

Pharmaceutical Information

Traditional and not-so-traditional
sources

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Information audits - workshops - marketing - training

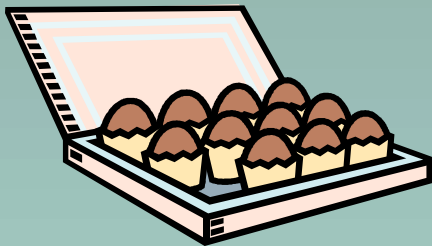
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An express journey through

- The R&D process
- Primary and secondary sources
- Business information
- Patient information

The Drug Development Process

Development of a new product



1 year



4 -10 years



12 years

The R&D Process



↓
Identification
of new
molecule

↓
Launch

← 10 - 15 years →

← \$800m - \$1.2bn →

(10,000+) 10 ← Attrition → 1

New models

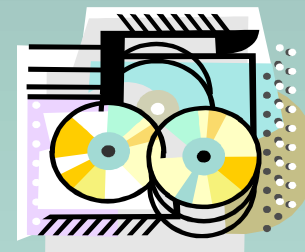
Pre-clinical/Discovery Research Characteristics

- Developed and expanded substantially during the past few years
- Made extensive use of new technology
- Developed its own culture of collaboration
- Given rise to new disciplines

Discovery research information

Target identification; target validation; lead identification; lead optimisation; preclinical - technology, CMC, Pharmacology/Tox.

- **Sources of information come from**
 - **Internal chemical compound and reaction databases**
 - **Internal biological databases**
 - **Internal archives**
 - **External literature/databases and patents**
 - **External collaborations**
 - **Sharing knowledge**
 - **Integrating databases**
 - **Serendepity**



Pharmacogenomics is used to identify the genetic basis for individual response to medicines; thus can identify why side effects occur in some but not others. Personalised medicine or – **the right medicine for right patient.**

- **Human Genome Project**
<http://www.genomics.energy.gov>
- **Pharmacogenomics portal**
<http://www.personalizedmedicine.com/>
- **PharmGKB** pharmgkb.org

R&D Pipeline databases



- Tracking the development of new medicines over the 10 year period
- Structured - Name/code, chemical name, originating/developing company, indication, therapeutic activity, phase of development
- Uses - competitive intelligence, first mention, trends, time, attrition, R&D management information etc

Pipeline databases

- PJB: PharmaProjects
- Thomson: IDdb
- IMS: R&D Focus
- ADIS: R&D Insight
- Prous: Integrity
- Elsevier: :Inteleos:

Also - Company web sites



Beware

- Definitions: New drug, vaccines, biotech products, formulations, NME, NCE
- Development phases, discontinued, withdrawn
- Active development, no development
- Selection, editing, updating methods
- Verification by originator
- Extras eg commercial comment/reviews
- True picture? NB = CI

Primary sources – literature, Journals - key players

- The journal *BMJ*
- E-Journal and family *BMJ.com*
- Publisher *Elsevier*
- Publishers' search engine *Science Direct*
- Database *Medline*
- Aggregator *Ingenta*
- Subscription agent *Swets*

Patents

Issuing Authorities

Guides, basic information, introduction, how-to etc

- UK Patent Office www.patent.gov.uk
- European Patent Office www.european-patent-office.org
- US Patents and Trade Mark Office
www.uspto.org
- German Patent and Trade Mark Office
www.dpma.de
- Japan Patent Office www.jpo.go.jp
- World Intellectual Property Organisation
www.wipo.org

Patent databases

- **CAS**
 - Now determine which patents are in which family
 - Can trace old patents from new - 'circle of content'
- **Thomson Scientific**
 - WPI, PatentWeb, MicroPatent [//thomsonderwent.com](http://thomsonderwent.com)
- **Delphion**
 - Full text access to US, Europe Japanese and WIPO databases and commercial databases [//scientific.thomson.com/products/delres](http://scientific.thomson.com/products/delres)
- **Dolphin**
 - consolidates the family and legal status information from INPADOC [//scientific.thomson.com/products/dolphin/](http://scientific.thomson.com/products/dolphin/)

Patent database hosts

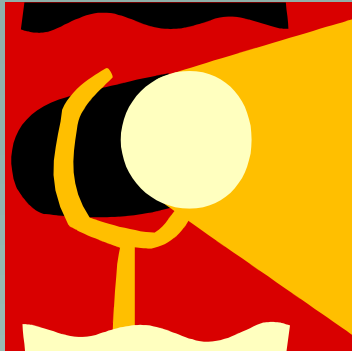
- STN
 - STN Easy and STN Express
- Thompson Dialog
- Questel.Orbit
 - PatCite feature - forward and backward searching.

Secondary sources of information

Regulatory Bodies, Associations.
Gateways, 'Groups' eg EBM.

Characteristics

- Evaluated information for a specific group or user
- Information provision sometimes a secondary objective (Associations)
- Not always available to non-members
- Commentaries, value-added, organised
- Quality varies from excellent to variable
- Often unique information



Regulators

- Increased pressure to shorten the regulatory review times
- Focus on safety and more risk-averse
- Pressure for more frequent and early dialogue with manufacturers
- Increased transparency of activities
- Web sites now become a good source of information on the progress of products

Regulatory Bodies

- **MHRA** mhra.gov.uk **Medicines and Healthcare Products Regulatory Agency**
 - Ensures that all medicines on the UK market meet appropriate standards of safety, quality and efficacy
- **FDA** fda.gov
 - US Regulatory authority for food and drugs, including devices, cosmetics and radiation-emitting products)

Approved drugs

Links  » Norton AntiVirus  Address  a.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist 

**U.S. Food and Drug Administration**
Department of Health and Human Services

CENTER FOR DRUG EVALUATION AND RESEARCH

Drugs@FDA [FAQ](#) | [Instructions](#) | [Glossary](#) | [Contact Us](#) | [CDER Home](#)

[Drugs@FDA Demo **New!!**](#) | [What's New in Drugs@FDA](#)

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Label and Approval History

Drug Name(s)	BECONASE AQ (Brand Name Drug)
FDA Application No.	(NDA) 019389
Active Ingredient(s)	BECLOMETHASONE DIPROPIONATE MONOHYDRATE
Company	GLAXOSMITHKLINE

[Go to Approval History](#)

Label Information

[What information does a label include?](#)
Note: Not all labels are available in electronic format from FDA.

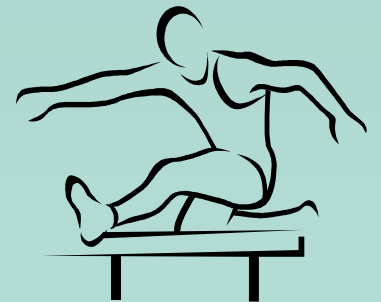
Approval history

<p>Links Address a.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist </p>				
Approval History				
<p>Note: Not all reviews are available in electronic format from FDA. Older labels are for historical information only, and should not be used for clinical purposes. Action dates can only be verified from 1984 to the present.</p>				
Action Date	Supplement Number	Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
10/27/2005	027	Labeling Revision	Label Letter	
12/19/2002	021	Labeling Revision	Letter	Label is not available on this site.
12/16/2002	025	Labeling Revision	Letter	Label is not available on this site.
03/04/2002	026	Control Supplement		This supplement type does not usually require new labeling.
08/31/2001	023	Labeling Revision	Label	
07/09/2001	024	Control Supplement		This supplement type does not usually require new labeling.
02/24/2000	020	Labeling Revision		This supplement type does not usually require new labeling.

NICE

National Institute for Health and Clinical Excellence nice.org.uk

- Part of NHS
- Provides guidance for healthcare professionals, patients and carers that will help to inform their decisions about treatment and healthcare
- Not involved with the licensing procedure
- Guidance documents, progress of appraisals, e-newsletter





Four types of guidelines

Full, NICE, Quick reference, For the public








[on an illness or condition?](#)
[Technology appraisals](#)
[Clinical guidelines](#)
[About clinical guidelines](#)
[Published guidelines and cancer service guidance](#)
[Guidelines and cancer service guidance in development](#)
[Stakeholder registration](#)
[Interventional procedures](#)
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Published guidelines and cancer service guidance ▶

Long-acting reversible contraception  

Full title: Long acting reversible contraception: the effective and appropriate use of long-acting reversible contraception

NICE and the National Collaborating Centre for Women and Children's Health have issued a clinical guideline on the effective and appropriate use of long-acting reversible contraception within the NHS in England and Wales. Listed below are the key documents for this guideline, click on the title to link to the relevant document.

 CG30 Long-acting reversible contraception: Full guideline	26 October 2005
 CG30 Long-acting reversible contraception: NICE guideline	26 October 2005
 CG30 Long-acting reversible contraception: NICE guideline (Word version)	26 October 2005
 CG30 Long-acting reversible contraception: Quick reference guide	26 October 2005
 CG30 Long-acting reversible contraception: Information for the public	26 October 2005
 Scope: Long-acting reversible contraception: the effective and appropriate use of long-acting reversible contraception	10 January 2003
 2005/024 New guidelines on long acting contraception promote greater choice for women	26 October 2005

European Agency for the Evaluation of Medicinal Products emea.eu.int

- Coordinates the evaluation and supervision of medicinal products throughout the European Union
- Brings together the scientific resources of the EU Member States in a network of national competent authorities
- On the basis of the agency's opinion, the EU authorises the marketing of medicinal products and acts as an arbitrator

EPAR for Avandia

European Medicines Agency Home

emea

[About Us](#) [What's New](#) [Human Medicines](#) [Veterinary Medicines](#) [General Reporting](#) [Inspections](#)

Product Overview

Name of the Medicinal Product
Avandia

Marketing Authorisation Holder
SmithKline Beecham Plc
980 Great West Road,
Brentford,
Middlesex, TW8 9GS
UK

Active Substance
Rosiglitazone maleate

International Nonproprietary Name

Avandia
European Public Assessment Report

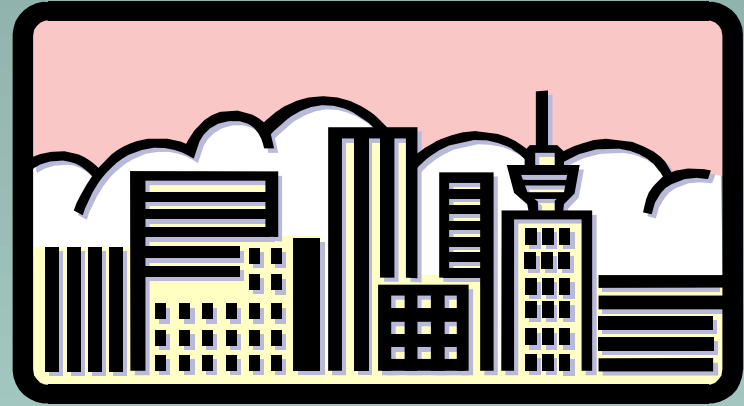
ES	CS	DA	DE	ET	EL	EN	FR	IT	LV	LT	HU	MT	NL	PL	PT	SK	SL	FI	SV		
◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	See Glossary of language codes...
◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	1. Abstract
◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	2. All Authorised Presentations
For Product Information , please see below																				3. All Patient Information Leaflets	
																				4. All Summary of Product Characteristics	
																				5. All Labellings	
◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	6. Scientific Discussion
◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	7. Procedural steps taken before authoris
◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	8a. Procedural Steps taken until cut-off da
◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	8b. Procedural Steps taken and Scientific

Other regulations-based information

- FDC Reports 'Pink Sheet' - newsletter on regulatory activities (US)
- RAJ - Regulatory Affairs Journal Articles, opinion, regulations (UK)
- MAIL – from MHRA
- TOPRA - The Organisation for Professionals in Regulatory Affairs (UK based)
- ESRA - European Society for Regulatory Affairs

Associations

- Industry Associations
 - ABPI abpi.org.uk
 - PhRMA phrma.org
 - EFPIA efpia.org
 - IFPMA ifpma.org
- Basic facts and figures
- Industry position papers
- Current issues (local)
- Publications and links



Membership based

Research Organisations

- **CMR International** cmr.org
 - **R&D Processes and metrics** - development times, new medicines, costs
 - **Benchmarking the R&D Process**
 - **Regulatory affairs** - processes, efficiency, policy
- **CSDD Center for the Study of Drug Development**
[//csdd.tufts.edu](http://csdd.tufts.edu)
 - **US based surveys**
 - **Development costs**
 - **Disease management/Orphan drugs/Fast Track**

Membership based

Pharmaceutical Information Organisations

- **DIA Drug Information Association** diahome.org
 - individual membership, meetings professional development, Drug Info Journal
- **PIPA Pharmaceutical Information and Pharmacovigilance Association** pipaonline.org.uk
 - Medical Information, R&D Information
- **PDR Pharma Documentation Ring** p-d-r.com
 - Scientific Information Departments. 22 companies.
 - Assess new products, encourage commercial development of new services, networking forum, LINKS.

Health Statistics

- Office of National Statistics (ONS)
statistics.gov.uk
 - Health and Care - Cancer, Social Care etc
- NHS dh.gov.uk
 - Stats related to above, plus eg hospital care, workforce
- OHE ohe.org
 - Office of Health Economics (ABPI)
- OECD Health data oecd.org
 - Health stats for 30 OECD countries. Expenditure, demographics etc *OECD Health Data 2006*
 - Statistical analyses, Health systems, Ageing society

..... Health Statistics

- USA - CDC Nat Center for Health Statistics

cdc.gov/nchs

– Wide variety of stats. Incl 'Health Data for All Ages' tables

- WHO Statistics Information System

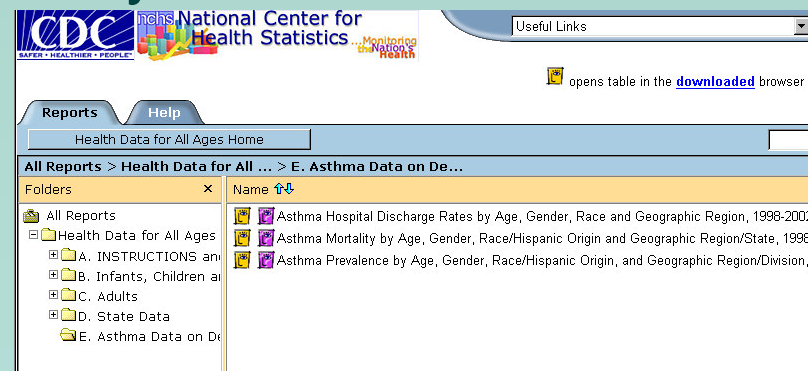
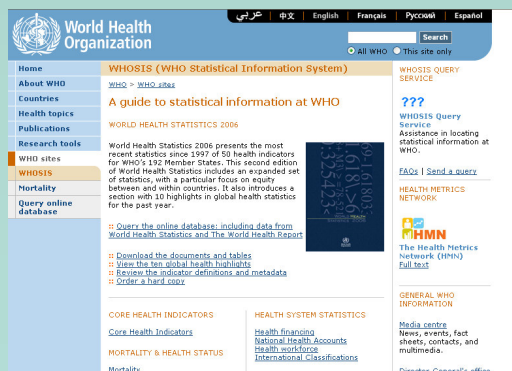
– www.who.int/whosis/en/

- United Nations Statistics Division

<http://unstats.un.org>

– births, deaths and life expectancy

– human functioning and disability



Specialist Internet Resources

Evaluated subject gateways

- **INTUTE (was OMNI)** intute.ac.uk
 - access to searchable catalogue of the internet covering health and medicine
 - Browse by subject or keywords (NLM or MESH headings) or search free text
- **BUBL** bubl.ac.uk
 - Subject based resources, focus on library and information science
 - Logical, consistent, hierarchical, evaluated
- **HON Health on the Net** hon.ch
 - Swiss based. Evaluated sites
 - (survey of health and medical internet users)

Other Internet Resources

- **NELH National Electronic Library for Health** nelh.nhs.uk
Now part of NLH: library.nhs.uk/
 - digital library for health professionals, patients and public. Specialist libraries, guidelines, EBM and clinical databases
- **British Library** bl.uk
 - eg Healthcare information on the internet
- **National Library of Medicine** nlm.nih.gov/hinfo.html
 - Health information sites and resources
- **UK Medicines Information network** ukmi.nhs.uk
 - New drugs database, drugs in pipeline, therapeutic guidelines. Pharmacy resource

Web-based pharma sources

- Inpharm.com
 - News, jobs, directories and links. Marketing biased
- The PharmYard //thepharmyard.networkpharma.com
 - Access to medical and pharmaceutical information; Sells publications on behalf of independent publishers
- Pharmweb.net
 - For business, pharmacists and patients (US).

Evidence-Based Medicine

- **Bandolier** jr2.ox.ac.uk/bandolier
 - Print and internet journal about healthcare using ebm techniques to provide advice about treatments
- **Cochrane** cochrane.org
 - Up-to-date, accurate information about the effects of healthcare readily available worldwide. Produces and disseminates systematic reviews of healthcare interventions
 - Cochrane Library: Regularly updated collection of evidence-based medicine databases, including The Cochrane Database of Systematic Reviews.

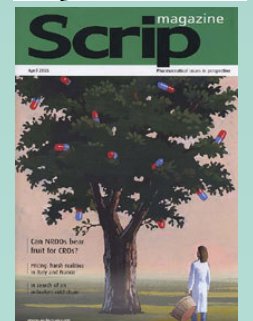


Evidence-Based Medicine

- Centre for Reviews and Dissemination
york.ac.uk/inst/crd
 - Publications and also DARE, NHS EED, HTA databases. York
- Centre for Evidence-Based Medicine
cebm.net
 - Methodology for ebm. Oxford based
- NHS NLH Evidence resources and Prodigy
library.nhs.uk prodigy.nhs.uk
 - Databases, Clinical Guidance guidelines etc

Business Information Key Players

- **IMS** imshealth.com
 - Originally data collection, now analysis, solutions, and consulting
 - Captures data on 70% of Rx worldwide
 - Tracks sales volumes at territory level
 - Data
- **PJB Publications**
 - SCRIP Newsletter and Magazine
 - Reports – Geographic region, market, strategy
 - Pharmaprojects

The logo for IMS (International Medical Statistics) features the letters "ims" in a bold, blue, sans-serif font. A small blue dot is positioned above the letter "i".

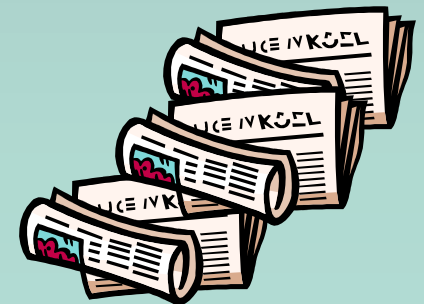
Market data

- Decision Resources dresources.com
- Marketresearch.com
- Factiva Dow Jones and Reuters factiva.com
- Datamonitor datamonitor.com
- Profound profound.com
- Frost & Sullivan frost.com

News

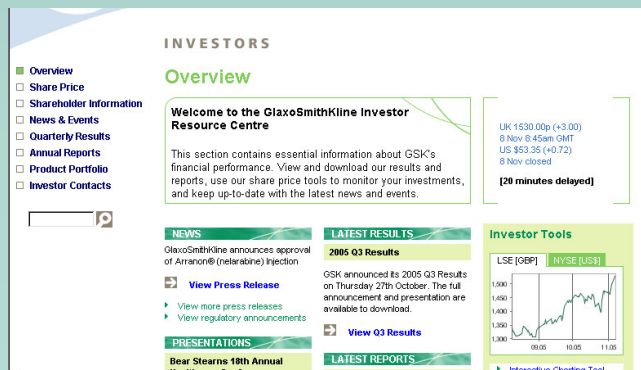


- Reuters Health
- Dow Jones
- FT.com
- NewsEdge Intelliscopes



Company information on web sites

- Millennium Pharmaceuticals mlnm.com
- GlaxoSmithKline GSK gsk.com
 - Investor Information
 - Share price, shareholder info, financial results, pipeline, Stock charts, Stock information, SEC filings, Annual Report, Earnings, Webcasts etc
 - Media Section
 - News, archives, photo library (people and locations) Corporate Profile, Overview, 10Ks, Press releases etc



Consultants

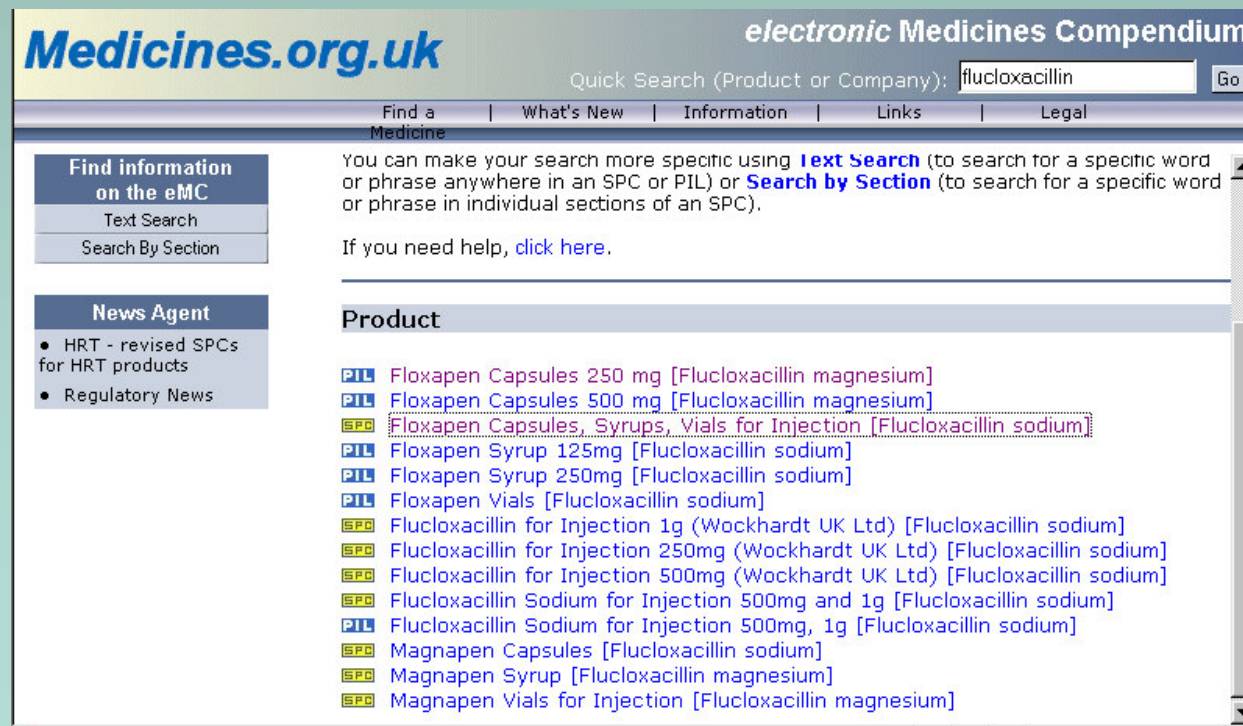
- WoodMackenzie woodmacresearch.com
- PWC pwc.com
- BCG bcg.com
- Ernst & Young ey.com
- Accenture
- IBM Business Consulting www.ibm.com

Patient information

- Access to information
 - Increased interest in personal health (worried well)
 - Informed consent
 - Patients as consumers
 - Easier access to health information via the web, including NHS performance as well as medicines
 - e-government
 - FOI
- Barriers
 - Activities of NICE
 - Pricing
 - Focus on safety
 - More litigious society
 - Legislation on promotion of medicines

General drug information

- Electronic Medicines Compendium - eMC
medicines.org.uk
- POM and OTC medicines in the UK
- SPC or PILs can be viewed and printed



Company Web Sites

- Detailed product information/lists datasheets
- Specific areas for general public or for healthcare professionals
- Disease areas
- Links to support groups



Other (Company) Sites

- Herceptin.com (breast cancer)
 - Information on disease, treatment and product
 - **A Genentech site**
- Zomig.com (Migraine)
 - Clinical data
 - Prescribing information etc
 - **An AstraZeneca site**

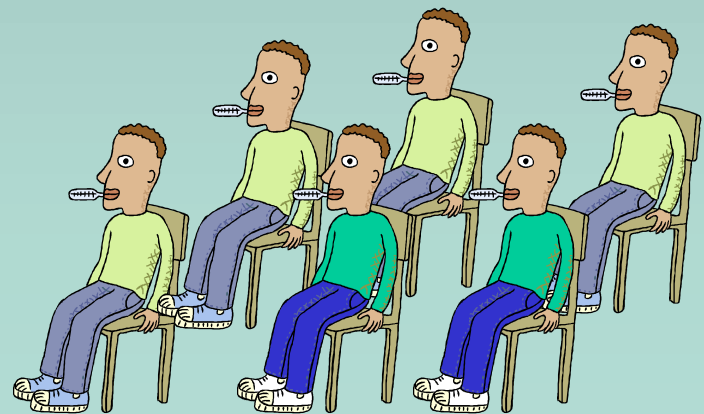


Patient Groups

- National Asthma Campaign Asthma.org.uk
 - Information, news, fundraising, donations etc
- National Migraine Association - Migraine Awareness Group migraines.org (US)
 - Treatment and product profile info
 - Public awareness/education, Help, Links etc

Portals etc

- Patient.co.uk
- MedicineNet.com
- Netdoctor.co.uk



*Knowledge is of two kinds.
We know a subject ourselves, or we know
where we can find information upon it.*

Samuel Johnson



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