A Little Bit of History....

1841
unite the profession into one body
protect its members' interests
advance scientific knowledge

1843
Royal Charter

1933
Pharmacy and Poisons Act, 1933

1933
membership compulsory
regulatory role

2010
professional leadership body for pharmacists
no regulatory role
membership no longer compulsory
prior to 2010 the RPS had ..... 

provided expert scientific advice to policy makers 

promoted pharmaceutical science and research 

assisted with science-based enquiries 

Royal Pharmaceutical Society and the Science of Pharmacy
prior to 2010 the RPS had ..... 

provided expert scientific advice to policy makers 

promoted pharmaceutical science and research 

assisted with science-based enquiries 

Royal Pharmaceutical Society 
and the Science of Pharmacy 

At the Court at Buckingham Palace 
THE 17th DAY OF NOVEMBER 2009 
PRESENT, 
THE QUEEN’S MOST EXCELLENT MAJESTY 
IN COUNCIL. 

Her Majesty has allowed the amendments to the Supplemental Charter of 2004 of the Royal Pharmaceutical Society of Great Britain set out in the Schedule to this Order, which shall come into effect on a date to be notified in writing by the Clerk of the Council 

Judith Simpson 

SCHEDULE 
AMENDMENTS TO THE SUPPLEMENTAL CHARTER OF 2004 OF THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN 
Delete articles 2 to 13 inclusive and replace with the following: 

2. The objects of the Society (hereinafter referred to as "the objects") shall be: 

   (1) to safeguard, maintain the honour, and promote the interests of pharmacists in their exercise of the profession of pharmacy; 

   (2) to advance knowledge of, and education in, pharmacy and its application, thereby fostering good science and practice; 

   (3) to promote and protect the health and well-being of the public through the professional leadership and development of the pharmacy profession; and 

   (4) to maintain and develop the science and practice of pharmacy in its contribution to the health and well-being of the public.
Pharmaceutical Science
Expert Advisory Panel

call for applications – received nearly 50 nominations of senior people spanning the whole of pharmaceutical sciences*, and from across the whole UK and internationally

*pharmaceutical science defined as

going forward the pharmaceutical science expert advisory panel would........

provide strategic direction and assess future developments in pharmaceutical science

advise, horizon scan and independently review critical issues facing the profession that will impact on patients and the public
Process of Production of the ‘Road Map’

initial scoping exercise undertaken by the Panel ‘Road Map’

started to draft the ‘Road Map’ - experts recruited where Panel had none

small sub-team from the Panel worked to pull all the sections together into a consistent format

extensive stakeholder consultation > 60, response rate ~ 50%

final document endorsed by the RPS

launch event at the Royal Society

RPS Scotland – 2 science events based on ‘Road Map’s’ recommendations in Scottish Parliament

‘Road Map’ intended as a living document – currently being up-dated
New Medicines, Better Medicines, Better Use of Medicines

A Guide to the Science Underpinning Pharmaceutical Practice
May 2014

Executive Summary: A Guide to the Science Underpinning Pharmaceutical Practice
May 2014

http://www.rpharms.com/what-we-re-working-on/promoting-pharmaceutical-science.asp
New Medicines, Better Medicines, Better Use of Medicines
From Science to Compliance

- summarises role pharmaceutical science has played/continues to play in medicines development & use
- demonstrates the breadth of scientific knowledge/understanding necessary to underpin pharmaceutical practice
- highlights major challenges and opportunities faced when creating new medicines, improving existing medicines or ensuring the better, safer, use of medicines
- 7 recommendations
New Medicines, Better Medicines, Better Use of Medicines

1. Ensuring the safe use of medicines
   - Promote further research into the causes of medication errors
   - Ensure consideration is given to the safe use of medicines, from drug discovery to patient administration
   - Improve pharmacovigilance
   - Encourage the development of safer medicines

2. Stimulating new antimicrobial development and improving antimicrobial stewardship
   - Educate the public and patients on the use of antimicrobials
   - Encourage further development of antimicrobial stewardship, and support the development of new antimicrobials

3. Adopting new technologies
   - Educate the public about the use of new technologies such as gene therapy, therapeutic vaccines and stratified medicines
   - Ensure new technologies and medicines fulfil their potential
   - Encourage the development of appropriate reimbursement models

4. Supporting the development of new and innovative medicines
   - Encourage the adoption of new technologies and innovative approaches that assist in drug target identification, reduce drug attrition and improve the safety profile of medicines
   - Reduce the cost and time to bring medicines to the patient
   - Reduce the regulatory burden associated with approval
   - Encourage participation and transparency in clinical trials

5. Increasing the evidence base for pharmacy
   - Increase the health services research expertise within the profession
   - Demonstrate the effectiveness of NHS pharmacy services through trials to enhance the role of pharmacy in the treatment of patients

6. Supporting pharmaceutical science in the UK
   - Encourage investment in education to ensure a highly skilled pharmaceutical science workforce
   - Ensure that the UK remains a major player in the development of new medicines
   - Increase support for more academic/NHS/industrial partnerships

7. Recommendations at a global level
   - Tackle disease in developing countries and ensure the equitable access of quality medicines to all patients
   - Support the responsible re-use of medicines
   - Prevent harm to patients by the removal of falsified and counterfeit medicines
New Medicines, Better Medicines, Better Use of Medicines

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NEW MEDICINES,
BETTER MEDICINES,
BETTER USE
OF MEDICINES

A Guide to the
Science Underpinning
Pharmaceutical
Practice

‘New Medicines’ Launch
Developing new drugs

The challenges of drug development have been much in the news lately. This process begins primarily by screening the proposed actions of natural products by plants and other natural compounds. However, the process can be lengthy and expensive, and the supply of effective new antibiotics could be dwindling. Though the current output is faster than in the 1990s, many challenges remain, as the National Institutes of Health report.

Among many points in the report is the fact that developing new medicines is a long and expensive process. New potential drugs often start with the synthesis of thousands of compounds, many of which are not biologically active. As the process continues, the number of candidates becomes smaller, and costs increase. The research is expensive, and the failure rate is high. The ultimate goal is to develop new medicines that are effective, safe, and affordable. The challenge is to develop new medicines that are effective, safe, and affordable. The research is expensive, and the failure rate is high.

In conclusion, though the process of developing new medicines is expensive and time-consuming, it is essential for the future of healthcare. The need for new antibiotics is critical, and the research community must continue to work towards finding effective treatments for infections.

Elizabeth Sukkar finds that every pharmacist and pharmaceutical scientist can play a vital role in shaping the future of healthcare. The need for new antibiotics is critical, and the research community must continue to work towards finding effective treatments for infections.

As a pharmacist, when I counsel a patient about their medicine, I cannot help but think about the work that went on before it arrived as easily as a package in the pharmacy. The work of pharmaceutical scientists, formulation pharmacists, researchers, clinicians, pharmaceutical companies, and regulatory bodies is essential in bringing new medicines to patients.
Implementation of the Recommendations

Pharmaceutical Science Expert Advisory Panel divided into sub-groups

Recommendation 1 – Phil Routledge

Recommendation 2 – Simon MacKay

Recommendation 3 – Luigi (Gino) Martini

Recommendation 5 – Christine Bond

science and technology stream of the 2016 RPS annual conference organised round the RPS led recommendations of the ‘New Medicines’ Guide
Work to Date on the Recommendations

Ensuring the safe use of medicines
Increasing understanding of the causes of medication errors and the impact of pharmacy interventions and improving awareness of patients and the public of the risks and benefits of taking medicines.

Stimulating new antimicrobial development and improving antimicrobial stewardship
Educating the public, patients and current and future healthcare professionals on the place of antimicrobial treatment and non-medical infection control interventions.

Ensuring the safe use of medicines
Increasing understanding of the causes of medication errors and the impact of pharmacy interventions and improving awareness of patients and the public of the risks and benefits of taking medicines.

Supporting pharmaceutical science in the UK
Ensuring that the UK remains a major player in the development of new and innovative medicines by expanding current Government initiatives aimed at making the UK an attractive location for companies of all sizes to base their activities, as well as increasing support for more academic/NHS/industrial partnerships.

Improving access to medicines at a global level
Supporting the responsible reuse of medicines to improve access to medicines in developing world communities thereby improving health.
Recommendation 1 – Ensuring the Safe Use of Medicines

approached by the Pharmacovigilance Expert Network (PEN) of the Association of the British Pharmaceutical Industries (ABPI)

One stop shop: Delivering excellence in patient safety across the UK
September 2014

Chaired by June Raine | MHRA
Dr Mary Baker MBE | European Brain Council
Angela Carrington | Belfast Health and Social Care Trust
Matt Griffiths | Royal College of Nursing
Cathy Harrison | Department of Health Social Services and Public Safety in NI
Laura McVey | Healthcare Improvement Scotland
Janet Thomas | Betsi Cadwaladr University Health Board

Dr Hall provided an example of risk minimisation in action, citing how patients incorrectly sticking on and inappropriately disposing of clear transdermal fentanyl patches contributed to a number of cases of accidental exposure in young children and the introduction of further guidance to ensure the safe handling of these medicines.

into interventions to reduce those errors. We will also help improve patient understanding of the risks and benefits of their medication and pharmacovigilance and reporting of suspected ADRs by HCPs and patients.”

According to Professor Lawrence ADRs account for 4.5 percent of hospital admissions with more than 70 percent of these being avoidable. There were an estimated 1.7 million prescribing errors in general practice in England in 2013. Professor Lawrence commented: “We heard of a case of a 92 year old patient who was being prescribed 19 different drugs and after a full medication review when the amount she was prescribed was reduced to four drugs all her side-effects and problems ceased.”

spoke about Medicines Optimisation work that the RPS was involved in and the ‘New Medicines’ Guide

Strategies for optimising use of medicines

Panel Discussion (AM)
L-R: Mick Fay, Ben Rooke, David Cousins, Lucy Humphries, Jayne Lawrence and June Raine (Chair)
Recommendation 1 – Ensuring the Safe Use of Medicines

Safe and Effective Use of Medicines: Risk Minimisation Activities - Quick Reference Guide

Why this guidance is important to you
This guide provides an overview of pharmacovigilance risk management and risk minimisation activities, highlighting the roles that healthcare professionals (HCPs), including pharmacists, play in supporting the safe and effective use of medicines.

What this guidance will tell you
This guide describes what pharmacovigilance is, highlights the importance of risk management plans, explains the difference between routine and additional risk minimisation activities, and discusses the way in which risk minimisation information can be accessed.

What is pharmacovigilance?
Pharmacovigilance involves monitoring the safety of medicines and taking action to reduce any identified risks, thereby supporting the safe and effective use of medicines by patients. In general terms, it includes errors in the drug use process and effects arising directly from the use of medicines.

Why is pharmacovigilance important?
Once a medicine has been authorised and is on the market, pharmacovigilance activities carried out by pharmaceutical companies and regulatory authorities continue to monitor the safety profile of the medicine and take action to minimise the risks of any changes in that safety profile.

What activities comprise pharmacovigilance?
Pharmacovigilance activities include:
- The collection and assessment of safety-related information to determine the benefit/risk impact
- Implementing risk management strategies to minimise risks associated with medicines use
- Communication of any risk to the public and HCPs
- Assessing the effectiveness of pharmacovigilance activities

Who contributes to pharmacovigilance?
For pharmacovigilance to be effective, it requires the input of a wide range of stakeholders including:
- HCPs, including pharmacists
- The public including patients or their carers
- Regulatory authorities and pharmaceutical industry associations
- Pharmaceutical companies

What is a risk management plan?
A risk management plan (RMP) is a set of activities designed to identify and prevent or minimise risks related to a medicine. An RMP is written by a pharmaceutical company and is continually updated throughout the lifecycle of a medicine as the understanding of a risk increases and the missing information decreases.

What is a risk minimisation strategy?
A RMP must include a risk minimisation strategy which documents the risk minimisation measures (routine or additional). Risk minimisation can either reduce the severity of the risk when it occurs or reduce its frequency.

What are routine risk minimisation activities?
Routine risk minimisation activities are for most medicines and consider sufficient and includes tools such as:
- Summary of Product Characteristics
- Patient Information Leaflet
- Labelling and packaging of the medicine
- Legal status of the medicine

What are additional risk minimisation activities required?
Additional risk minimisation activities apply to some new medicines, or for older products where a safety issue has been identified to improve the benefit/risk profile. Examples of additional risk minimisation activities include:
- Educational programmes for HCPs, patients, and carers
- Patient screening or monitoring
- Patient alert cards (e.g., anticoagulants)

Safe and Effective Use of Medicines: Risk Minimisation Activities

Advice for pharmacists

What is pharmacovigilance?
The World Health Organization defines pharmacovigilance (PV) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

Why do we need pharmacovigilance?
In order for a medicine to be authorised by a regulatory authority for use in the UK, the benefits and risks of a medicine are carefully considered. As it is impossible for absolutely all information about a medicine to be known prior to it being authorised, a balance must be struck between making a new medicine available to patients and having adequate information on its product’s quality, safety, and efficacy. Once a medicine is launched, ongoing safety monitoring is usual as at the time the marketing authorisation is granted the medicine will have been tested in a relatively small number of patients for a limited amount of time.

Patients participating in clinical trials are selected carefully and followed closely under tightly controlled conditions. However, once a medicine receives its marketing authorisation, it will be available for use in a wider range of healthcare settings and in patients who may differ from the study population (e.g., ethnicity, age, genetic background and other medical conditions). Patients may also be taking several other medicines and/or using complementary and alternative therapies. It is possible that rarer adverse reactions may only start to be reported once the medicine has been used in a larger number of patients and/or over a long period of time. It is therefore important to be able to identify any new or changing risk associated with a medicine and promptly report them (for example reporting suspected adverse drug reactions to the Yellow Card Scheme).

The legislation concerning pharmacovigilance
Pharmacovigilance legislation, which came into effect in the European Union (EU) in July 2012, was the biggest change to the regulation of human medicines in the EU since 1995. It had implications for marketing authorisation holders (MAHs), as well as for patients, healthcare professionals and regulators. The activities introduced fell into four main areas:
Recommendation 1 – Ensuring the Safe Use of Medicines

Black Triangle: Additional Monitoring of Medicines

Advice for Pharmacists

Why do we need pharmacovigilance? In order for a medicine to be authorised by a regulatory authority for use in the UK, the benefits and risks of a medicine are carefully considered. It is important for absolutely all information about a medicine to be known prior to its obtaining a marketing authorisation, so a balance must be struck between making a new medicine available to patients and having adequate information on its safety and efficacy. Once a medicine is authorised, ongoing safety monitoring continues. If new information about a medicine is obtained following the marketing authorisation granted the medicine will have been tested in a relatively small number of patients for a limited amount of time in clinical trials.

Patients participating in clinical trials are selected carefully and followed closely under tightly controlled conditions. However, once a medicine receives its marketing authorisation and is subsequently placed on the market by a company, it will be available for use in a wider range of healthcare settings and in patients who may differ from the study population, for example, age, and genetic background. It is possible that rare adverse reactions may only start to be reported once the medicine has been used in a larger number of patients and over a longer period of time. In addition, some patients may also be taking several other medicines and/or using concomitant and alternative therapies which may result in new or unexpected drug-drug interactions being identified. Therefore, it is important to be able to identify any new or changing risk associated with a medicine quickly.

The aim of this document is to explain how a specific pharmacovigilance activity, the black triangle, is used to monitor the safety and efficacy of new medicines that are placed on the market.

What is the black triangle? The black triangle has been running in the UK for many years to highlight medicines that are subject to intensive safety monitoring. The black triangle is a mechanism to strengthen monitoring and to actively encourage patients and HCOS to report any possible adverse reactions observed with these medicines.

On what medicines can I expect to find a black triangle? A black triangle is assigned to any new medicine when approved for the first time, if it contains a new active substance or is a biological medicinal product such as plasma-derived medicines, vaccines or biosimilars. Other criteria include specific conditions of authorisation e.g. the conduct of a Post-Authorisation Safety Study (PASS) by the monitoring authorisation holder after approval or restrictions with regards to the safe and effective use of the medicinal product, e.g. a controlled access scheme. The black triangle can also be assigned or re-assigned in some cases at later stages of a medicine’s lifecycle if a new safety concern has been identified that requires monitoring.

What types of suspected adverse reactions should be reported for black triangle medicines? Pharmacists other HCOS and patients are encouraged to report any suspected adverse reaction for black triangle medicines. For other established medicines, all serious suspected adverse reactions should be reported even if the effect is well recognised. Reports can be submitted via the Yellow Card Scheme at: Yellow Card Scheme - MPA or directly to the marketing authorisation holder.

For biologics (including biosimilar medicines), adverse reaction reports should clearly state the brand name and the batch number of the suspected medicine.

Where will I find the black triangle symbol? The black triangle symbol appears next to the name of relevant medicines on their Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL), in publications such as the BNF on advertising and educational materials for HCOS and on patient support materials. It does not appear on the outer packaging of medicines.

How long does a medicine have a black triangle symbol and under what circumstances will it be removed? Typically, new medicines are assigned a black triangle for a period of five years following first authorisation in the EU in some cases the period may be longer than five years. If there are ongoing safety concerns or, to complete (K3) studies, the decision to remove the medicines from the additional monitoring list must be agreed by the EU regulators following which there may be a delay before updated product information is available.

What roles can pharmacists play in handing black triangle medicines? Pharmacists should vigilantly and report all suspected adverse drug reactions for black triangle medicines and help support and educate patients with any questions they may have regarding the scheme. Pharmacists should be familiar with any risk minimisation materials a medicine may have and ensure that they are distributed to patients and that patients are counselled on their use.

Issued September 2016
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Recommendation 1 – Ensuring the Safe Use of Medicines

5 things you should know about Pharmacovigilance (PV)

1. What is pharmacovigilance?
   The World Health Organization defines pharmacovigilance (PV) as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.

2. How does pharmacovigilance help to improve patient safety?
   Medicinal products are authorised on the basis that the likely benefit outweighs the potential harms. Other and rare adverse drug reactions (ADRs) may only occur when the medicinal product is used in the wider population. On-going safety monitoring detects any changes in the risk profile so that the necessary steps to further optimise safe and effective use of the medicinal product can be taken.
   All medicinal products come with information on how to minimise risk, such as how to use medicinal products properly, how to store them, whether they can be used with existing medicines and whether there are any patients who should not use the product.

3. What tools are available to help reduce risk?
   A Risk Management Plan (RMP) is designed to identify, prevent or minimise risks relating to a particular medicinal product. The RMP documents the PV activities which are in place and the risk minimisation measures (RMMs) or tools needed to minimise risk by healthcare professionals (HCPs) and patients.
   These tools are non-promotional and approved by the regulator.

4. How can we work together to reduce risk?
   Regulatory Authority
   - Approves the risk management system
   - Agrees the RMP and approves medicinal products for marketing
   - Publishes public-friendly RMP summaries
   - Approves the additional RMMs
   - Agrees a RMP communication plan with the MAH
   - Oversees the additional monitoring for black triangle medicines

   Pharmaceutical Company (or MAH)
   - Creates a RMP for medicinal product
   - Prepares RMP as directed by the Regulator and distributes them as agreed and appropriate
   - Continuously implements and updates the RMP during the lifecycle of the medicinal product, including the associated RMMs

   Healthcare Professionals
   - Prescribes medicines and administers medicinal products and keeps patients informed
   - Selects the right medicinal product for the right patient taking account of any screening requirements or contraindications
   - Encourages patients to read labels, PLCs (and additional RMMs if applicable) and helps them to understand any adverse reactions
   - Monitors patients and manages suspected ADRs
   - Reports any suspected ADRs with the use of a medicinal product to the Yellow Card Scheme or directly to the MAH
   - Takes part in surveys to evaluate the effectiveness of additional RMMs

   Patient/Carer
   - Reads back information and becomes more aware of safety
   - Understands and uses routine and additional RMMs to help manage or minimise ADRs
   - Reports suspected side-effects to NCPDs, the MAH or the Regulator themselves e.g. through the Yellow Card Scheme
   - Takes part in surveys to help evaluate the effectiveness of additional RMMs
   - Takes or administers medicines as directed

5. What can I do to help improve patient safety?
   - Report suspected adverse drug reactions promptly (via www.mhra.gov.uk/yellowcard or via the Yellow Card mobile app)
   - Use the educational programmes for HCPs, patients and carers
   - Provide feedback to help monitor the effectiveness of risk minimisation measures

   MAHs and Regulators are legally required to evaluate the success of risk minimisation activities. This ensures the contributions from all stakeholders are being used to maximise patient safety.

Where can I find out more...

Reference section
Recommendation 1 – Ensuring the Safe Use of Medicines

Educating the Public about the Danger of Buying ‘Medicines’ On-Line

September 2016

in collaboration with Dr Cristina Legido-Quigley

estimated 10% of the global supply of medicines are fake
- 1% in developed countries,
- 33% in developing countries
- 50% of those purchased on internet
Recommendation 1 – Ensuring the Safe Use of Medicines
Educating the Public about the Danger of Buying ‘Slimming Pills’

campaign started January 2015

in 2015 the RPS spoke on
- national media 9 times
- regional media once
- national radio 6 times
- regional radio 4 times

appeared in
- national press 5 times

with an estimated reach of ~28 million

on-line figures ~2 million

2 blogs produced

campaign still on-going..........

in collaboration with Dr. Cristina Legido-Quigley

in 2 of the 9 national TV appearances in 2015 we analysed the content of the slimming products
Recommendation 1 – Ensuring the Safe Use of Medicines

Clinical Trial Safety

Pharmacists and Clinical Trials

Posted on 20/05/2016 by Elizabeth Gorrie — No Comments

By Professor Jayne Lawrence, Chief Scientist, Royal Pharmaceutical Society and Dr Rachel Joyner, Head of Research and Evaluation

Today is International Clinical Trials Day (ICTD). Now in its 11th year, ICTD is celebrated around the world to commemorate the day James Lind started his famous clinical trial

Adaptive clinical trials – could patients benefit?

Posted on 04/04/2016 by Melissa Dear — No Comments

by Liz Allen, Visiting Professor, Faculty of Life Sciences and Medicine, King’s College London and Quintiles, Early Clinical Development

What is a clinical trial?

Clinical trials are studies designed to evaluate the effectiveness and safety of potential new medicines. Clinical trials are divided into four phases (Phase I, II, III and real world late phase studies sometimes called Phase IV).

Phase 1 requires a small number of subjects, usually healthy volunteers though more recently such studies involve small numbers of patients. As the development moves from phase to phase increasingly large numbers of patients become involved and the cost escalates. It is estimated that about 40% to 50% of drugs that enter phase III studies will fail, by which point a pharmaceutical company will have invested close to one billion pounds. Read more

Media Comment

18/01/2016 - RPS Chief Scientist speaks to BBC News at Ten

Following the news that one man had died and five others were being treated in hospital in France following a phase 1 drug trial, RPS Chief Scientist Professor Jayne Lawrence appeared on BBC News at Ten. Her comments were also picked up by 51 radio stations across the UK, as well as appearing online in over 60 international and 25 UK outlets and in the Financial Times and Daily Express,

Prof Jayne Lawrence, Chief Scientist, Royal Pharmaceutical Society, said: “This type of incident is tragic but very rare in the world of clinical trials. There are very strict regulatory standards across the EU for performing clinical trials and phase 1 trials, where a drug molecule is tested for the first time in humans, are subject to particular scrutiny to minimise any risk to human health. Those in charge of the trial would have had to show they had done everything they could to protect patient safety before the trial was allowed to go ahead. There are many commercial companies who run phase 1 trials on a regular basis to establish the effects of a new molecule in humans. All medicines have side-effects, but these are generally mild and severe reactions are incredibly rare.”

comments picked up by 51 radio stations across the UK, appeared on-line in > 60 international and 25 UK outlets and the Financial Times & Daily Express

wrote a statement for the Science Media Centre
Recommendation 1 – Ensuring the Safe Use of Medicines

Other Work In-Progress

- working to better inform pharmacists, particularly those working in the community, of what a psychoactive substance is and where to find more information on the subject

- provide information on the available scientific information on e-cigarettes and their components to the RPS*

- writing guidance/advice on dinitrophenol (DNP) for community pharmacists

- exploring if it is possible to get dinitrophenol banned

- further development of a successful campaign on sunscreens

*information used to up-date RPS policy
Stimulating new antimicrobial development and improving antimicrobial stewardship

Educating the public, patients and current and future healthcare professionals on the place of antimicrobial treatment and non-medical infection control interventions.
Recommendation 2 – Stimulating New Antimicrobial Development and Improving Stewardship

spoken at public meetings – PHE England antibiotic awareness day
participated in high level think tanks – Foundation for Science, PriceWaterhouseCoopers
participated in public debates – Science Week
organised science cafés – PharmSci conference
blogs – RPS web-site and the Hippocratic Post
media work – TV, radio, on-line, national press
lead and hosted a national summit on antibiotic resistance for doctors, nurses and pharmacists (RCGP, RCP, RCN)
Antimicrobial Stewardship Expert Advisory Group set up
Recommendation 2 – Stimulating New Antimicrobial Development and Improving Stewardship

in support of Recommendation 2 of the New Medicines Guide and coinciding with the European Antibiotic Awareness Day 2014, RPS Scotland and the RPS Science Team held a parliamentary reception and debate sponsored by Jim Eadie MSP

in February 2015, the Scottish Parliament debated the motion on antimicrobial resistance (AMR), which Jim Eadie MSP had lodged in support of the parliamentary reception and debate

during the debate Mr Eadie specifically mentioned the ‘New Medicines’ Guide and Recommendation 2 therein
Recommendation 3 – Adopting New Technologies

**Ensuring the safe use of medicines**
Increasing understanding of the causes of medication errors and the impact of pharmacy interventions and improving awareness of patients and the public of the risks and benefits of taking medicines.

**Stimulating new antimicrobial development and improving antimicrobial stewardship**
Educating the public, patients and current and future healthcare professionals on the place of antimicrobial treatment and non-medical infection control interventions.

**Adopting new technologies**
Educating the public and patients about the ethical and moral issues surrounding the use of new technologies such as stratified medicine, gene therapy, regenerative medicine, therapeutic vaccines and biomarkers.

**Supporting pharmaceutical science in the UK**
Ensuring that the UK remains a major player in the development of new and innovative medicines by expanding current Government initiatives aimed at making the UK an attractive location for companies of all sizes to base their activities, as well as increasing support for more academic/NHS/industrial partnerships.

**Improving access to medicines at a global level**
Supporting the responsible re-use of medicines to improve access to medicines in developing world communities thereby improving health.
Recommendation 3 – Adopting New Technologies

Why this guidance is important to you

Recent advances in biotechnology have resulted in an increasing number of biological molecules and materials being used as medicines. This is a trend that is expected to continue, at least for the foreseeable future. A number of patents and periods of marketing exclusivity for biological medicines are expiring and biosimilar versions of the medicines are becoming more widely available, e.g., insulin glargine. The introduction of biosimilars offers potential benefits in terms of cost savings for the NHS and increased access to treatments for patients.

What this guidance will tell you

Biosimilars are not the same as a generic medicine and as a pharmacist, you will need to be aware of the guidance around the use of biosimilars in order to ensure their safe and effective use.

What is a biologic?

A biologic is a medicine made from a variety of natural sources that may be human, animal, or microorganism in origin.

Examples of biologics include vaccines, blood and blood products, somatic cells, DNA, human cells and tissues, and therapeutic proteins.

In general, the first or original biologic on the market is termed the originator or reference product.

What is a biosimilar?

A biosimilar is a biologic medicine that is similar to an already licensed biologic medicine in terms of quality, safety, and efficacy.

A biosimilar is specifically developed and licensed to treat the same disease(s) as the original innovator product.

A biosimilar can only be marketed after the patent protecting the originator product and any period of marketing exclusivity have expired.

Why is a biosimilar medicine not a generic medicine?

Due to the complexity of structure and larger size of biologics as well as their inherent heterogeneity resulting from their production methods, it is not possible to make an identical copy of the originator biologic. Biosimilars are licensed for use based on extensive data on quality, safety, and efficacy compared to the originator product. It is not possible to characterize a biologic to the same extent as a small molecule drug, where an identical copy can be produced known as a generic medicine.

Is it possible to switch between an originator biologic and a biosimilar?

Any decision to change the brand of a biologic used to treat a patient must only be made by a prescriber following discussions with the patient. It is recommended that, at the point of dispensing, the pharmacist confirms the patient has received the biologic they expect and that they are aware of how to store and use the medicine.

How will a biosimilar be prescribed?

In contrast to generic products, all biosimilars will have their own unique brand name and differ from their originator product. The Pharmaceutical Services Negotiating Committee (PSNC) recommends that all biosimilars are prescribed by brand to avoid automatic substitution.

How are adverse drug reactions to biosimilars reported?

It is important that both the brand name and batch number of a biologic medicine are provided when reporting suspected adverse drug reactions to biologics. To facilitate effective monitoring and support, patient safety pharmacists should consider it good practice to record the brand name and batch number of any biologic medicine supplied to a patient.

Table showing examples of biologics and biosimilars

<table>
<thead>
<tr>
<th>Non-proprietary name</th>
<th>Originator Product</th>
<th>Example of Biosimilar</th>
</tr>
</thead>
<tbody>
<tr>
<td>insulin glargine</td>
<td>Lantus</td>
<td>Abasagtir</td>
</tr>
<tr>
<td>infliximab</td>
<td>Remicade</td>
<td>Inflectra/Remsima</td>
</tr>
<tr>
<td>filgrastim</td>
<td>Neupogen</td>
<td>Nevasim/Krogacim</td>
</tr>
<tr>
<td>epoetin beta</td>
<td>Epoxi</td>
<td>Bioepo/Bioscide</td>
</tr>
<tr>
<td>somatropin</td>
<td>Genotropin</td>
<td>Omnitrope</td>
</tr>
</tbody>
</table>

Further information

- British National Formulary
- EMA Q&A on biosimilar medicines
- ASHP position on biologic medicines, including biosimilar medicines
- NICE update on evaluation of biosimilar medicines
- UKHSA England document: “What is a biosimilar medicine?”
- Biomedical Briefing Paper on biosimilar medicines
- EU consensus document What you Need to Know about Biosimilar Medicinal Products
- HUMA: Scottish Medicines,A National Prescribing framework
- NICE: Drug safety update - biosimilar products

Where to go for further information:

Members can contact RPS Support
Order: 0845 257 3370
Phone: 0845 257 3370
Email: support@rpharms.com
Recommendation 3 – Adopting New Technologies

Developed member webinars

> 250 dialled in

Manufacturing Chemist webinar: biologicals and biosimilars – what are the differences?
Recommendation 3 – Adopting New Technologies

because of RPS’s work on biosimilars

– invited to be part of an initiative lead by NHS England, along with a number of stakeholders

– invited by the ABPI along with the MHRA to part of a science media centre briefing on biosimilars
Recommendation 3 – Adopting New Technologies

National Press

Science Museum

Organised scientific debates
- Malarial vaccines

Participated in scientific debates
- Medicines innovation and the value of medicines
- Life sciences and the future of medicines
- Second use of medicines
- Should medicines be more about me?
- Developing effective medicines in the modern age

More articles in progress to inform profession of new developments

What impact will personalised medicine have on pharmacy?

Until just over 15 years ago, the medical and pharmaceutical communities took a standardised approach to drug therapy in that we treated all patients as if ‘one size fits all.’ This approach was challenged in 2003 when Allan Roses, then worldwide president of genetics at GlaxoSmithKline (GSK) noted that “the vast majority of drugs – more than 90% – only work in 10–50% of the people.” In other words, while we have effective drugs, they do not work in everyone.
Recommendation 5 – Increasing the Evidence Base for Pharmacy

**Increasing the evidence base for pharmacy**

Supporting the development of an improved evidence base to enable pharmacists to optimise the care of patients and the public and increasing the research capacity and capability within the profession.

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**Supporting pharmaceutical science in the UK**

Ensuring that the UK remains a major player in the development of new and innovative medicines by expanding current Government initiatives aimed at making the UK an attractive location for companies of all sizes to base their activities, as well as increasing support for more academic/NHS/industrial partnerships.

**Improving access to medicines at a global level**

Supporting the responsible reuse of medicines to improve access to medicines in developing world communities thereby improving health.
Recommendation 5 – Increasing the Evidence Base for Pharmacy: Developing Researchers

- Research resource hub - cradle to grave support for research

- 1:1 advice surgeries to support designing studies, grant writing and reporting results

- Research and evaluation skills toolkit to facilitate users to identify skill gaps in research and help them gain the required competency

- Research ready - developing and evidencing competencies in community pharmacy
Recommendation 5 – Increasing the Evidence Base for Pharmacy

- pharmacy landscape mapping project to establish a baseline of practice in medicines research, so far covers all patient facing work (phase 1 onwards), to be extended to cover ‘pre-clinical’ research

- working with the NIHR to articulate priorities for pharmacy (practice) research

- working to support pharmacy research uk to fund high quality research to both develop professionals and strengthen the evidence base

- RPS map of evidence - an interactive database of pharmacy research and best practice aiming to reduce duplication and foster collaboration – is being enhanced
A Big Thanks for the Pharmaceutical Sciences Expert Advisory Panel....

...and RPS’s Communications Team, the RPS’s Research Team and last, but not least, my partner in crime in the RPS’s Science Team
A Big Thanks for the Pharmaceutical Sciences Expert Advisory Panel....

....and RPS’s Communications Team, the RPS’s Research Team and last, but not least, my partner in crime in the RPS’s Science Team – Dr Colin Cable