist in promoting pharmaceutical innovation. For instance, the EU could create and support a broad research agenda through which the European Agency for Evaluating Medicines (EMA), national regulatory authorities, scientists, industry and the public would critically review the regulatory requirements within the medicine development process for their relevance, costing, and predictive value.

Health authorities are responsible for medicine reimbursement decisions that aim to ensure safe and effective treatment for all patients, while reconciling this with budgetary constraints. The EU Commission and national authorities should support a research agenda on the various methods of rewarding clinical performance and linking prices to national income levels.

The report points out that major pharmaceutical gaps have been closed in the past. For example, until 1975 the main treatment for severe peptic ulcer – a common ailment – was surgery. After a long period of focused research in biological mechanisms underlying ulcer disease, effective medical treatments were discovered. These breakthrough discoveries, combined with the discovery that most ulceration was caused



by bacteria treatable with antibiotics, made surgery unnecessary.

The recommendations contained in the report could have a significant impact on research innovation and policy, with support from European leaders.

WHO AWARDS MILLION DOLLAR CONTRACT FOR GLOBAL TREATMENT PREPAREDNESS ACTIVITIES

The World Health Organization (WHO) is awarding a US\$ 1 million contract to a global consortium of people living with HIV/AIDS (PLWHA) and treatment activists to help prepare them for antiretroviral treatment (ART).

Following a competitive process, the Collaborative Fund for HIV Treatment Preparedness consortium – a programme created in 2003 to channel funds for community-based education, managed by the US-based organisation Tides Foundation – was awarded the contract through the WHO's 'Preparing for Treatment' programme.

The WHO initiative supports community-based treatment preparedness activities as part of the drive to increase access to treatment and prevention in line with the '3 by 5' target to get 3 million people living with AIDS on ART by the end of 2005.

'People living with HIV/AIDS need to know about antiretroviral medicines. Those who currently have access to treatment need this knowledge to be informed about their treatment and to ensure they know how and when to take their medicines. Those without access need this knowledge in order to become active in advocating for scale up in their countries', said Dr Lee Jong-wook, WHO Director-General.

The Collaborative Fund distributes funding to regional networks of PLWHA which then establish grant initiatives and tendering processes at the community level. In each of these regions, workshops are already under way to help develop the treatment preparedness agenda. Supporting the 'Preparing for Treatment Programme', UNAIDS has contributed over US\$100 000 over the past year to these regional meetings and will be providing a 'best practices' document based on experiences of programmes in late 2005.

'This proposal ensures the participation of people living with HIV/AIDS in all aspects of the programme and at all levels of decision-making and activity', said Dr Jim Yong Kim, Director of the HIV Department at the WHO.

Treatment preparedness activities aim to give people on or in need of ART easy-to-understand information about issues such as how HIV works in the body, HIV testing, opportunistic infections, different treatment types available and how they work, how to take treatment correctly and support services available.

All treatment preparedness activities aim to ensure the meaningful involvement of PLWHA and their communities in decisions regarding their care, including the distribution of resources.

'This is perhaps one of the greatest UN-led examples of implementation of the GIPA (Greater Involvement of People with AIDS) principle [established in 1994]. The contract award shows a commitment to a community-driven model, relying on the expertise of people living with AIDS and community-based groups to developing projects they need to do. It also acknowledges that treatment preparedness is as important a component of the "3 by 5" success as is receiving the drugs', said David Barr, Senior Philanthropic Advisor for Tides Foundation.

The million dollar contract is the first of what the WHO hopes will be an ongoing process within the Preparing for Treatment Programme with the aim of supporting additional community-based treatment preparedness activities as funding becomes available.

SOUTHERN CROSS AND UCT PRIVATE ACADEMIC HOSPITALS TO AMALGAMATE

Network Healthcare Holdings (Netcare) and Community Healthcare Holdings (CHH) announced the amalgamation of the clinical and support services of the Southern Cross and UCT Private Academic Hospitals.

The announcement came just days after Professor Nicky Padayachee, head of the University of Cape Town's Medical School and president of the Health Professions Council, said at a briefing of Parliament's Health Portfolio Committee that state hospitals could no longer be relied on to provide sophisticated medical equipment and some procedures such as orthopaedic surgery. Padayachee said student doctors were not gaining enough experience in state hospitals, but co-operation with the private hospital sector ideally had to be kept under the supervision of universities.

Dr Kerrin Begg, Hospital Manager of Southern Cross Hospital, explained that the clinical and support services of this hospital will be relocated to the premises of UCT Private Academic Hospital by 31 December 2004 following months of careful planning and negotiations. 'Southern Cross Hospital will remain operational until the amalgamation with UCT Private Academic Hospital has been completed successfully. Patients will in the interim continue to benefit from the vast experience and exceptional service on offer within the Wynberg based operation,' added Dr Begg.

With UCT Hospital and Groote Schuur Hospital already cooperating in several areas to provide their patients with better care and easier access to good quality medical facilities, the amalgamation is expected to further strengthen ties between

these two institutions. 'By pooling our strengths, experience and resources, we are creating a win-win scenario for both state and private patients in the Western Cape,' said Riel du Toit, CEO of UCT Private Academic Hospital.

FNS