

Former President Clinton Announces New Agreements to Lower Prices and Ensure New Supply of Malaria Drugs

Former President Bill Clinton, joined today by the UN Special Envoy on Malaria and the Chairman and CEO of Novartis, announced agreements with six companies - Calyx Chemicals, Cipla, Holley Pharmaceuticals, Ipca Laboratories, Mangalam Drugs and PIDI Standard - that lower by 30 percent the price of a leading artemisinin-based combination therapy (ACT) for malaria and that reduce by 70 percent the price volatility of artemisinin, the key raw material for this and other ACTs.

Up to 500 million people around the globe need malaria treatment each year. Today's agreements make prices for malaria drugs more affordable and sustainable to help meet growing global demand. The prices will be available to the 69 countries in Africa, Asia, Latin America and the Caribbean that make up the Clinton HIV/AIDS Initiative (CHAI) purchasing consortium. 'Nearly every life lost to malaria could have been saved with access to effective medicines,' **President Clinton said**. 'My Foundation has helped organize markets for HIV/AIDS drugs and green technologies, and I am proud that we have been able to extend this model to malaria. Today's announcement is an important step forward in global efforts to increase access to affordable and effective malaria treatment, and I applaud the commitments of these companies to lower volatility in this market and offer low and sustainable prices that will save more lives.'

The scale up ACT access has been challenged by significant volatility in the artemisinin market. Beginning in 2004, a rapid but uneven increase in ACT demand led to the price of artemisinin fluctuating by more than 700 percent. Novartis, the dominant ACT supplier to date, absorbed much of the financial impact, shielding patients from higher prices which would have decreased access. However, acting alone Novartis cannot meet increased future demand across the globe. Today's agreements will help to mitigate risk so new suppliers can enter the market.

Under the agreements negotiated by CHAI, Ipca and Cipla (both based in Mumbai, India) will offer a co-blister formulation of artesunate+amodiaquine (AS+AQ) — one of the most widely used ACTs — at or below an average ceiling price of 48 cents per treatment, a reduction of more than 30 percent from current market rates. They also will offer artemether-lumefantrine (AL), the other most common ACT, at or below an average ceiling price of 91 cents, the current price available from Novartis. Among the other manufacturers party to the agreements, Calyx (Mumbai) and Mangalam (Mumbai) are active ingredient suppliers, and Holleypharma (Beijing) and PIDI (Guangzhou) are suppliers of the raw material, artemisinin. 'I come from a family of farmers and know first hand about both agricultural production and pharmaceutical production,' **said Premchand Godha, Managing Director of Ipca**. 'Poor planning, bad weather and other factors can dramatically influence price and cause volatility. We appreciate the Clinton Foundation's holistic approach to reducing that volatility and making lower drug prices sustainable in the long term.' 'Since 2001, Novartis has supplied more than 180 million treatments of Coartem® to malaria-endemic countries,' **said Daniel Vasella, Chairman and CEO of Novartis**. 'We know first-hand addressing the health problems of the developing world is challenging and no single player can be successful. To make a meaningful and sustainable impact for patients, governments, international institutions, industry, and civil society must join forces.'

CHAI has taken several additional steps to ensure a sustainable supply of ACTs. In June, CHAI published a global ACT demand forecast to improve the predictability of demand and enable suppliers to make informed production planning decisions. CHAI also has provided extensive

technical assistance to partner ACT manufacturers to expedite regulatory approval. As the Global Fund, UNITAID, and the U.S. President's Malaria Initiative increase funding for ACTs, this support will help expand the set of high-quality suppliers able to meet growing demand. In addition to their price commitments, Ipca and Cipla have agreed to pursue rapid development and regulatory approval of a fixed-dose combination for AS+AQ, which is not yet available from any supplier approved by the World Health Organization (WHO) but is preferable to the co-blister form.

CHAI is committed to ensuring that its agreements offer high-quality products at sustainable prices, and these products meet the quality assurance standards of the Global Fund to Fight AIDS, Tuberculosis, and Malaria. Ipca's AS+AQ formulation has been approved by the WHO. All other formulations included in the agreement have been submitted for review with data establishing bioequivalence, based on studies conducted by contract research organizations that have been successfully audited by the WHO or a stringent regulatory authority. In many countries, half or more of all malaria patients buy their drugs from local shops, where ACT prices include distribution mark-ups and are too expensive despite the low prices offered by

manufacturers. To help ensure these low prices are translated to access for everyone who needs ACTs, CHAI has piloted the use of subsidies to lower prices in these shops. This pilot has had rapid impact, decreasing retail prices from \$10 to \$0.50 and increasing ACT access among children by 60-fold. CHAI now is helping Tanzania and other countries take this model to scale.

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