

RESOURCES FOR CLINICAL PROFESSIONALS

GlaxoSmithKline Website

Pharmaceuticals company websites are designed for several audiences: healthcare professionals, the general public, and company employees. From the information on the websites, medical writers and journalists can learn a lot about research and development, the drug approval process, as well as detailed information about each product approved for marketing by the FDA.

The GlaxoSmithKline website (<http://www.gsk.com>) includes an overview of the history, business development objectives, commitment to several global and local health initiatives, and financial reports. It also includes information on 68 prescription medicines, 9 vaccines, and 104 consumer healthcare products that are marketed in the United States.

The *Research and Development* page reports that GlaxoSmithKline had 157 investigational drugs and biologics in clinical development by the end of February 2008. The *Research and Development* page explains the purpose for clinical trials.

The *Clinical Trials* page includes a description of the pharmaceutical research and development process, its phases, and a description of participating population for each phase. The following table summarizes the explanation of each phase purpose and population given on the *Clinical Trials* page.

Phase	Participants	Purpose
I	Volunteers	Safety, drug metabolism
II	Patients with a specific disease	Efficacy, proper dose
III	A larger number of patients	More information supporting safety and efficacy of the product
IV	Patients with a specific disease	Further evaluation of efficacy

The *Research and Development* page includes a statement that the company is targeting treatment and prevention of diseases in developing countries through research and development of new preventive and therapeutic products.

The *Product Pipeline* page includes 7 categories of products that the company is developing. The table

Type/ Indication	Phase I	Phase II	Phase II/ III	Phase III	FDA review	FDA approved, approvable	Total
Cardiovascular and metabolic	5	5	1	4	2	1	18
Infectious diseases	3	3					6
Musculoskeletal, urology inflammation, gastrointestinal	7	9		6		1	23
Neuroscience	13	14		3	1	3	34
Oncology	6	10		13	1	2	32
Respiratory	4	15				1	20
Vaccines	3	7		7	5	2	24

GlaxoSmithKline initiatives

These initiatives target lymphatic filariasis, HIV/AIDS, and malaria: all diseases that affecting African humans. These efforts include donating albendazole tablets, a treatment for lymphatic filariasis, and opening a new manufacturing facility in Cape Town, South Africa, to produce albendazole.

A Positive Action program established by GlaxoSmithKline in 1992 provided AIDS training for 8,000 for community and healthcare workers in East Africa; sponsored international AIDS Global Village conferences. Currently GSK developing HIV and antimalarial medicines and vaccines, and has a preferential pricing on antimalarial medicines for the least developed countries of sub-Saharan Africa.

From <http://www.gsk.com>

at the bottom of this page describes the development phase of the 157 products in the development. Most are in neuroscience and oncology, 34 and 32 respectively, followed by vaccines, then by musculoskeletal, inflammation, gastrointestinal, and urology category, then by respiratory, and finally by cardiovascular and metabolic products, with 24, 23, 20, and 18 respectively. Altogether 6 products are in development in infectious diseases.

The *Product Development Pipeline* chart includes information on the indication for every product, and on an estimated submission date for products in later development phases.

The *Clinical Trial Register* page includes protocol summaries for drugs only. These are summaries of the protocols of clinical trials.

Prescription Medicines sub-title of the *Clinical Trials* page is linked to the list of prescribing information for all Prescription Medicines drugs that have been approved by the FDA.

On the *Clinical Trials* page, product names on the

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Result Summaries page link to the list of clinical studies summaries. Each study title links to that study's summary, which contains information about phase of the development, an indication, a generic name, a trade name, a summary of the study, and an approved drug label.

A product's prescription information link from the *Prescription Medicines* page, the prescription information is also called the package insert. Drugs and vaccines names on *Our Products* page are linked to their package inserts too. Consumer healthcare products are linked to web-sources that provide information about these products:

The package insert summarizes information on the prescription medicine with information in sections:



From the GlaxoSmithKline website at <http://www.gsk.com>, above and below.

- Name, brand and generic
- Black box warning
- Description of chemical structure, and drug form
- Clinical pharmacology
- Indication and usage
- Contraindications
- Warnings



- Precautions
- Adverse reactions
- Drug abuse and dependence
- Overdosage
- Dosage and administration
- How supplied (drug forms)
- Medication guide.

The website allows tracking the development of new investigational drugs and biologics for patients, investors, and health professionals.

By Elana Stolpner MD

Dr Stolpner has worked in pediatrics, cardiology, gerontology and diagnostic medical sonography and nonclinical and clinical research. She completed a fellowship in cardiology at Kazan State Medical Institute, Russia before relocating to Ohio, where she worked in diagnostic ultrasound. She earned a regulatory writing certificate from University of the Sciences in Philadelphia. Dr Stolpner is a member of the MJoTA Editorial Board, a member of the American Medical Writers Association. Her profile is included in LinkedIn. E-mail: ehealthcare@hotmail.com.

