

## Draft proposal for clinical trials of rhinoceros horn

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### Introduction

It is estimated that around 85% of the world's rhinoceroses have been killed for their horns since 1970. The killing continues, despite a ban on international trade in rhinoceros horn in 1976 since when all five species of rhinoceros have been listed on Appendix 1 of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), a 1987 CITES Resolution calling for a ban on internal trade, and, with the exception of Laos, national legislation protecting rhinos throughout their range. Although the trade has been eliminated or greatly reduced in some countries there is such a great demand for rhino horn in Chinese communities in the Far East and even in Europe and North America, that there are still good profits to be made by poaching rhinos and smuggling the horns onto the market. There is a long tradition of the use of rhinoceros horn in Chinese medicine, and it is on this tradition that the trade is based. The main markets are in Taiwan (where the retail price for Indian rhino horn has reached US\$60,000 per kilogram), Thailand, South Korea, China (mainly for manufacture of medicines for re-export), and to a lesser extent in Hong Kong and Macau. In all these places import and export of rhino products are banned, and in all but China and South Korea the domestic trade is also illegal.

At a meeting in February in Taipei the first steps were taken to legalize internal trade in rhinoceros horn. The following month in Kyoto the 8th Conference of the Parties to the Convention on International Trade in Endangered Species (CITES) considered proposals from Zimbabwe and South Africa to legalize a certain amount of international trade in rhinoceros horn. Although there have been no relaxations of the international trade ban yet, there is a continuing debate on the matter, and there will shortly be further moves to reopen legal trade in rhino horn.

Proponents of legalizing the trade in rhino horn say that there is a real need for this substance and that in some cases it can save life. They point out that legalization of the trade would provide much needed funds that could be put back into protection of rhinos in the wild, and claim that the 16 year trade ban has contributed to the decline of the rhinos. <sup>Some</sup> Opponents claim that rhino horn has no medical properties and that its effects, if any, are purely psychosomatic. They point out that although legalization of the trade may provide funds for certain countries, any kind of controlled harvest will help to increase demand, that rhinos in other countries would suffer as a result of the opening of legal trade routes, that breakdowns in law and order will always pose a threat to rhinos as long as there is a demand for it, and that killing poachers to protect rhinos is wrong and could be avoided if the demand was eliminated. Others, <sup>however</sup> while conceding that rhino horn may have some medical properties, oppose the legalization of trade because they consider that (a) there are many adequate substitutes for rhino horn in Chinese medicine, and (b) the benefits of continued use of rhino horn do not justify the risks to the continued existence of the five species of rhinoceros that would be caused by a relaxation of the trade bans.

There is no unequivocal scientific evidence that rhino horn has medical properties, and it is important for the continuing debate on this subject and decisions on the future management of the world's rhino populations, that reliable data are made available. In order to resolve the central question of whether or not rhino horn is or is not a valuable medicine it is proposed to carry out clinical trials on humans.

## Background

Rhinoceros horn has been used in Chinese medicine for over 2000 years. It is used for a variety of conditions, but is termed a 'cold' drug in Chinese medicine and is most often used in hyperthermia (But et al, 1990). A number of studies have been carried out on animals to test rhino horn for antipyretic effects. Huang et al (1959) and Yuan (1987) found no antipyretic effect when they administered rhino horn by mouth to hyperthermic rabbits, but Ogata et al (1960) showed an antipyretic effect in rabbits when they injected rhino horn intravenously. But et al (1990a, 1990b) from the Chinese University of Hong Kong demonstrated a reduction in artificially induced fever in rats following injection of rhino horn extract at concentrations of 10 to 100 times the equivalent normal human oral dose, but showed too that extracts of the horns of saiga antelope, water buffalo and cattle also caused a significant drop in fever, and that there was no difference in the fever reducing effect of a traditional mixture of herbs and rhinoceros horn when the horn was omitted from the mixture. There are various case histories published (eg Xu, 1986), but they are not controlled studies. There is more negative published evidence than positive, and rhino horn has not been proved to be irreplaceable as a medicine. What is needed to resolve this dispute is a set of double blind placebo controlled experiments on human patients suffering from the conditions for which rhino horn is normally prescribed by practitioners of Chinese medicine.

## Proposed study

As rhinoceros horn is most often used in hyperthermia (But, 1990a) the proposed trial will test whether or not rhinoceros horn has an antipyretic effect in humans with a raised body temperature. The likelihood of individuals developing a fever in everyday life is low, so the population for the trial will be drawn from the patients admitted to the infectious diseases ward of a major hospital. Over a period of several months all consenting patients admitted to the ward with a fever greater than 1° C above normal will be given, on a random basis, either a standard course of rhino horn or a course of placebo, in addition to the normal treatment for the underlying condition diagnosed. The patients' temperatures will be taken at appropriate intervals over the following 48 hours, in the same place, at the same ambient temperatures, and under double blind conditions such that neither the patients, nor the nurses taking the temperatures, know which patients have taken rhino horn and which have taken placebo.

The study should take place in a country where the authorities will allow patients to be given rhino horn as a drug: this probably rules out most European countries, but Hongkong or Singapore might agree to the proposal. It is essential to gain the cooperation of medical practitioners in the country selected for the study, and the costs of the study will depend to a large extent on what kind of cooperation can be secured, and how quickly the required sample size of patients can be attained. Until further consultations have taken place on details of the study it is hard to give a firm idea of the amount of funds required. It is hoped that the study could be completed within six months of being commissioned. The budget should include:

- Fees and living expenses for project manager in Far East
- Fees for statistical and medical consultant in UK at planning stage
- Travel to and from Far East for project manager.
- Fees for medical consultants in Far East
- Extra pay for nurses involved in study.
- Fee for assistant/translator/interpreter in Far East
- Telephone, telex, fax, postage
- Photocopies, library searches, translation
- Data analysis and report preparation

A sum of US\$90,000 should cover all contingencies, but the costs could be reduced considerably if the study can be completed in less than six months. Once decisions have been reached on location of the study and some preliminary work has been done to determine the rate at which subjects will be admitted and the sample size that will be necessary, a clearer idea of the costs can be given.