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## Anti-malarial Treatments (ACT): R&D and dissemination

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### Summary:

ACTs recommended in WHO guidelines (2005) at a global scale and still the most effective anti-malarial treatments, result from a long-term, gradual and specific process of basic research and development. ACT R&D process and the circulation of these pharmaceuticals raise but also bring about economic, science and policy issues. These issues and their links to economic development will be discussed.

Key-words : medical research, ACT, history of treatments, drug development, health policy, economic development, Chinese medicine, China, Vietnam, Mekong region

### Presentation:

ACTs (Artemisinin-based Combinations Therapies): R&D, diffusion, and economic&science issues in Southeast Asia

### Introduction

The paper builds

on results from two research work packages: one is about « History&Anthropology of anti-malarial treatments in Southeast Asia » conducted within the framework of the SOREMA Programme (Societies, Resistances, Malaria), Cambodia and borderlands (Vietnam, Laos) (F. Bourdier, P.I. 2012-2015); the other focuses on « Medical research in Chinese Medicine&Integrated Medicine in China », a key line in the Social Sciences Programme of IRD-PUMC/CAMS (Peking Union Medical College/Chinese Academy of Medical Sciences, Tsinghua University, Beijing (E. Micollier, P.I., 2006-2011).

The objective is to inform on a global context of circulation of knowledge and drugs with a focus on medical research (production/dissemination), to help in documenting resistance, treatments current access&availability, and to follow up the implementation of local/national guidelines based on international guidelines adapted to local contexts regarding anti-malarial treatments.

Using ethnographic tools, the method includes archival research in lab&research centers and observation on sites as far as possible: access, availability, pharmacies&health programmes, documentation about clinical trials. Theoretical keys are as follows: Whyte al. (2002) trace the « social life » of industrial pharmaceuticals products from their production to their circulation on the market; the « chaîne du médicament » (Garnier, Levy 2007) takes into account actors' network, procedures, regulations, uses and ideas from the R&D to the marketization process, a heuristic for bringing out biomedical, socioeconomic, cultural and ethical issues. Micollier (2013) applies Latour's concepts (1991) of « hybrid object » and « extended actors' network » to the anthropology of pharmaceuticals.

Brief chronology: basic research, R&D process, legal framework for production & marketization  
Artemisinin is extracted from qinghao su (*Artemisia Annua L.*, a plant registered in ancient Chinese

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pharmacopeia). The molecule was discovered in China by Chinese researchers (Zhou 2009; Tu 2011). Over time, development, production and marketisation have become global. ACTs are normally used for cure and not for prevention.

- 1964: Vietnam war; China was supporting North Vietnam providing medical aid; malaria stroke soldiers reducing military force up to 90%; from a report to China's Central Military Committee, the government decided to mobilize military and civil scientists to develop new anti-malarial treatments (Zhou 2009)
- 1967: launching of Project 523: top secret state mission  
Two research groups were involved, one in biomedicine, the other in TCM (Traditional Chinese Medicine) (Ongoing research in TCM : Micollier 2011)
- 1970: shift to TCM only research while developing these treatments were not a priority anymore;

*Artemisia Annua L.* is selected for further research

- 1972: extraction of artemisinin from the plant
- 1979: identification of its molecular structure
- 1981: research project on ACT while parasites could not be completely eradicated with Artemisinin used in monotherapy
- 1985: development of first ACT tablet (combination of artemisinin and artemether: derivative&lumefantrin)

- 1992: registration as a new medicine in China (Coartem); that same year, official PRC pharmacopeia registered for the first year at WHO
- 1991: partnership Novartis&Chinese Academy of Military Medical Sciences, Institute of Microbiology&Epidemiology and Kunming Pharmaceutical Corporation
- 1994: Novartis acquired worldwide licensing rights for Coartem outside China
- 1998: international approval for the drug/China first internationally approved&patented pharmaceutical product

From this case-study, the main points are discussed as follows. Co-R&D has been ongoing at a regional scale (China-Thailand-Vietnam): clinical trials and local development were conducted in China (Yunnan, Hainan), in Thailand (in cooperation with Thai researchers) and in Vietnam. In the 1980-1990s, Thailand has been involved in close research and development cooperation with China. As for medical issues, resistance has been confirmed in Southeast Asia (firstly in Cambodia; in Southern Laos: Attapeu, Champassak; regions in Vietnam, Thailand, Myanmar). The circulation of artemisinin used in monotherapy in Southeast Asia (1980s) before the development and diffusion of ACTs still needs to be documented. The dissemination of fake drugs (ACTs containing fewer or none artemisinin&derivatives) in Southeast Asia and elsewhere remains a big issue (Newton et al., 2006; Karunamoorthi 2014 ‘crime against humanity’).

Regarding science issues, science development is closely related to economic development as biomedical&integrated medical research need funding, infrastructure, well trained staff, knowledge and technology transfer. Basic research, R&D, innovation have to be scaled up among ASEAN+3 countries (China, Korea, Japan) on the move towards a knowledge economy, and more specifically cooperation in knowledge production and research&innovation policy in times of economic integration among ASEAN nations (2015). In Lao PDR, a significant bilateral research agreement in medical sciences with Chinese institutions has been approved in 2012. Standardizing process and upgrading quality standards are needed as well as legal framework building up and regulations enforcement strengthening.

Last but not least, the issue of drug security needs to be discussed at national, regional, international levels following a number of food&drug scandals and assessment of many fake&low quality drugs circulating in the informal/formal market; the consequences of these latter have a

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disastrous impact on economic and human development as demonstrated with ACTs case-study (Karunamoorthi 2014).

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