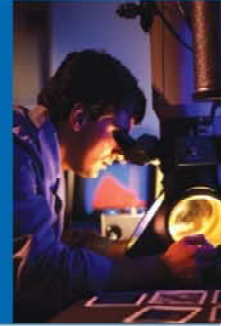




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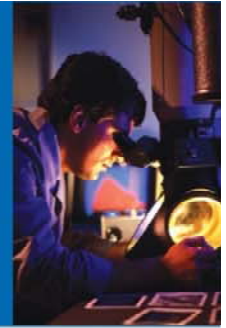
# Benefit: Risk Communication

## “Understanding your customer”

*PIPA Annual Conference 2006, 4th July*  
*Nicky Lilliot – Director of Regulatory Affairs*  
*Association of the British Pharmaceutical Industry*



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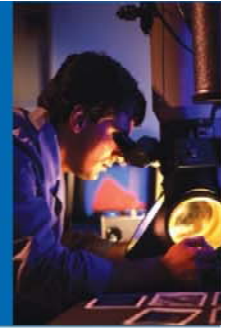


# Presentation Overview

- About ABPI
- Benefit:risk decision making
- Initiatives in medicines benefit:risk communication
- How can you help.....



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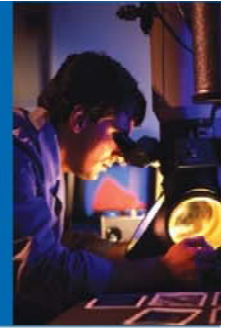


## About ABPI

“The ABPI is the voice of the innovative pharmaceutical industry, working with Government, regulators and other stakeholders to promote a receptive environment for a strong and progressive industry in the UK, one capable of providing the best medicines to patients.”



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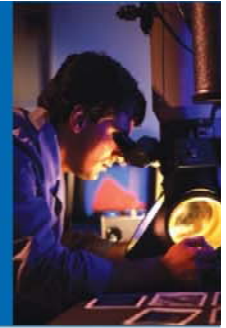


## About ABPI

- Trade association for 75+ companies in the UK producing prescription medicines
- Our member companies research, develop, manufacture and supply more than 80 per cent of the medicines prescribed through the NHS
- The ABPI also represents companies engaged in the research and/or development of medicines for human use
- In addition, general affiliate membership is for all other organisations with an interest in the pharmaceutical industry.



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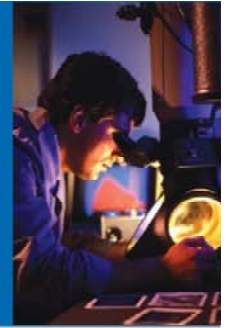


## About ABPI

- Policy setting & decision making within committees/task forces e.g. Regulatory Committee, Medical Committee, Pharmacovigilance Advisory Group
- Coordinate industry position
- Work with Government to implement changes that impact the industry
- Stakeholders include Government, media, patient groups, other trade associations



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# Benefit:risk decision making – everyday life

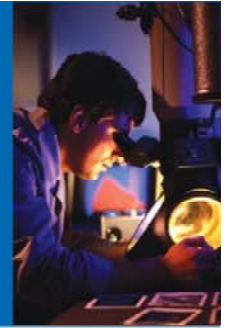


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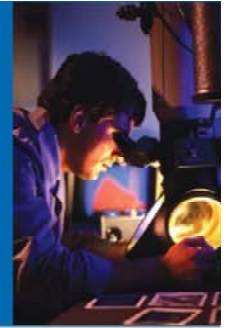


## Benefit:risk decision making – about health

- The Expert Patient Programme
- 'Our Health, our care, our say: a new direction for community services' (Jan 2006, Department of Health)
  - Information prescription
- Extended prescribing (nurses, pharmacists, opticians)
- Internet (unregulated for health, regulated for medicines)
- NICE decisions (e.g. Herceptin)
- Ask About Medicines Week (6-10 Nov 2006)



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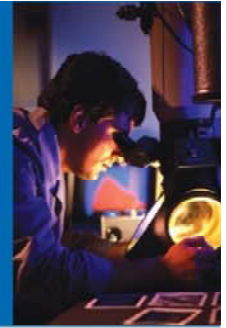
## Benefit:risk decision making – about medicines

- Who makes the decisions
  - Industry based on investment
  - Regulator protects public health
  - Payor based on health budget
  - Prescriber based on diagnosis
  - Patient compliance and concordance
  - Carer e.g. MMR vaccine



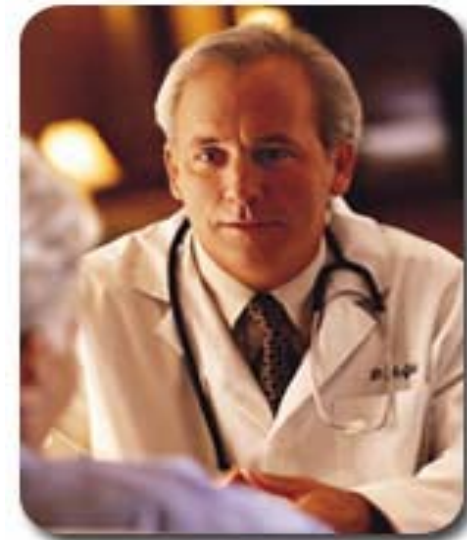


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## Benefit:risk decision making - patient sources of information

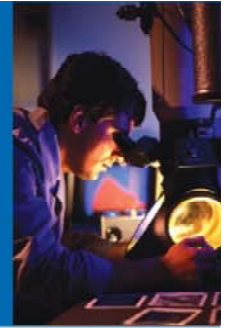
- Doctor (69%)
- Pharmacist (52%)
- Patient Information Leaflet (30%)
- Nurse (18%)
- Internet (14%)
- Friends/Family (13%)
- NHS Direct/NHS telephone helpline (12%)
- Media (8%)
- Other health professional (4%)
- Pharmaceutical company (4%)
- Patient organisations (2%)



*Source: MORI Research sponsored by Medicines Partnership: The Public and Prescribed Medicines, 2004*



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## Benefit:risk decision making - what patients want to know

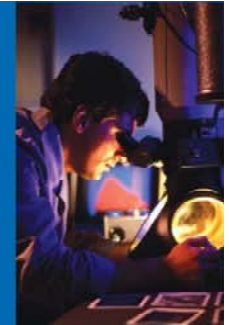
- Approx. 50% of patients don't take their medicines as prescribed



*Source: Cochrane Collaboration, 2002*



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Health

## Keep on taking the pills

Half of all prescription drugs are being thrown away unused, says Dr Simon Atkins

**O**n a busy morning when the surgery waiting room looks like Heathrow's departure lounge during an air traffic control strike, it can be hard to believe that half of the people who have crammed into the building, apparently desperate for their doctor's advice, will never take the medicines they have been given.

But that is what the statistics show. According to a 2002 report by the Cochrane Collaboration (the experts in reviewing evidence-based medicine), about half of all medicines are not taken as prescribed. And what's more, it's not because patients are forgetful. It's because they're not convinced the treatment which their doctor has prescribed is the right one. This mistrust costs the NHS £230m a year in unused pills – which is one reason this week has been declared Ask About Medicines Week.

This chronic mistrust is no surprise. It's something I see every day in surgery. Take antidepressants, for example. I may see a person crippled with severe depression who desperately wants help. You might think I was home and dry: that accepting a prescription that the evidence says will help was a no brainer. But you'd be wrong.

Either the patient has heard a scare story about antidepressants or they have a relative who took some for a similar condition and was never the same again. If I could arrange counselling for them it wouldn't be so bad, but on the NHS that is a rare commodity, so they leave untreated and often return far worse.

Beta blockers – such as atenolol – are another example. They have come in for a lot of stick in the press recently following the publication in the med-



reason to be cautious, these drugs can really help in the treatment of conditions such as acute anxiety, back muscle spasm and whiplash.

Perhaps this shouldn't be surprising. The days of people being unquestioningly deferent to anyone in authority are long gone. And, thanks to the media, people are much savvier about health matters. Every newspaper has a health page and you can go online and Google a drug such as Prozac and discover more than five million opportunities to find out more about it. But does that mean that patients now think they

**Into the bin . . . increased fear of the side-effects of drugs is costing the NHS £230m a year in unused pills**

know better than their doctors? Or do they simply not trust us any more?

Research conducted by the Medicines Partnership – a group of doctors, patients and representatives from the drugs industry – suggests that the issue is thankfully not about trust but about lack of information. And that in all demographic groups, most patients want to take a more active role in decisions about their treatment. They don't want their doctor to assume a

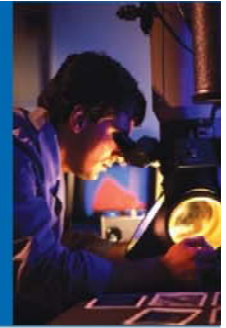
the guardian

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Source: Ask About Medicines



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# Benefit:risk decision making - what patients want to know

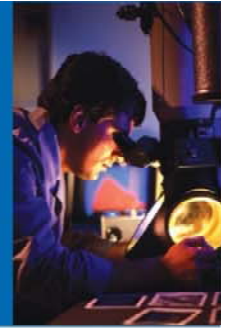
- Patients want more information about their medicines
  - Understanding the side effects
  - Why they are taking the medicine
  - What impact it will have on their lifestyle
  - How to take it
  - Interactions



*Source: Berry et al 1997, Psychology & Health*



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# Benefit:risk decision making - what patients want to know

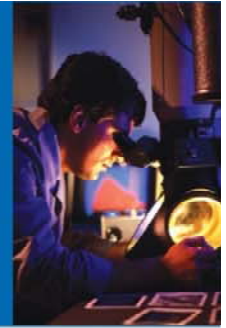
## Understanding side effects

- Often poorly described in PIL (based on SPC)
- Grouping side effects based on severity & action
- Use of numerical and verbal descriptions
  - Public, patients & doctors often overestimate risk involved when based on verbal descriptors
  - General misunderstanding of percentages & statistical presentations
- Positive & negative framing
  - E.g. 90% likelihood of no side effects vs. 10% probability of side effects
- Define absolute vs. relative risk
  - E.g. 3 in 1000

*Source: Always Read the Leaflet*



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## Benefit:risk decision making - what patients want to know

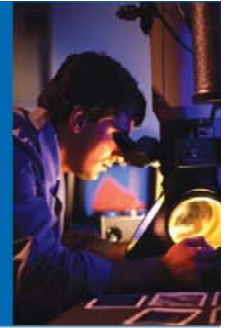
Understanding the benefits of taking a medicine

- Why its important to treat the disease and possible outcome if left untreated
- Whether the medicine is for short term or chronic use
- Whether the medicine is curative or to control symptoms of an underlying disease
- Whether the effects will last after medication is stopped
- What indication the patient has been given the medicine for

*Source: Always Read the Leaflet*



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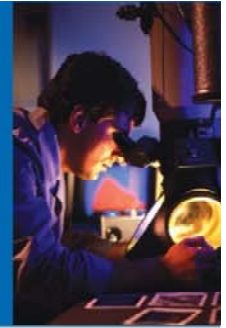
# What can industry do to help

- User testing patient leaflets
- Internet information
- Higher profile during debate in the media to balance 'wonder' drug/'killer' drug news stories
- Greater information for patients and prescribers during safety issues





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# What can regulators do to help

- MHRA created new communications division in 2005



**The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.**

**No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks.**

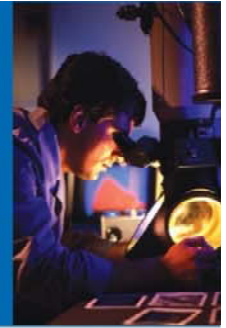
**We keep watch over medicines and devices, and we take any necessary action to protect the public promptly if there is a problem.**

**We aim to make as much information as possible publicly available.**

**We enable greater access to products, and the timely introduction of innovative treatments and technologies that benefit patients and the public.**



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# What can regulators do to help

- CSM working group on patient information
- Always read the leaflet publication
- Publication of UK Public Assessment Reports, Risk Management Plans, Freedom of Information responses

**Always Read The Leaflet**  
Getting the best information with every medicine

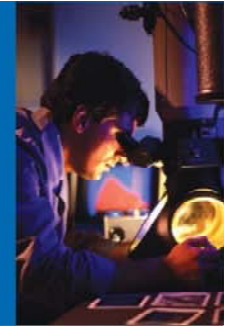


Report of the Committee on Safety of Medicines  
Working Group on Patient Information

Medicines and Healthcare products Regulatory Agency  
Committee on Safety of Medicines



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# What can regulators do to help

- Patient reporting of side effects
- Leaflet on side effects of medicines

## 7. What should I do if I feel unwell after taking my medicine?

Check your patient information leaflet for information on side effects and action to take.

If in doubt, speak to your doctor, nurse or pharmacist or call NHS Direct, NHS Direct Wales/Galw Iachyd Cymru or NHS 24 (Scotland) on the numbers at the end of this leaflet.

For worrying or serious effects you may be told to stop taking the medicine, or receive other treatment.

For less serious side effects, you may be advised to continue with your medicine, or change the dose.

You or your healthcare provider can report suspected side effects in confidence to the drug safety watchdog (MHRA) on a Yellow Card.

## 8. Will my medicine affect my lifestyle?

Although most medicines will not affect your lifestyle, some can. For example:

- Some medicines may affect your vision or co-ordination or make you sleepy. This may affect your ability to drive, ride a bicycle or perform skilled tasks safely.
- Some medicines may affect your sex drive.
- You may need to stop drinking alcohol or eating certain foods while taking some medicines.

Important: your patient information leaflet will tell you about the effects a medicine might have on lifestyle issues and things you should avoid.

## Need further advice?

If you need further advice about medicines you can ask your doctor or pharmacist or call NHS Direct & NHS Direct Wales/Galw Iachyd Cymru on 0845 46 47 (text phone 0845 936 46 47) or NHS 24 (Scotland) on 08454 24 24 (textphone 18001 08454 24 24).

## How do I report a suspected side effect?

Yellow Card forms are available from pharmacies and other outlets across the NHS or from the Yellow Card hotline on freephone 0800 100 3352. Reports can also be completed on the web at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)

## What is the MHRA?

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. We keep watch over medicines and devices, and take action to protect the public promptly if there is a problem.

For more information on the MHRA and its work visit [www.mhra.gov.uk](http://www.mhra.gov.uk), email [info@mhra.gov.uk](mailto:info@mhra.gov.uk) or telephone 020 7084 2000.

## Taking medicines - some questions & answers about side effects



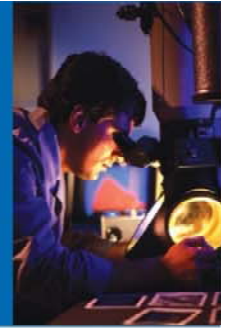
You will find more information about your medicine in the patient information leaflet provided with your medicine.

If you have received a medicine but no leaflet, please ask your pharmacist to get one for you.

Most people take medicines without suffering any side effects. But some people react badly, so read on ...



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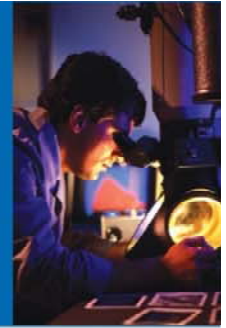


# EFPIA risk communications group

- Developed key messages:
  - What does industry do to ensure safe & effective medicines are made available to those who need them?
  - Why are all medicines not safe for everyone? How are risks communicated?
  - How do new medicines become available?
  - Once approved by regulatory authorities, why do some medicines have greater risks than benefits for certain patients?
  - How do the risks of taking medicines compare with other activities in life?



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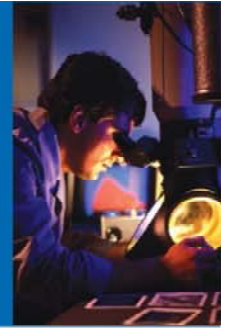


## ABPI Benefit:Risk group

- Part of ABPI's Reputation of the Industry programme
- Looking at providing balanced benefit information
- Looking at how medicines fit in broader field of therapy



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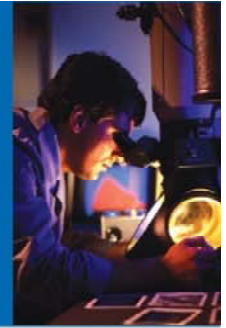


# Long Term Leadership Strategy

- Jointly lead by ABPI and Government (MHRA)
- Patient & Public Involvement
- Multi-stakeholder group
- Review research already undertaken in the area
  - MHRA commissioned MORI survey



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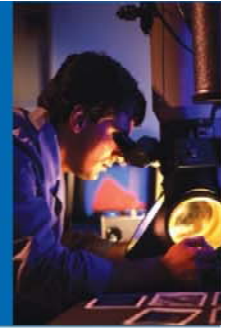


# Long Term Leadership Strategy

- Develop core messages on benefits & risks of medicines and the management of these
- Communication plan to promulgate messages
- Involvement of patients and the public in regulatory process as a longer term objective



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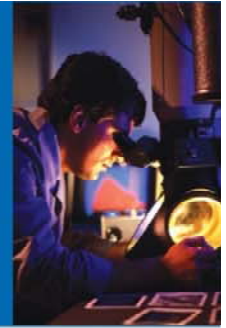


## How can you help.....

- Medical information department is key interface for companies with patients
- What types of information are patients seeking?
- What 'language' do patients use?
- What research have companies done to know what information patients want?



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## Conclusions

- Patients want better medicines information
- Need to empower the relationship between the prescriber and patient to make the best benefit:risk decisions
- Industry has a role to play in providing benefit:risk information
- Further work needed to develop common language about benefit:risk of medicines