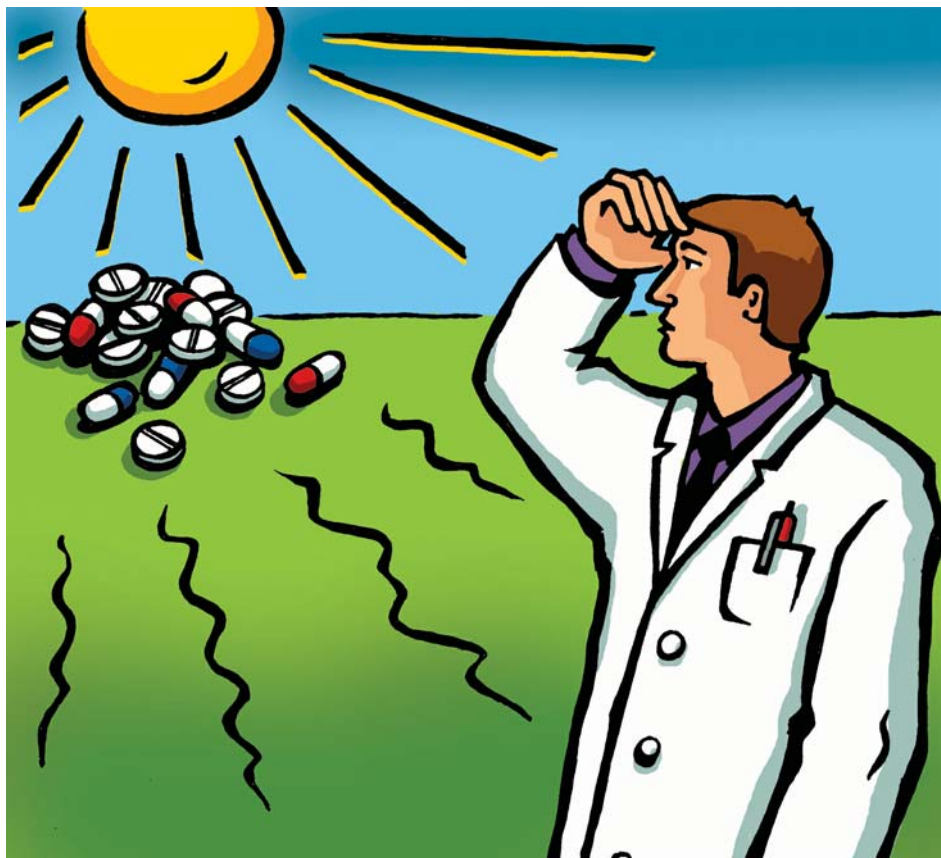


Is the information out there? What the UKMi new medicines portfolio offers

In this article, **Helen Davis** advises on the information available from the UKMi network for pharmacists to find out about new drugs



Hundreds of new drugs are in development. Of course, many do not make it to market or even phase III trials, but those that do can offer hope for patients with conditions where there is little or no choice of treatment or where the treatments available are not ideal.

As experts in medicines, pharmacists are expected to be aware of new drugs on the horizon. One way of accomplishing this is to keep up to date with coverage in the pharmacy press. For example, *The Journal's* R&D news section (published in the second issue of each month) reports on drugs in development. However, often the first a pharmacist hears about a new drug is when a patient brings it to his or her attention. This scenario is often accompanied by questions like:

- Is this new drug more effective than what is currently available?
- Does it have fewer side effects?

Helen Davis, MSc, MRPharmS, is manager of North West Medicines Information Centre and editor of *Prescribing Outlook* part A

- Will it be easier for me to take?
- Will I be able to use it with my other medicines?
- Will I be able to take it with my other conditions?

In order to answer such questions, pharmacists often require more detailed information than provided by reports in the pharmacy press and this is where information from the UK Medicines Information (UKMi) network is useful (see below).

In addition, for pharmacists who are involved in budget planning, the practice of "horizon scanning" is essential. There is a need within the NHS to plan ahead for the introduction of new drugs, especially where there may be a significant impact on prescribing budgets. Research and development and getting drugs to market requires huge investment so many new drugs are more expensive than current therapies. And where current therapy is limited, all drug expenditure in a disease area can be new. Similarly, licence extensions and new product formulations can impact on budgets. It is, therefore, helpful to have an idea when new

drugs will be launched or when licence extensions will be approved in the UK. For example, if you know that in six months a drug that will revolutionise the treatment of multiple sclerosis will be launched, you can prepare a contingency fund.

Pre-launch information

Often, the media will highlight new drugs before they are launched, bringing them to the attention of the public. To help health care professionals in the NHS plan for the introduction of new drugs the UKMi network works with the National Prescribing Centre (NPC) to produce two types of pre-launch drug review. These provide an in-depth appraisal of the current evidence and the likely place of the drug in therapy. They also estimate the possible cost implications for the NHS.

The first type of review ("New drugs in clinical development") is based around the National Institute for Clinical Excellence work programme and an evaluation of the drug is produced approximately 12 months before launch. NICE guidance has a large influence on drug budgets and it is moving towards evaluating new drug therapies at the point of launch.

The second type of review covers new drugs that NICE is not considering. The NPC, independently and also in collaboration with medicines information centres, produces

Panel 1: Recently published pre-launch monographs*

Drug	Monograph publication
Aprepitant [†]	January 2004
Bortezomib for relapsed and refractory multiple myeloma [†]	April 2004
Ximelagatran in atrial fibrillation and venous thromboembolism [†]	April 2004
Duloxetine for stress urinary incontinence [†]	May 2004
Ropinirole for restless legs syndrome [†]	June 2004
Ezetimibe-simvastatin combination	August 2004
Etanercept for psoriasis [†]	August 2004
Bevacizumab [†]	September 2004
Docetaxel in hormone refractory prostate cancer	September 2004

* Available at www.ukmi.nhs.uk and the www.npc.nhs.uk, but access is restricted to NHS staff with prescribing budget responsibilities

[†]UKMI-NPC collaborative monographs

an evaluation (“On the horizon: future medicines”) around six months pre-launch, with an update at launch (“On the horizon: rapid review”). This pre-launch information can be found on the UKMi and NPC websites, but access is restricted because commercially sensitive information is provided by pharmaceutical companies solely for the purpose of budget planning. Pharmacists with responsibility for budget setting in the NHS can access the information by contacting their local medicines information centre or the NPC, which will be able to supply the required passwords.

Panel 1 (p19) gives examples of recently published reviews.

Information on newly launched products

The UKMi network produces a portfolio of independently evaluated information on new products that can help pharmacists answer questions from patients and prescribers. Monographs of newly launched products, known as “new medicines profiles”, are produced soon after launch. Their aim is to assess the available evidence on efficacy and safety of a drug as well as to discuss its place in therapy and risk management issues. These monographs are freely available. Panel 2 lists recently published profiles.

Not all new drugs are covered by the portfolio but if a product is first or second in its therapeutic class (eg, fulvestrant is the first in a class known as selective oestrogen receptor down-regulators) or has a significant licence extension (eg, infliximab was first licensed for use in Crohn’s disease before obtaining a licence for use in rheumatoid arthritis) then it will be considered.

The UKMi network works with the London New Drugs Group, which also produces new product evaluations of drugs (both pre- and post-launch) in order to reduce duplication.

Horizon scanning

There are more drugs in development than there is capacity to produce detailed monographs. There is also a need for a longer term view of how new drugs or significant licence extensions might impact on budgets in terms of high cost or high target population. To address this, *Prescribing Outlook*, a horizon scanning resource, is produced annually by the UKMi network. Part A focuses on drugs with market launches planned in the next 12 to 18 months. It lists up to 50 drugs and gives brief details on pharmacology, relevant clinical studies, target population, service implications and costs, where possible. It is produced by UKMi in collaboration with the NPC and the National Horizon Scanning Centre based at the University of Birmingham. The resource is available at www.ukmi.nhs.uk and at www.npc.nhs.uk, but access is restricted to NHS staff with prescribing budget responsibilities.

It is not possible to include information on every drug in development. Drugs in phase III clinical trials in the EU or those that

Panel 2: Recently published UKMi new medicines profiles*

Drug	Date marketed in UK	Date of monograph publication
Metformin/rosiglitazone (Avandamet) [†]	November 2003	May 2004
Nicotinic acid, modified release (Niaspan)	November 2003	February 2004
Palivizumab (licence extension) (Synagis)	November 2003	February 2004
Emtricitabine (Emtriva) [†]	December 2003	March 2004
Aprepitant (Emend)	January 2004	March 2004
Intravenous paracetamol (Perfalgan) [†]	April 2004	November 2004
Fulvestrant (Faslodex)	May 2004	June 2004
Tramadol-paracetamol combination (Tramacet)	May 2004	October 2004
Aripirazole (Abilify)	June 2004	June 2004
Atomoxetine (Strattera)	July 2004	September 2004
Pregabalin for epilepsy (Lyrica) [†]	July 2004 (secondary care); September 2004 (primary care)	November 2004
Solifenacin (Vesicare)	August 2004	September 2004
Duloxetine (Yentreve)	September 2004	November 2004

* Profiles freely available via www.ukmi.nhs.uk

[†] Based on more detailed reviews produced by London New Drugs Group (for use within the NHS only) via www.druginfozone.nhs.uk

have been submitted to licensing authorities in the EU or US are considered for inclusion in *Prescribing Outlook* part A. Other determining questions include:

- Will the drug provide a significant improvement in disease management?
- Is it a new chemical entity, or a major new indication or formulation?
- Will the costs have a large impact on budgets?
- What is the size of the potential patient population? — the larger the disease population, the greater the impact there will be on prescribing budgets
- What are the service implications for the NHS? — some drugs will need more outpatient visits or special devices for administration

The pressure on drug budgets is not solely associated with new drugs; a significant pressure is due to the impact of national guidance such as that issued by NICE and the Department of Health (eg, national service frameworks). To support budget planners further, the UKMi network produces *Prescribing Outlook* part B. This highlights the impact of national guidance and clinical developments (eg, the National Service Framework for Coronary Heart Disease, NICE guidance on use of atypical antipsychotics, British Hypertension Society guidelines etc) on prescribing. It includes information on relevant documents, target populations, potential financial implications for the NHS and issues that might need to be considered by commissioners and providers of services. *Prescribing Outlook* part B is produced annually and is available to NHS staff with budget setting responsibilities at www.ukmi.nhs.uk.

Part C of *Prescribing Outlook* consists of an Excel spreadsheet, based on parts A and B, and allows crude calculations of potential costs of prescribing changes for a local population.

Drugs in early development

There is no one source of information available for drugs in early development and commercial databases are often biased towards the US market. Much of the information used in the production of *Prescribing Outlook* part A is derived from a dynamic database (“New drugs online”) maintained by UKMi. This is updated daily with information from a number of sources including medical news, journals and company and licensing authority press releases, together with information from a commercial database (“new drug file”).

Brief details on indication, pharmacology, stage of development and trial data on several hundred drugs are included. Access via www.ukmi.nhs.uk is limited to pharmacists employed by the NHS.

Conclusion

There is a wealth of evaluated independent information available from UKMi. This is supported by the UKMi network’s systematic process of data collection to inform the horizon scanning process for new products likely to be launched in the UK. However, in recent years there have been some high profile drugs that have failed to obtain a product licence in the UK even when they have been approved elsewhere (eg, ximelagatan is approved in Europe but not in the UK or US — the Food and Drug Administration had concerns about the risk of liver damage).

All information used in any forecasting or horizon scanning system is based on speculation, but careful speculation can prove a valuable practice for pharmacists and the NHS.

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