2007 IPM Worldwide Manufacturing Capabilities Survey

(Conducted by Regulatory Compliance Initiatives, Inc; Funded by U.S. Agency for International Development)

Background

Current manufacturers of microbicide test products and applicators for Phase III trials may not at the present have sufficient production capacity to supply product for launch in developing countries. Moreover, the manufacturing facilities currently being used for Phase III trials are located in developed countries, and are not local to the intended use populations. Scaling-up manufacturing supply capacity sufficient for product launch will require timely investment in process development and manufacturing facilities. Emerging manufacturers in developing countries may provide attractive options for low cost, high volume manufacturing of quality microbicides (active pharmaceutical ingredient, or API, and final drug product), and applicators (or partial production – e.g. formulation, filling and packaging etc). Bringing production to where demand geographically is may also provide benefits in terms of reducing shipping and distribution costs, as well as reduce regulatory burdens.

However, the primary objective of microbicide manufacturing must be achieving reliable and cost-effective production of high quality (cGMP) product that can be distributed effectively to countries where it is required. While labor costs may be considerably lower in many developing countries, access to capital, access to export markets, availability of trained human resources, availability of API and sufficient regulatory oversight can provide real barriers to viable pharmaceutical manufacturing.

Currently there is no comprehensive information resource on manufacturing capabilities available to the microbicide field. Recently, IPM has undertaken a systematic survey of potential manufacturing capacity in selected developing countries to assess the options for and viability of large-scale production of microbicides.

Methods

Approximately 250 companies were invited to participate by providing information. They were qualified as potential manufacturers of microbicides through a three step process:

1. Providing company contact information and agreeing to be in the data base
2. Providing GMP information by completing a comprehensive survey
3. Agreeing to be audited (at no cost to their company), providing GMP information from an expert auditor's perspective, and meeting the standards of the audit.

Results

IPM and RCI have assembled comprehensive GMP survey information and GMP audit reports of several companies capable of assisting with the development and commercial manufacture of API and microbicide dosage forms for the prevention of AIDS. The information has been captured in a database that is being made available to the microbicide field and other interested parties. The database includes many valuable

fields of information including complete company contact information for more than 110 entries from over 80 companies. Product developers seeking resources through this data base are able to explore potential manufacturers based on physical location and company size. The data base includes companies from many regions of the world including Asia, Africa, North America, South America, and Europe. It includes small private companies and large multinational public corporations.

GMP Survey Information
Attached with the data base are surveys completed by 20 companies that provided GMP information about their company. Companies providing survey information included the following:

Alkem Laboratories Ltd, Mumbai, India
Aspen Pharma, Port Elizabeth, South Africa
Beijing Keyifeng Biotech Develop. Co., Ltd, Beijing, China
Boehringer Ingelheim, Itap de Serra, Brasil
Boehringer Ingelheim Promeco, D.F., Mexico
Ciron Pharma, India
Dabur
Dawnrays Pharmaceutical (Holdings) Limited, Jiangsu, China
Granules India Limited, Gagilapur, India
Groupe Parima, Montreal, Canada
Grunenthal, Quito, Equador
Hubei Haosun Pharmaceutical Co., Ltd, Hubei, China
IND Swift, Camillus, India
Jiangsu Zhongdan Pharmaceutical Co, ltd, Jiangsu, China
Mega Fine Pharma (P) Ltd, Mumbai, India
Tianjin Pharmaceuticals (H.K.) Co. Ltd, Aberdeen, Hong Kong
Zhejiang Jiuzhou Pharmaceutical Co, Zhejiang, China

cGMP Audit Reports
Also included on the CD are cGMP audit reports for 17 companies. Audits were conducted by GMP experts from within the pharmaceutical industry.

Alkem Laboratories Ltd, Mumbai, India
Boehringer Ingelheim, Itap de Serra, Brasil
Boehringer Ingelheim Promeco, D.F., Mexico
Chemshop, Weert, Netherlands
Grindus America Inc, Cincinnati, Ohio
Groupe Parima, Montreal, Canada
Grunenthal, Quito, Equador
Hubei Haosun Pharmaceutical Co., Ltd, Hubei, China
IND Swift, Camillus, India
Jiangsu Zhongdan Pharmaceutical Co, ltd, Jiangsu, China
Mega Fine Pharma (P) Ltd, Mumbai, India
Saanxi Hanjiang Pharmaceutical Group, Shaanxi, China

Shasun Chemicals and Drugs, India
Strides Arcolab Ltd, Bangalore, India
Zhejiang Excel Pharmaceutical Co Ltd, China
Zhejiang Hisun Pharmaceutical, Taizhou, China
Zhejiang Hisyn Pharmaceutical, Zhejiang Province, China

Contacts

Contact information for IPM is as follows:

Vimala Raghavendran
Policy Associate
International Partnership for Microbicides
8401 Colesville Road
Silver Spring, MD 20910
Phone: 301-608-2221
Fax: 301-608-2241
Email: vraghavendran@ipm-microbicides.org

Contact information for RCI is as follows:

James E. Carter, Ph.D., Principal, RCI
PO Box 95651
Las Vegas, Nevada 89193
Phone: 702 914 0798
Fax: 702 269 9341
Email: Inquiries@regulatorycomp.com

This project was conducted under the United States Agency for International Development Cooperative Agreement No. GPO-A-00-05-00041-00 awarded to the International Partnership for Microbicides.