

All Wales Medicines Strategy Group

**Annual Report
2018–2019**

www.awmsg.org



*"Supporting prudent prescribing
to obtain the best outcomes from
medicines for patients in Wales"*

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AWTTC

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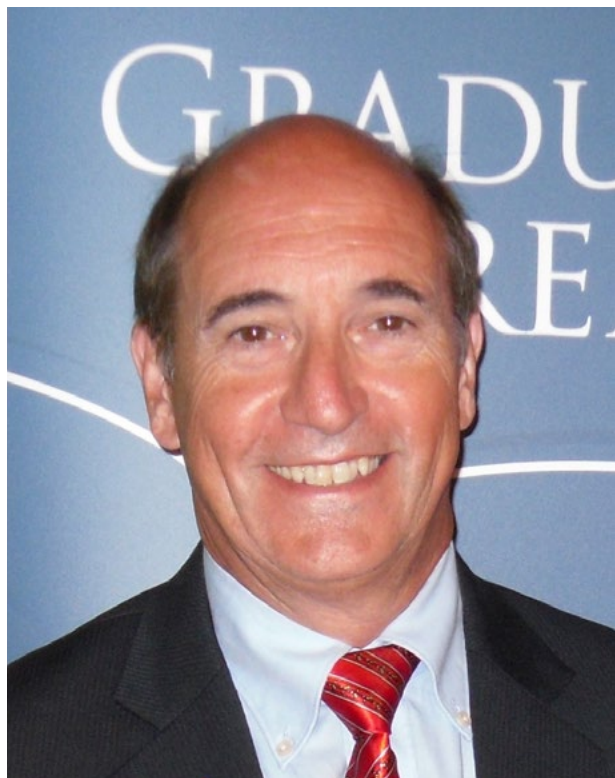
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For latest information, please visit www.awmsg.org

Chairman's welcome

A review of April 2018 – March 2019 and a look to the year ahead



When Dr Stuart Linton resigned as the All Wales Medicines Strategy Group (AWMSG) Chair in July 2018, I was pleased to move into the role of Interim Chair, pending the outcome of Welsh Government's public appointment process. Leading this group has been an exciting and rewarding experience for me. Using the underlying principles of AWMMSG (transparency, safety and equity), the group has produced a variety of resources to optimise the use of medicines and support prescribers. In doing so, AWMMSG has helped health boards across Wales achieve efficiencies in response to the medicines cost challenge.

I have been interested to learn more about how the All Wales Therapeutics and Toxicology Centre provides professional support to AWMMSG and its sub-committees from its base in the Routledge Academic Centre in University Hospital Llandough. A multi-disciplinary team of scientists, pharmacists, clinical pharmacologists, general practitioners, health economists, managers and

administrators all work together to ensure that the best evidence is made available to the committees so that members can make important and often difficult decisions on medicines in the delivery of its five-year strategy.

AWMSG aims to reduce inequity in access to medicines and improve the health outcomes for patients living in Wales. We can only achieve this if all sections of the healthcare sector, patients and their families, and the pharmaceutical industry, all work towards a common goal. It is vitally important that we meet the needs of NHS Wales and the review of the role and remit of AWMMSG, announced in February 2019, has been welcomed. Like any good team, to achieve success we need to be effective communicators, agile and responsive, show commitment and dedication, and utilise modern advances in technology. With Brexit looming there is no doubt we are facing many uncertainties, but one thing is certain and that is Wales is punching above its weight in terms of innovation and outputs and, whatever the outcome of Brexit and the review of AWMMSG, we will continue to work together in advising Welsh Government, supporting NHS Wales and promoting the best use of medicines for patients in Wales.

Professor John Watkins
MRCGP, FFPH

Interim Chairman, AWMMSG
Consultant Epidemiologist

Milestones reached this year



16 years



108th AWMSG meeting



371st appraisal

2018–2019 in numbers



21 medicines appraised (see page 27)



100% positive appraisals (see page 27)



11 medicines optimisation publications (see page 18)



8 meetings held (see page 3)



5 Wales Patient Access Schemes processed (see page 29)



12 National Prescribing Indicators monitored (see page 20)

Top stories



Best Practice Day 2018

AWTTC hosted its third annual Best Practice Day (See page 9)



AWMSG Masterclass 2018

AWMSG held its annual Masterclass for the pharmaceutical industry (See page 14)

Review of the process for appraising orphan and ultra-orphan medicines and medicines developed specifically for rare diseases

All Wales Medicines Strategy Group
Grŵp Strategaeth Meddyginiathau Cymru Gyfan

Review of the process for appraising medicines for rare diseases

AWMSG reviewed the impact of changes to the policy for appraising medicines for rare diseases (See page 16)



Patient and Public Involvement Group

PAPIG met three times during the year (See page 7)

Profile of AWMSG

Our vision for Wales – “A vision which focuses on patients”

Name: All Wales Medicines Strategy Group (AWMSG)

Established: 2002

Role: To advise Welsh Government on strategic developments in prescribing as outlined in the AWMSG Five-year Strategy

Members: Doctors, nurses, pharmacists, academics, health economists, a pharmaceutical industry representative and a lay member (see Membership on page 30 for individual members)

Meetings: Eight public meetings held in 2018–2019

Subgroups: New Medicines Group (NMG) and All Wales Prescribing Advisory Group (AWPAG)

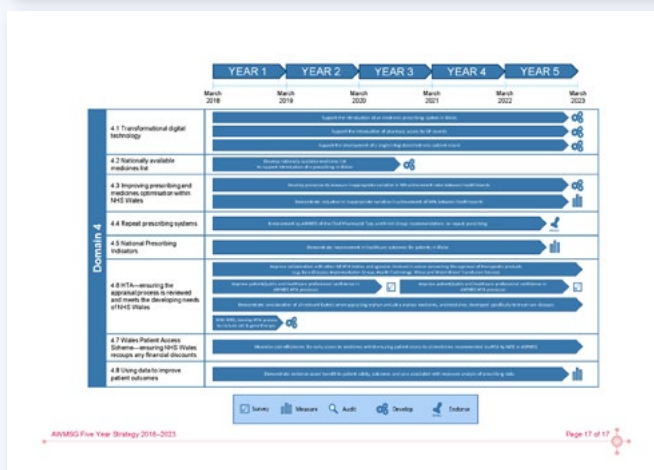
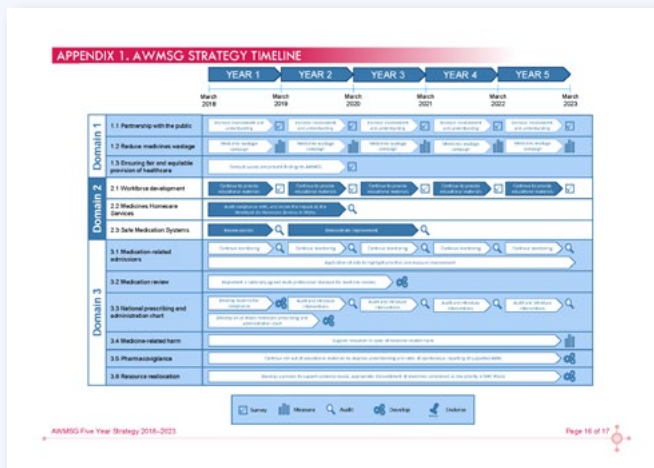
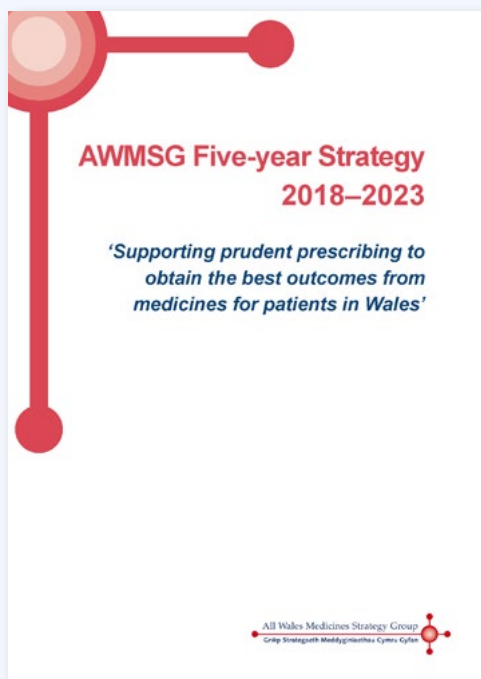
Organisational: Work is planned by the AWMSG Steering Committee and secretariat support is provided by the All Wales Therapeutics and Toxicology Centre (AWTTC)

More info: www.awmsg.org



View from the public gallery at the AWMSG meeting held in July 2018. During 2018–2019 AWMSG held 8 meetings at which 21 medicines were appraised and 11 medicines optimisation documents were endorsed.

Review of AWMSG's new Five-year Strategy 2018–2023: The first 12 months



In March 2018, AWMSG published its strategy for the next five years (2018–2023). The strategy is aligned with the recommendations of the 2018 Parliamentary Review of Health and Social Care in Wales: A Revolution from Within – Transforming Health and Care in Wales. These recommendations began to be rolled out in April 2018.

AWMSG works in partnership with patients and the public. AWMSG and its sub-committees have lay representatives who play an integral role in decision-making. The Patient and Public Involvement Group (PAPIG) provides a forum for patient organisations, individual patients and carers and patient support networks. To further promote patient and public involvement, AWMSG collaborated with HealthWise Wales during 2018–2019. As part of this project, more than 1,000 people were asked to watch a patient information film that summarised AWMSG's process

for approving new medicines for use in Wales; they then filled in a questionnaire. The results of this survey will be presented to AWMSG at a later date.

During 2018–2019, PAPIG supported two public health campaigns: Your Medicines Your Health and Making Choices Together. Both aimed to reduce medicines waste in line with AWMSG strategy recommendation 1.2 "Reduce medicines wastage". These campaigns were presented to AWMSG in February 2019 and acknowledged as good practice.

AWMSG agreed to work with Health Education and Improvement Wales (HEIW) to provide educational opportunities in line with strategy recommendation 2.1 "Workforce development". An educational slide set on the National Prescribing Indicators (NPIs) is being developed and will be hosted on HEIW's website.

The Yellow Card Centre (YCC) Wales, part of the All Wales Therapeutics and Toxicology Centre (AWTTC), is also working with HEIW to develop a module on pharmacovigilance to encourage patients and healthcare professionals to report suspected adverse drug reactions. To increase public understanding of the yellow card scheme, and in line with strategy recommendation 3.5 "Pharmacovigilance", the YCC Wales has also worked with HealthWise Wales to promote the scheme. The results of this work are due to be presented to AWMSG.

The World Health Organization's Global Patient Safety Challenge, Medication Without Harm, aims to support countries to reduce serious avoidable harm from medicines by 50% over the next five years. To support this challenge in Wales, the AWMSG strategy includes recommendation 2.3 "Safe medication systems" and recommendation 3.4 "Medicine-related harm". As a first step to delivering on these recommendations, during 2018–2019 AWTTC began developing a medicines safety dashboard with the aim of bringing together Prescribing Safety Indicators from Audit+ and hospital admission data (Patient Episode Database for Wales), with a focus on three harm categories of falls, bleeds and acute kidney injury by health board and primary care cluster.

In 2019, AWMSG will be hosting a Task and Finish group to consider an all Wales, nationally agreed, multi-professional standard for medication reviews in line with recommendation 3.2 "Medication review". AWMSG is also working with the All Wales Clinical Reference Group to develop an all Wales homecare prescribing and administration chart in line with recommendation 3.3 "National prescribing and administration chart".

AWMSG is committed to making the most effective use of healthcare resources in Wales in line with recommendation 3.6 "Resource reallocation". Working with the centres for health economics in Wales, AWMSG is developing a process to support evidence-based disinvestment of medicines to ensure the optimised use of medicines in NHS Wales.

AWMSG continues to support the introduction of an electronic prescribing system and pharmacy access to GP records in Wales. This aims to improve patient safety, reduce harm and increase efficiency. During 2018–2019 Welsh Government approved the Wales Hospital Electronic Prescribing Pharmacy and Medicines

Administration (WHEPPMA) committee's submission for an electronic pharmacy system for Wales.

AWMSG regularly reviews its processes and methodology for appraising medicines, to ensure that it meets the needs of patients and healthcare professionals in NHS Wales. During 2018-2019 AWMSG reviewed its process for assessing medicines developed specifically for treating rare diseases; recommendations have been agreed for roll-out during 2019–2020.

Wales Patient Access Schemes (WPAS) allow the pharmaceutical industry to offer financial concessions to NHS Wales which help to improve the cost-effectiveness of medicines appraised by AWMSG. AWTTC, in collaboration with the pharmacy service in Wales, is working on a project to ensure that NHS Wales has achieved the savings expected from implementing all patient access schemes in Wales. To date, this project has identified over £2 million in potential missed savings, 80% of which has already been recouped which has already been recouped. To find out more about the project, see page 11.

AWMSG is committed to evidence-based and value-based medicine and, through AWTTC, collaborates with the National Clinical Lead for Value-based and Prudent Healthcare in Wales. AWMSG is also committed to using data to improve patient outcomes (see recommendation 4.8 "Using data to improve patient outcomes"). Therefore, AWTTC is working with colleagues in Swansea University to explore how the Secure Anonymised Information Linkage (SAIL) Databank and machine learning might be used to study patient outcomes.

As in 2018–2019, AWMSG is committed to using all its available resources over the next 12 months to ensure that patients in Wales experience the best possible outcomes from the medicines they take.

Working in partnership

The All Wales Medicines Strategy Group (AWMSG) works with patients, healthcare professionals and representatives of the pharmaceutical industry, as well as Welsh Government and relevant UK organisations, to make recommendations on new medicines and provide guidance on medicines optimisation to improve the care of patients in Wales.

Two subgroups support the work of AWMSG:

AWPAG

The All Wales Prescribing Advisory Group (AWPAG) advises AWMSG on strategic developments in prescribing and medicines optimisation to promote the safe and effective use of medicines in Wales. The main functions of the group are to:

- develop and implement strategies that promote safe, rational, cost-effective prescribing
- monitor prescribing patterns and develop appropriate indicators
- advise on appropriate training, education and professional development for those persons employed in providing prescribing advice
- advise on the impact of developments that involve the use of medicines
- work in collaboration with other groups and organisations to promote the best use of medicines for patients.

NMG

The New Medicines Group (NMG) supports the work of AWMSG in the appraisal of new medicines. NMG considers the clinical effectiveness and cost-effectiveness of a medicine, along with written evidence from the pharmaceutical company, clinical experts in the field and relevant patient organisations, support groups, patients and/or patient carers. NMG makes a preliminary recommendation to AWMSG in relation to each medicine undergoing appraisal.

Secretariat support is provided by the All Wales Therapeutics and Toxicology Centre (AWTTC).



Patients and public

Patients, and their families and carers, are best placed to explain how a condition or medicine affects them, or the person they care for.

We ask for patient views as part of all new medicine appraisals, and also strongly encourage patients to take part in consultations for medicines optimisation resources.

The Patient and Public Interest Group (PAPIG) was set up to help us involve patients and patient organisations in the most effective ways we can. Members meet quarterly and provide vital input into our work.

AWMSG is looking for lay members to sit on their groups. Members of the public are invited to email awttc@wales.nhs.uk or telephone Ruth Lang on 029 218 26900 for more information on getting involved.

○ NEWS

AWMSG's Patient and Public Interest Group

AWMSG's Patient and Public Interest Group met three times during 2018-2019

9 May 2018

In May 2018 there were presentations from Jan Davies, Patient Champion at HealthWise Wales, who encouraged people to take advantage of the unique opportunity to be part of shaping the health and wellbeing of future generations in Wales, and help NHS Wales to plan for the future. Barbara Moore and Sian Jones talked about the work of Health and Care Research Wales and shared the vision for Wales to be internationally recognised for the excellent health and social care research that has a positive impact on health, wellbeing and the prosperity of the people in Wales.

Dr Alison Thomas, Clinical Pharmacologist and Director of the Yellow Card Centre (YCC) in Wales, gave an update on the work of the YCC and encouraged prescribers and patients to report adverse reactions.

AWTTC staff updated on the review of the process for appraising orphan and ultra-orphan medicines, and medicines developed specifically for rare diseases. There was also an update on the recent AWMSG initiatives that had been undertaken to help prescribers make the best use of medicines for people living in Wales.

26 September 2018

In September 2018, people shared information and views about AWMSG's work and other patient-focused topics. Robert Bracchi, Medical Advisor to AWTTTC welcomed attendees and introduced the day.

Rachel Williams, Campaigns, Policy and Communications Officer in Wales for Parkinson's UK Cymru, presented their "Get It On Time" campaign. The campaign aims to ensure that everyone with Parkinson's disease who goes into hospital gets their medication on time, every time they need it.

Jennifer Dickson, Public Involvement Coordinator at the Scottish Medicines Consortium (SMC), gave a presentation. She talked about how SMC had developed and strengthened patient and public involvement in health technology assessment in Scotland.

Two presentations focused on diabetes. Dai Williams, Director of Diabetes UK Cymru, talked about the future of diabetes in Wales and what is being done about the growing numbers of people with diabetes. Rob Lee, Service and Community Champion for Diabetes UK, highlighted the value of peer support for people with diabetes.

There were also updates from AWTTTC staff. Dr Alison Thomas gave a further update on YCC Wales.

23 January 2019

At the January 2019 meeting members received an insight into the role of the Patient Support Officer at Cwm Taf University Health Board from Chris Davies, Patient Forum representative. Chris spoke to members about the situation within Cwm Taf University Health Board before the initiative was set up and explained how the Patient Advice and Liaison Service (PALS) is now helping patients and their relatives. Chris informed members of his involvement in setting up the role, the barriers he and his colleagues faced, and how these barriers were overcome.

Gillian Cooper, Specialist in Poisons Information, National Poisons Information Service (NPIS) in Cardiff, gave an introduction to the UK NPIS and the Welsh National Poisons Unit. Gillian informed members about the work that the Gwenwyn Ward do within the NPIS. Members were told about how the NPIS has helped to gain information about which medications may need extra monitoring or increased preventative controls, such as child resistant caps, limited number of tablets in a pack, increased education etc.

continued overleaf...

Working in partnership *continued*



Dr Paul Myres, Public Health Wales, outlined the initiative "Making Choices Together". He gave members background to the scheme, what the scheme involved, and how two-way communication benefits both the patient and the clinician. PAPIG members were fully supportive of this initiative, and members were informed that it would be presented to AWMSG on 13 February 2019 for acknowledgement.

The fourth presentation was from Shahad Latif, Specialist Information Pharmacist – Pharmacovigilance and Patient Safety, and Dr Alison Thomas, Clinical Pharmacologist and Director of YCC Wales. Members were updated on the YCC Supporter Pledge (which can be accessed at www.awttc.org/yccwales) and given information about getting involved. The YCC team informed

members about projects in the pipeline and explained to members how yellow card reporting was now a National Prescribing Indicator (NPI) in Wales.

The meeting concluded with an update on NPIs from Claire Thomas, Welsh Analytical Prescribing Support Unit (WAPSU) Pharmacist, AWTTTC. Members were given the background to the NPIs and informed about which indicators had been chosen for 2018–2019. Claire explained how NPIs are developed and how a good indicator is identified. Members were provided with an overview of how the Medicines Optimisation Project Process works and how PAPIG members can input into AWMSG consultations to ensure the voice of the patient is heard.

PAPIG is made up of patients, carers, and representatives from patient organisations, AWTTTC and AWMSG. Patients are at the centre of everything we do, and we want to ensure that your views are considered when we're making decisions. PAPIG meetings are an opportunity for you to meet us. Come and hear about our work and find out how you can get involved.

To find out more about joining PAPIG, coming to a PAPIG meeting or presenting to PAPIG, please contact Ruth Lang (AWTTTC Patient Organisation Lead) on **029 218 26900** or at awttc@wales.nhs.uk.

To find out how you can get involved in AWMSG's work, please go to www.awmsg.org.

Get involved

Join PAPIG

PAPIG meetings are held quarterly and members contribute to the work of AWMSG in lots of ways, including providing feedback on resources, appraisal processes and web content. Send us an email if you would like more information: awttc@wales.nhs.uk

Come to a meeting

AWMSG meetings are open to the public and dates are listed on the Meetings page of the AWMSG website.

Take part in a consultation

Consultations are open to anyone who would like to give a view on our ongoing work. Current consultation papers are published on the AWMSG website and you can email AWTTTC if you would like to hear when new consultations are open.

Have your say on new medicines

When a new medicine is launched, patients with the condition, their carers and patient organisations are invited to complete a questionnaire on their experience of the condition and any existing treatments. You can see which medicines are waiting for patient views on the AWMSG website.

Be a lay member

AWMSG and its subgroups have lay members to provide the patient/public voice. Email awttc@wales.nhs.uk to find out if there are any vacancies and register an interest.

Volunteer to be a member of a reader group

When we produce information for patients, we need members of the public and patients to read them and let us know whether they are clear, user friendly and getting the right message across. If you would like to be a part of our reader group, please get in touch on awttc@wales.nhs.uk

Visit our website

For more details of our work and ways you can get involved, please visit www.awmsg.org.

Healthcare professionals

Healthcare professionals play a fundamental role in the work of AWMSG and are involved at every step of our processes: authoring resources, contributing on committees and working groups, providing clinical expert views, taking part in consultations, and implementing the advice and resources that AWMSG produces.

It is vital that healthcare professionals are engaged in our work, and we receive enormous support from such colleagues across Wales, without which we would not be able to achieve our aims.

NEWS

Best Practice Day 2018



Three years ago, the All Wales Medicines Strategy Group (AWMSG) highlighted significant improvements in prescribing made across Wales in line with the National Prescribing Indicator (NPI) aims, and asked the All Wales Therapeutics and Toxicology Centre (AWTTC) to explore and share the work that had led to these positive trends. To deliver this, AWTTC hosted the first multidisciplinary Best Practice Day in 2016.

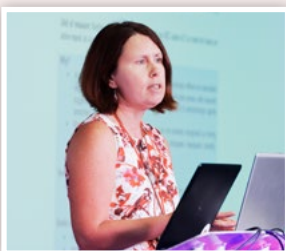
Since the first event, the scope of the day has expanded to include more therapeutic areas and not just those that are the focus of the current set of NPIs. In July 2018, AWTTC hosted its third annual Best Practice Day at Cardiff City Stadium. As with previous years, the intention of the Best Practice Day 2018 was to share some of the excellent work going on in relation to medicines optimisation in Wales.

What was presented?

Chaired by Professor John Watkins (Vice Chair of AWMSG) and Dr Stuart Linton (Chair of AWMSG), the day's agenda included talks covering a wide range of topics presented by healthcare professionals from across Wales who are working to make a difference, drive improvements and overcome some common prescribing challenges. There were also opportunities for the delegates to ask questions of the presenters in dedicated Question and Answer sessions. Topics included:

Anticholinergic burden

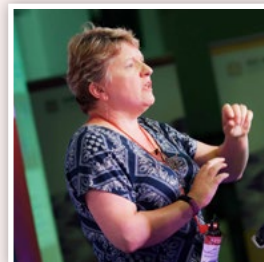
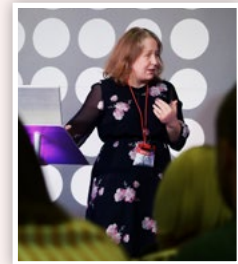
Fiona Walker (Locality Lead Pharmacist) and Allan Donnithorne (Western Vale Cluster Pharmacist) from



Cardiff and Vale University Health Board kicked things off with a presentation of their work on routine review of patients' anticholinergic medication based on their Anticholinergic Effect on Cognition (AEC) score. This work supports one of the Prescribing Safety Indicators included in the current set of NPIs. Fiona and Allan presented multiple patient case studies to illustrate the possible benefits of this approach to patient reviews.

Deprescribing

Non Lewis (Practice Pharmacist) from Hywel Dda University Health Board presented her work on deprescribing in a GP practice. This centred around the concept of carrying out regular Polypharmacy Clinics to improve patient safety while also potentially improving NHS sustainability. She highlighted how deprescribing acknowledges co-morbidity and provides the 'perfect marriage' between clinical good practice and cost-effectiveness.



Finding the best evidence

Julia Terry (Associate Professor and National Institute for Health and Care Excellence [NICE] Fellow) from Swansea University gave a presentation on the usefulness of the NICE Evidence Search website, the NICE Evidence Search student champion scheme, promoting confidence and competence when it comes to searching for healthcare evidence.

Medicines monitoring

Professor Susan Jordan and Karen Davies, representing the Medicines Management Group of the Department of Nursing for Swansea University, gave a presentation on medicines monitoring using the Adverse Drug Reaction (ADRe) profile which has been developed for use as a checklist by nurses. The talk explored how it can be used to recognise and act on possible observed adverse drug reactions and how its use has impacted patients' lives.



Working in partnership *continued*

Update on the Server for Prescribing Information Reporting and Analysis (SPIRA)



Dr Helen Adams (Principal Business Information Analyst) from the Welsh Analytical Prescribing Support Unit (WAPSU) highlighted the latest updates to SPIRA which is

now accessible via the WAPSU page of www.awttc.org. Two additional dashboards are now available for viewing data on medicines classed as having a 'Low Priority for Funding' and tracking the usage of biological medicines, and users will soon have more ways to download graphs and data for their own use. Find out more at www.awttc.org/spira.

Medicines wastage

In the first session of the afternoon, Julie Paton (Pharmacy Technician) from Betsi Cadwaladr University Health Board presented on an initiative undertaken within the



health board to reduce medicines wastage through the reuse of partially used packs of medication that would have otherwise been discarded. Since the project's launch in April 2015, the reuse of 'part packs' has already achieved savings of almost £500,000 for the health board.

Prudent respiratory prescribing

Jackie Reynolds (Medicines Management Pharmacist) from Aneurin Bevan University Health Board presented on prudent respiratory prescribing and improving value



for both the patient and the health board through a 'whole system approach', and working collaboratively across primary and secondary care with doctors, nurses and pharmacists. This work has resulted in significant reductions in respiratory spend

which has facilitated increased investment in expanding pulmonary rehabilitation services.

Medicines management in a care home

Lynwen Jones (Prescribing Advisor) from Abertawe Bro Morgannwg University Health Board gave a talk on a medicines management project that has been undertaken in a local care home within her health board. The work highlighted that improvements are needed in how medicines are ordered, prescribed, dispensed, administered and monitored for care home patients; and demonstrated how better use of pharmacists' skills would benefit care home residents and providers, and also the NHS.



Antimicrobial stewardship

The final presentation saw Gabriella Booth (Antimicrobial Pharmacist) from Cwm Taf University Health Board



delivering a session on antimicrobial stewardship and approaches to influencing prescribing and behaviours. The talk centred on how Cwm Taf Health Board has made changes to their antibiotic formulary and developed 'Myth Busting'

sessions for the public in an effort to dispel some common misconceptions on how antibiotics work, how to take them, and antibiotic resistance.

Where can you find out more?

The slides presented on the day are available to download through SHARE – AWTTTC's Online Community for NHS Wales – where you can also pose questions and discuss best practice initiatives. Videos of some of the presentations are also available on the AWTTTC website. AWTTTC would love to hear from you if you have made changes to your practice as a result of the work presented at the Best Practice Day; you can join in the discussion at share.awttc.org and visit www.awttc.org for news of future events hosted by AWTTTC.

NEWS

Biosimilar Best Practice Day 2019

National Prescribing Indicator (NPI) reports in 2018 had shown considerable variation in the uptake of biosimilar products across health boards in Wales, with the potential for significant cost savings if all areas prescribed in line with the best performing health board.

To help improve biosimilar prescribing practices, the All Wales Therapeutics and Toxicology Centre (AWTTC) hosted a Biosimilar Best Practice Day at Cardiff City Stadium on 21 January 2019. This event provided a forum to share good practice initiatives, prescribing data, behavioural change methodologies and procurement and commissioning information to support wider uptake of biosimilars across NHS Wales.

The day included a number of presentations, covering a range of perspectives.

- ▶ Richard Boldero (Pharmacist in WAPSU) gave an overview of the NPI that monitors the uptake of biosimilars, to encourage the appropriate prescribing of cost-effective biological medicines. This included how performance varied between health boards, and how SPIRA could be used to track biosimilar uptake.
- ▶ Claire Ganderton (Appraisal Pharmacist at AWTTC) spoke about the work involved with biosimilar horizon scanning, identifying new biosimilars in development, and how this supports the managed entry of these new medicines and the associated financial planning needed.
- ▶ Tracey Prothero (Senior Category Manager at NHS Wales Shared Services Partnership – Procurement Services) outlined the biologic procurement process, including an overview of the medicine contract cycle, who is involved in the contracting process, and what product factors are considered when tendering for a new biologic.

- ▶ Lois Lloyd (Medicines Procurement & Homecare Lead Pharmacist), Dr Yasmeen Ahmad (Consultant Rheumatologist) and Anne Breslin (Specialist Nurse) from Betsi Cadwaladr University Health Board gave a multidisciplinary team overview of how biosimilar implementation has been successful in their health board.
- ▶ Reuben Morgan (Medicines Homecare Manager at Abertawe Bro Morgannwg University Health Board) gave an insight into the homecare aspects of biosimilar implementation, discussing the challenges and opportunities this presents.
- ▶ Steve Brown (Regional Pharmacist NHS England/ NHS Improvement) gave a presentation on how implementation of biosimilar medicines had taken place in NHS England, the cost savings they have observed following their introduction, and how they are continuing to support implementation.
- ▶ To finish the day, Dr Delyth James (Principal Lecturer, Health Psychology/Pharmacist, at Cardiff Metropolitan University) ran a workshop session on understanding the barriers to behaviour change. It explored how a psychological framework could be applied to the prescribing of biosimilars. Delegates were asked to apply the model to their own work and to explore new approaches to overcoming barriers.

If you wish to find out more, some of the presentation slides are available on the AWTTC website: www.awttc.org.

Maximising benefits from Patient Access Schemes for medicines in Wales

An ongoing Invest to Save project is supporting health boards in Wales with implementing patient access schemes. This project will help to make sure certain new medicines are made available to patients as soon as possible, and any associated costs are kept to a minimum.

AWTTC is working with the All Wales Chief Pharmacist Group (AWCPG), the All Wales Medicines Procurement Specialist Pharmacist, all health boards and the Velindre Cancer Centre. The goal is to develop a robust and efficient process to help to fully implement and monitor three types of scheme.

- ▶ Wales Patient Access Schemes (WPASs) for medicines appraised by the All Wales Medicines Strategy Group (AWMSG).

- ▶ Patient Access Schemes (PASs) for medicines appraised by AWMSG and the National Institute for Health and Care Excellence (NICE).
- ▶ Commercial Access Agreements (CAAs) and Managed Access Agreements (MAAs) as part of any health technology appraisal (HTA) or Highly Specialised Technology (HST) process.

continued overleaf...

Working in partnership *continued*

The project aims to assure Welsh Government that access schemes agreed during a medicine appraisal are fully implemented. It will also identify any potential savings that have been missed due to non-compliance with schemes in NHS Wales.

Invest to Save

In 2009–2010, AWTTTC made a successful 'Invest to Save' bid to Welsh Government for £352k to set up WAPSU. WAPSU was tasked with monitoring the uptake of medicines 'approved' or 'not approved' by AWMSG. In addition they undertook three key initiatives, which were forecast to generate substantial savings of around £4.8 million in the NHS prescribing budget. The three initiatives were all based around AWMSG NPIs, and aimed to encourage the safe and effective prescribing of:

- ▶ non-steroidal anti-inflammatory drugs (NSAIDs)
- ▶ proton pump inhibitors (PPIs)
- ▶ hypnotics and anxiolytics.

The savings achieved as a result of these initiatives exceeded the original forecast and amounted to £5.8 million between 2009–2010 and 2011–2012 across the NHS in Wales.

Buoyed by the success of this project, a joint AWTTTC and AWCPG 'Invest to Save' bid was submitted to Welsh Government, for funding to address the burden on health boards to implement patient access schemes and maximise potential associated financial savings. Welsh Government awarded funding and a Project manager was recruited in May 2017 to start the project in September 2017.

The project team consists of a Project Manager, the Head of WAPSU in AWTTTC, the All Wales Medicines Procurement Specialist Pharmacist, and the Head of Medicines Management within Hywel Dda (Chief Pharmacists' representative).

Patient access schemes

Patient Access Schemes (PASs) vary in structure, but they are all designed to encourage pharmaceutical companies to engage in the appraisal process for medicines which may otherwise fall outside of the conventionally acceptable cost-effectiveness thresholds. This helps ensure that people in Wales have timely access to clinically effective new medicines. To guarantee that the maximum financial savings from such schemes can be accrued in Wales, it is essential to have efficient and comprehensive processes for monitoring these schemes centrally at an all-Wales and health board level, with close communication and co-ordination between them.

Project objectives

The primary objective of the project is to develop a single-system approach of implementing and monitoring patient access schemes across Wales. This required the project team to:

- ▶ establish a robust information technology system that provides some flexibility and negotiation options; to aid working in partnership with the pharmaceutical industry to explore alternative commercial arrangements.
- ▶ develop a robust and efficient process for full implementation of WPASs and PASs.
- ▶ scope all patient access schemes being used by individual health boards, identify where AWMSG/NICE guidance is implemented but access schemes are not being used, and assess reasons why schemes may not be adopted in all health boards.
- ▶ monitor actual cost savings achieved across NHS Wales associated with introducing a new system, identify potential cost savings, and identify any 'missed opportunity' costs incurred from non-uptake of schemes in NHS Wales.
- ▶ complete the quality assurance of a central reference source and point of communication in relation to all active WPASs and PASs, and notification of new Final Appraisal Determinations and Final Evaluation Determinations (FADs/FEDs) published by NICE with a PAS or CAA.
- ▶ implement a central All Wales Patient Access Scheme Administration System and establish a Task & Finish Group to oversee it.

Progress so far

To ensure that a central Medicine Reference Tool can be shared in confidence with health boards across Wales, the team developed an online workspace using the Vault which provides a secure online repository managed by AWTTTC.

The Medicine Reference Tool outlines the confidential details needed for the health boards to meet the New Treatment Fund (NTF) commitment to make a medicine available to patients within 60 days of a FAD being published. The tool was launched in April 2018 and shared with two colleagues in each health board who were nominated by their Chief Pharmacist. The Vault workspace and Medicine Reference Tool have been well received by the health boards and the pharmaceutical industry.

Feedback on the Medicine Reference Tool and the Vault

'Must say the Vault works fantastically with the recent new recommendations – at least for simple discount ones. Managed to sort two out today within 5 minutes of returning to work after 6 days off. Would have taken me two weeks otherwise.'

'Therapeutics Development Appraisal (TDA) Partnership Group were very supportive and impressed with the reference tool and thought it would be a definite flagship for best practice across the UK.'

'We introduced your way forward with the VAULT to WIG yesterday to general support.'

The Association of the British Pharmaceutical Industry (ABPI) Cymru Wales Bulletin, Summer 2018 edition: 'NHS Wales Securely Open for Business – the Vault workspace for commercially sensitive information'

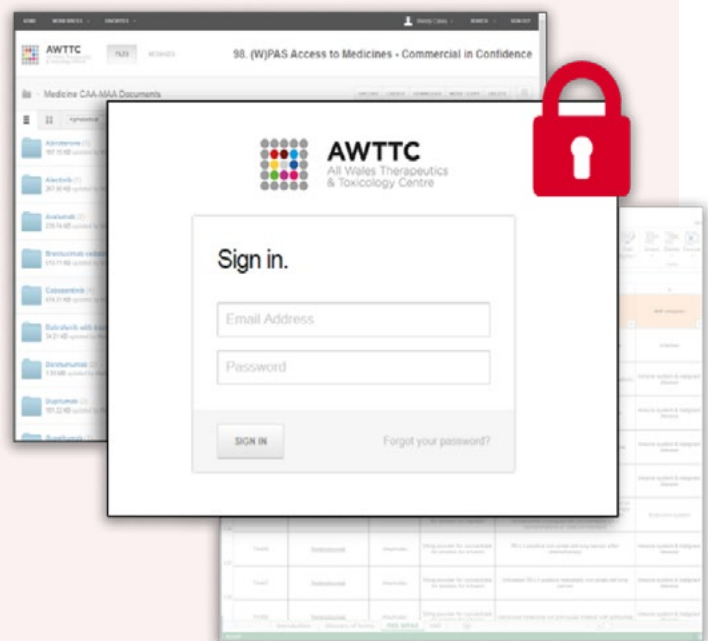
Monitoring

An initial baseline audit for 'simple' PAS schemes (i.e. a simple discount at the point of purchase or invoice) was developed, and initial exception reports for each health board were collated and shared with relevant health board representatives in February 2018. Ongoing exception reports are collated and shared on a quarterly basis.

A central approach for reviewing 'complex' WPAAs and PASs has also been adopted, with the support of health board colleagues. These more complex schemes may include, for example, free stock, dose capping or be based on patient outcomes. The project manager will collate the data for each of the complex schemes, generate a report by health board and highlight the audit findings to the rest of the project team. The relevant pharmaceutical company is notified when, as a result of the review, discrepancies have been highlighted with medicines for which they are the marketing authorisation holder. The companies are asked to confirm within 14 days that they will engage fully with the review and help the project team to provide Welsh Government with the required assurance.

A new central monitoring system

The project team are currently working with Blueteq to develop a system to support the monitoring of both simple and complex patient access schemes in NHS Wales. For each scheme the system will hold basic information (e.g. drug, scheme name/description, units of measure, expected price and/or discount from list price) and data on procurement of medicines will be uploaded into the system in an agreed format.



The Blueteq system will produce exception reports where there is a discrepancy in either the purchase or re-imbursment costs. It will be possible to analyse data on a hospital and health board level, for non-compliance with the agreed commercial terms for the approved medicine.

The future

This Invest to Save project has already received very positive feedback from various stakeholders. It aims to continue facilitating efficient implementation of patient access schemes across NHS Wales and ensuring that any potential savings are being achieved. The project team will:

- ▶ continue providing access to the secure workspace in the AWTTTC Vault
- ▶ develop the Blueteq central monitoring system and begin roll-out to appropriate users
- ▶ provide central monitoring and review of the implementation of patient access schemes and compliance with implementation guidance included within the relevant NICE technology appraisal or AWMSG advice
- ▶ maintain links with the pharmaceutical industry and negotiate on behalf of Wales a single All Wales reconciliation process to support compliance.

Working in partnership *continued*

Get involved		
<p>Join a committee AWMSG and its subgroups are always interested in hearing from you if you would like to volunteer to become a member. Email awttc@wales.nhs.uk to register an interest.</p>	<p>Take part in a consultation Register an interest or visit the consultations page on the AWMSG website to read the document(s) and give feedback.</p>	<p>Come to a meeting AWMSG meetings are open to the public and dates are listed on the AWMSG website.</p>
<p>Be a clinical expert Clinicians with a particular interest are encouraged to provide an expert view on appraisals. Access the questionnaire on the AWMSG website.</p>	<p>Propose a project If you would like to propose a medicines optimisation project for AWMSG's consideration please complete a New Project Proposal Form, available on the AWMSG website.</p>	<p>Attend the Best Practice Day This event is held each year to highlight some of the excellent work going on across health boards in relation to medicines optimisation. In 2018–2019 the event was held in July 2018. Check the AWTTTC website for details of future events.</p>
<p>Sign up to SHARE A forum for sharing and discussing best practice has been set up and is open to anyone with an NHS Wales email address. The link to sign up is share.awttc.org and more information including a user guide can be accessed here: www.awttc.org/share-awttcs-online-community.</p>		<p>Visit our website For more details of our work and ways you can get involved, please visit www.awmsg.org.</p>

Pharmaceutical industry

The pharmaceutical industry is an essential partner, particularly in the health technology assessment (HTA) process, where engagement enables prompt appraisal of new medicines within Wales.

The pharmaceutical industry also provides input into AWMSG medicines optimisation work, where they are able to provide a valuable perspective.

NEWS

AWMSG Masterclass | 21 November 2018

The All Wales Therapeutics and Toxicology Centre (AWTTC) hosted the annual AWMSG Masterclass for the pharmaceutical industry at Cardiff City Stadium on 22 November 2018.

The primary goal of these annual Masterclass days is to promote engagement from the pharmaceutical industry and answer any questions they may have regarding the appraisal process in Wales. It also provides an opportunity to network with people from AWMSG and AWTTC.

The latest AWMSG Masterclass included the following presentations:

- ▶ Gail Woodland (Appraisal Pharmacist at AWTTC) led an interactive session where delegates were guided through mapping out the decisions that form the different routes to medicines access in NHS Wales.
- ▶ Eifiona Wood (Health Economist for AWTTC) outlined some practical examples of what makes a good health economics submission, and how any proposals should be tailored for consideration within NHS Wales.
- ▶ Karen Samuels (Head of HTA at AWTTTC) gave a presentation on what has changed in the last year, which included an overview of: appraisals completed in the last year; information on orphan/ultra-orphan medicines; revisions to the format of AWMSG Secretariat Appraisal Reports; the recent All Wales Free of Charge Medicine Supply policy; and upcoming changes and challenges facing AWMSG and AWTTC.
- ▶ Pharmaceutical industry representatives Rob Thomas, Robyn Miles and Steven Lister spoke about how they work with AWMSG and its sub-committees; providing practical advice on preparing for an AWMSG appraisal.
- ▶ Mark Francis (All Wales Medicines Procurement Specialist Pharmacist) delivered a presentation on the NHS Wales procurement perspective on market access of therapies appraised by AWMSG, and the vital importance of early engagement of pharmaceutical companies with NHS Wales procurement that will result in benefits and opportunities for both parties.



- ▶ Paul Deslandes (Pharmacist in the Welsh Analytical Prescribing Support Unit [WAPSU]) and Wendy Casey (Project Manager in WAPSU) discussed Wales Patient Access Schemes: providing tips for pharmaceutical companies on submitting Patient Access Schemes for consideration and how some of the application form questions should be approached; and detailing the ongoing Invest to Save project that is monitoring the implementation of Patient Access Schemes across Wales.

A highlight of the day was a series of interactive workshops where delegates could learn more about various aspects of the work AWMSG and AWTTTC do, including:

- ▶ AWTTTC's horizon scanning process and how this links with early engagement
- ▶ AWMSG's current five year strategy
- ▶ the decision-making processes behind AWMSG exclusion criteria and what type of submission is required

- ▶ making a good submission and communicating clinical effectiveness, cost effectiveness and budget impact correctly
- ▶ the work of the All Wales Prescribing Advisory Group (AWPAG) and development of the National Prescribing Indicators (NPIs).
- ▶ patient access schemes and access agreements, their relevance to the HTA process and practical guidance on submissions where comparator medicines have patient access schemes.

If you wish to download any of the presentation slides from the Masterclass or download a summary of some of the questions addressed in Q&A sessions, visit www.awmsg.org/masterclass.html. Keep an eye on www.awmsg.org for any news of upcoming events and the next AWMSG Masterclass, due to be held in late 2019.



Working in partnership *continued*

NEWS

Review of the appraisal process for medicines for rare diseases in Wales

AWMSG reviewed the impact of the changes in September 2015 to the policy for appraising medicines for rare diseases. Between September 2015 and December 2017, AWMSG appraised 79 medicines and 20 (25%) of these were for medicines for a rare disease. Fourteen (70%) of the 20 appraisals were for a medicine that would not have met the criteria in the previous AWMSG ultra-orphan policy. There was a high positive recommendation rate for all medicines appraised by AWMSG, whether a medicine was indicated for a rare or non-rare disease.

AWMSG's recommendation rate for medicines appraised between September 2015 and December 2017

Type of appraisal	Number of appraisals recommended in full or given a restricted recommendation (%)
All appraisals	71/79 (90%)
Appraisals for medicines not indicated for a rare disease	53/59 (90%)
Appraisals for medicines for a rare disease	18/20 (90%)
Orphan*/orphan equivalent† appraisals (excluding subset of ultra-orphan [§] medicines)	10/10 (100%)
Ultra-orphan [§] /ultra-orphan equivalent† appraisals	8/10 (80%)

***Orphan medicine:** a medicine with European Medicines Agency (EMA)-designated orphan status and is used to treat a condition with a prevalence of not more than five in 10,000 people.

[§]**Ultra-orphan medicine:** a medicine that has been granted EMA designated orphan status and is used to treat a condition with a prevalence of 1 in 50,000 people or fewer in the UK (or 60 patients in Wales). By definition, ultra-orphan medicines are a subset of orphan medicines.

†**Orphan/Ultra-orphan equivalent medicine:** a medicine developed specifically to treat a condition with a prevalence equivalent to either an orphan or ultra-orphan medicine, irrespective of whether it is designated by the EMA as an orphan medicine.

Of the 20 appraisals considered under the new policy, 15 (75%) were associated with a patient access scheme (PAS). AWMSG recommended all medicines used to treat a rare disease that were associated with a PAS.

Clinician and Patient Involvement Group meetings

Five Clinician and Patient Involvement Group (CAPIG) meetings were convened between September 2015 and December 2017. Of these, three had a positive recommendation from AWMSG and two were not recommended. Convening a CAPIG meeting added up to 11 weeks to the AWMSG appraisal process. Feedback

from AWMSG members, clinicians, patient organisations and applicant companies who attended the CAPIG meetings was favourable.

Impact of the new policy

The number of medicines that could be considered by AWMSG under the updated policy increased. Twelve medicines that were appraised and subsequently given a positive recommendation would not have been eligible for consideration under the previous AWMSG ultra-orphan policy. One medicine, which was not recommended by AWMSG twice before introducing the new policy, was reappraised and recommended for use in NHS Wales.

The positive recommendation rate for medicines for rare diseases was high (90%) which contrasts with a previous analysis, conducted between 2002 and 2014, in which AWMSG recommended 20 (59%) of 34 orphan medicines (including ultra-orphan medicines). There was a marked increase (100%) in the positive recommendation rate of orphan/orphan equivalent medicines (excluding ultra-orphan medicines) compared with 52% in the previous analysis. The positive

recommendation rates for medicines considered to be ultra orphan or ultra-orphan equivalent (80% and 73%, respectively), were higher after introducing the new policy. These early findings suggest that the new policy has increased access to medicines for rare diseases by allowing additional considerations, particularly when the incremental cost-effectiveness ratio (ICER) is above the usually accepted threshold.

Get involved

Submit a medicine for appraisal

Companies are encouraged to submit their medicine to AWMSG for appraisal as soon as the marketing authorisation is granted. Information on the appraisal process and all relevant documentation can be accessed on the industry pages of the AWMSG website.

Take part in consultations

Register an interest or visit the consultations page on the AWMSG website to read the document(s) and give feedback.

Come to a meeting

AWMSG meetings are open to the public and dates are listed on the AWMSG website.

Come to the Masterclass

The Masterclass is held each year to encourage and facilitate pharmaceutical industry engagement in the HTA process. In 2018–2019 this event was held in November 2018 (see page 14).

Visit our website

For more details of our work and ways you can engage with the appraisal process and consultations, please visit www.awmsg.org

Our work this year – Medicines optimisation

Medicines optimisation focuses on patients and outcomes rather than process and systems. It aims to support healthcare workers in advising patients on how they can obtain the best outcomes from their medicines. In some cases, this may involve stopping some medicines and/or starting others to improve effectiveness and safety, and giving advice about how best to adhere to the treatment. To help patients and prescribers achieve the best outcomes from medicines, AWMSG publishes prescribing guidance and resources, as well as reports on prescribing performance.

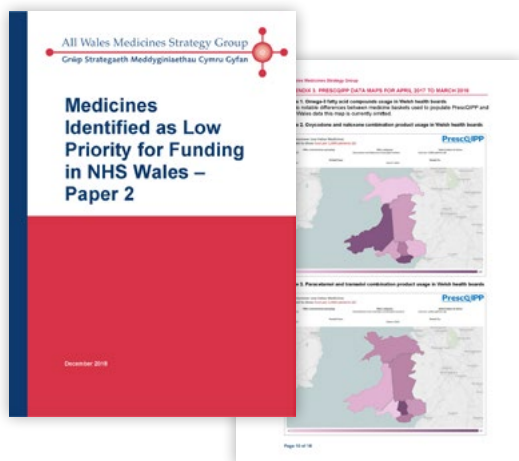
Guidance and resources

Medicines optimisation guidance and resources this year have focused on the following areas of healthcare.

Prudent Use of Medicines

It is vital that a prudent approach is taken to review medicines that offer a limited clinical benefit to patients and can therefore be considered a low priority for funding. In October 2017 the first Medicines Identified as Low Priority for Funding in NHS Wales paper was published. Over 2018–2019 this not only led to a decreased spend on this group of medicines of £1.03m, but also enabled patients to have a review of their medicines, and where appropriate, the prescribing of more suitable alternatives in line with national recommendations.

Medicines Identified as Low Priority for Funding in NHS Wales – Paper 2



The aim of this document is to minimise the prescribing of a second group of medicines that offer a limited clinical benefit to patients and where more cost-effective treatments may be available. Four medicines/medicine groups have been identified for the purposes of this document. These are:

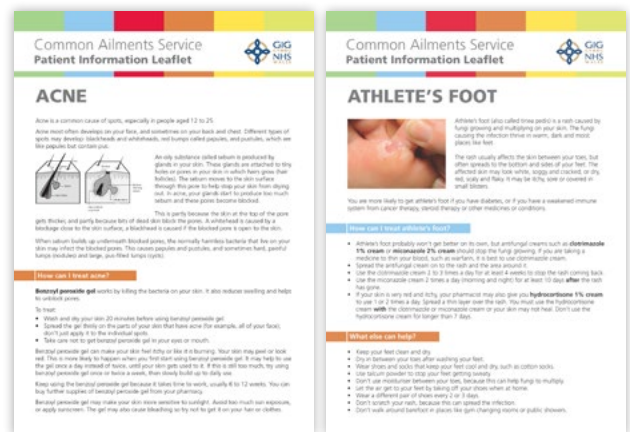
- ▶ omega-3 fatty acid compounds
- ▶ oxycodone and naloxone combination product
- ▶ paracetamol and tramadol combination product
- ▶ perindopril arginine.

Common Ailments

Many GP consultations are for common conditions that could potentially be self-treated. These common ailments

are often self-limiting conditions, and may require little or no medical intervention; others, which are not self-limiting and require treatment to prevent the conditioning worsening, can be treated with medicines readily available from pharmacies without a prescription. Many people consult GPs for conditions that could be dealt with effectively by a community pharmacist. Pharmacists are trained to deal with common ailments and already spend a good proportion of their time advising on these conditions, recommending over-the-counter products or referring people to other healthcare professionals.

All Wales Common Ailments Service Patient Information

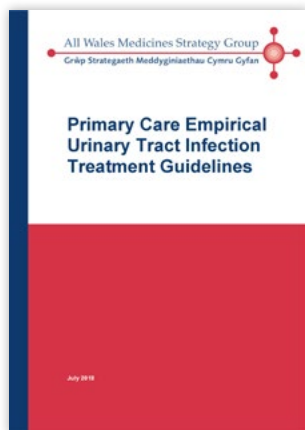


The Common Ailments Service aims to improve patient access to consistent, evidence-based advice for the management of common ailments. The Common Ailments Formulary was updated and presented to AWMSG for endorsement at its meeting in February 2018. In April 2018, patient information leaflets were published for each of the conditions in the formulary. The intention is that the healthcare professional advising the patient on a specific condition will offer a copy of the associated information leaflet to the patient. The leaflets are available in English and Welsh, and include diagrams to aid identification of the condition and ensure correct administration of treatments provided.

Antimicrobial Stewardship

The incidence of antimicrobial resistance in Wales is increasing, and widespread and often excessive use of antimicrobials is one of the main factors contributing to the increase. Prescribers must provide the most appropriate medicine to treat the condition while aiming to minimise the risk of antimicrobial resistance.

Primary Care Empirical Urinary Tract infection (UTI) Treatment Guidelines



This document represents a refresh of the empirical antimicrobial treatment guidelines for UTI in primary care. These have been updated to take into account increasing incidences of antimicrobial resistance in Wales. By treating UTIs more effectively it is hoped that the number of treatment failures, and hence progression to urosepsis,

will decrease. This is in support of a Department of Health ambition to halve the number of healthcare associated Gram-negative bloodstream infections by March 2021.

This guidance was adapted from Public Health England's antibiotic guidance for primary care, Management and Treatment of Common Infections. The intended audience is all prescribers in primary care, including GPs, pharmacists and Advanced Nurse Practitioners.

Antipsychotics

Antipsychotics are often prescribed to manage the behavioural and psychological symptoms of dementia (BPSD) such as delusions, hallucinations and aggression. More than 90% of people with dementia will experience at least one BPSD during the course of their condition. These distressing symptoms can often be prevented or managed without medication; however, antipsychotic medications are frequently prescribed as a first resort. It has been estimated that around two thirds of antipsychotic prescriptions for the treatment of dementia may be inappropriate.



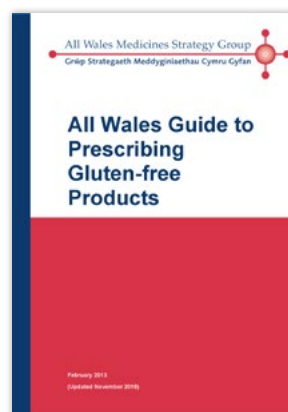
Clinical Effectiveness Prescribing Programme Audit – Antipsychotics in Dementia

The audit aims to ensure appropriate prescribing of antipsychotics in people aged 65 years and older with a diagnosis of dementia, with the objectives of:

- ensuring that antipsychotic prescribing in people aged 65 years and over, with a diagnosis of dementia, is in line with NICE guidance.
- identifying patients who may need a review of their antipsychotic prescription.

Gluten-free Prescribing

Gluten-free products are an essential part of the clinical treatment of coeliac disease.



Guide to Prescribing Gluten-free Products

The All Wales Guide to Prescribing Gluten-free Products aims to support GPs and other healthcare professionals in the management of patients with coeliac disease, and aid the decision-making process in relation to prescribing Advisory Committee on Borderline

Substances (ACBS)-approved gluten-free foods.

AWMSG Acknowledgement

AWMSG has acknowledged the following initiatives as good practice and aligning with the aims of the AWMSG Five-year Strategy 2018–2023:



Making Choices Together

www.1000livesplus.wales.nhs.uk/making-choices-together



Your Medicines, Your Health

cwmtaf.wales/services/pharmacy-medicines-management/medicines-health-ymyh/

Our work this year

– Prescribing monitoring and analysis

AWMSG monitors and analyses prescribing data in order to benchmark performance and drive improvements in the service.

National Prescribing Indicators

Where there are clear safety, stewardship or efficiency messages that can indicate good practice, prescribers often find it useful to benchmark themselves against others; whether at health board, cluster or practice level. To facilitate this, AWMSG agreed that National Prescribing Indicators (NPIs) were useful tools to promote rational prescribing across NHS Wales and the first set of NPIs were published in 2003.

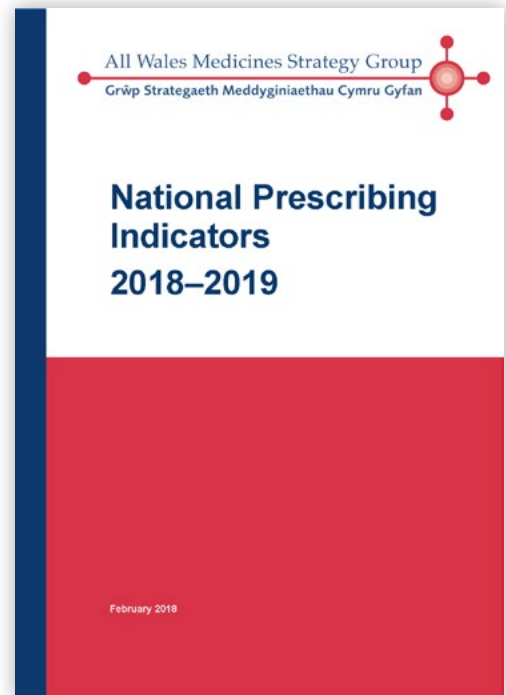
NPIs are used to highlight therapeutic priorities for NHS Wales and compare the ways in which different prescribers and organisations use particular medicines or groups of medicines. Prescribing indicators should be evidence-based, clear, easily understood and allow health boards/trusts, practices and prescribers to compare current practice against an agreed standard of quality. The NPIs should address efficiency as well as safety and quality, and targets should be challenging but achievable, and applicable at practice level.

National Prescribing Indicators 2018–2019

For 2018–2019, AWMSG endorsed 12 NPIs focusing on eight areas of prescribing and the reporting of adverse events (Yellow Cards), with each indicator categorised as either safety, stewardship or efficiency.

National Prescribing Indicator monitoring

During 2018–2019, NPIs were monitored quarterly and reports published on the AWMSG website. The report for the quarter ending March 2019 showed that the majority of NPIs with a threshold or target demonstrated improvements or target achievement in line with the aim of each indicator. Detailed NPI data for 2018–2019 are shown on page 21 and Appendix 1.



Monitoring data for the NPIs can be viewed and analysed through the Server for Prescribing Information Reporting and Analysis (SPIRA).



National Prescribing Indicator data to March 2019

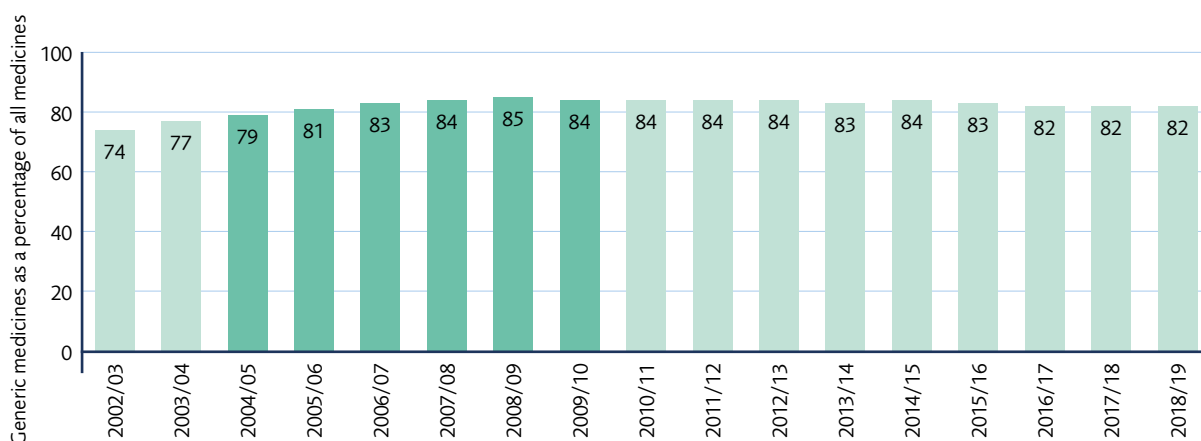
Data for the NPIs 2018–2019 show that, for the majority of NPIs with baseline data available, prescribing (or reporting of adverse drug reactions) is improving in line with the aim of the NPI. Only the prescribing of gabapentin and pregabalin has shown a negative trend. Prescribing of long-acting insulin analogues in primary care has not shown a change.

The following data are taken from the quarter ending March of each financial year, except Yellow Card reporting, which show data for the complete financial year.

Where the aim of the NPI is to increase prescribing the graph is green, where the aim is to decrease prescribing the graph is red. Years where the area has been monitored as an NPI are displayed as darker bars.

Generic medicines

Generic medicines are no longer monitored as an NPI but figures for prescribing of generic medicines as a percentage of all medicines indicate a value with minimal change over the last few years.



Safety

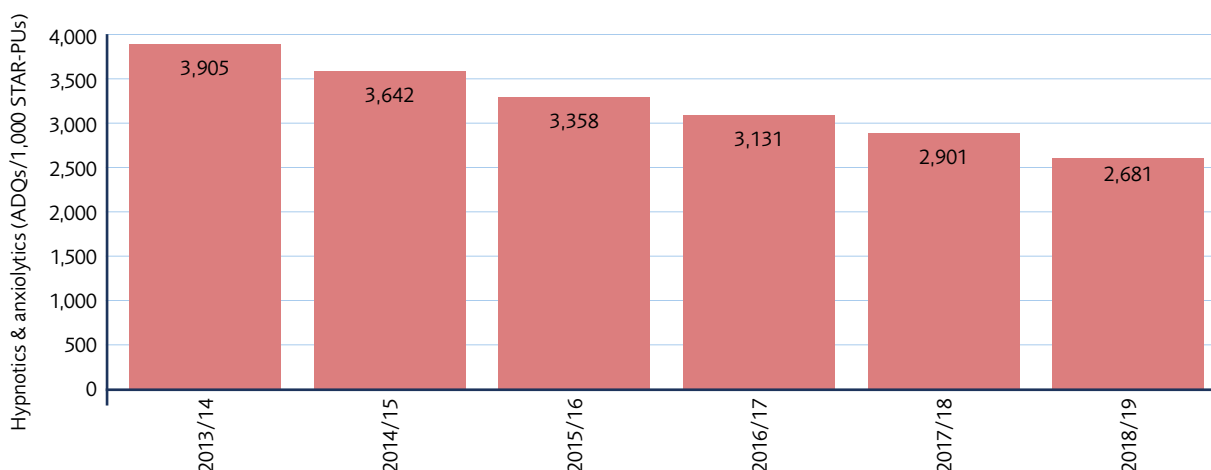
Prescribing Safety Indicators

The Prescribing Safety Indicators in primary care were introduced for 2018–2019, adapting some prescribing measures utilised in the pharmacist-led information technology intervention for medication errors (PINCER) trial, and tailored towards the needs of NHS Wales. No targets have been set for this NPI as yet; however, data from 2018–2019 can provide a baseline for future quarters. Baseline data for these new indicators are summarised on page 26.

Hypnotics and anxiolytics

There has been concern over high levels of hypnotic and anxiolytic prescribing in NHS Wales for some time. Some prescribing may be inappropriate and contribute to the problem of physical and psychological dependence, and/or may be responsible for masking underlying depression.

Prescribing (measured in average daily quantities [ADQs] per 1,000 specific therapeutic group age–sex related prescribing unit [STAR-PU]) has declined steadily in line with the aim of the NPI since its introduction.



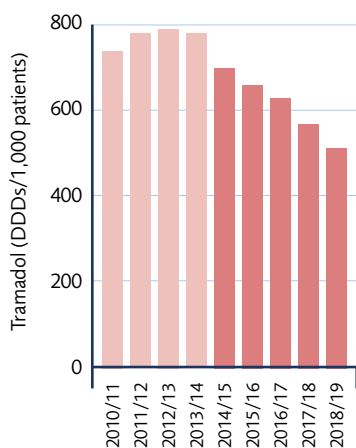
Our work this year – Prescribing monitoring and analysis *continued*

Analgesics

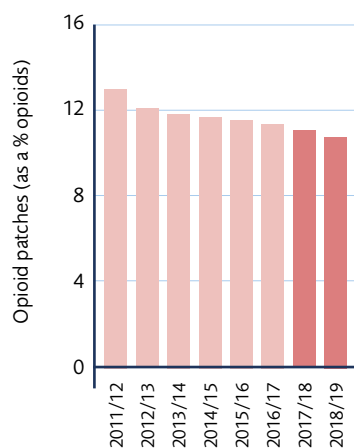
Three NPIs support the appropriate use of analgesics: tramadol, opioid patches, and gabapentin and pregabalin.

Tramadol defined daily doses (DDDs) per 1,000 patients and opioid patches as a percentage of all opioids have decreased in line with the aim of the NPI. Gabapentin and pregabalin prescribing (DDDs per 1,000 patients) continues to increase.

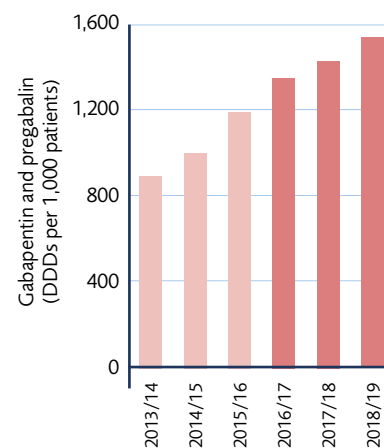
Tramadol



Opioid patches



Gabapentin and pregabalin



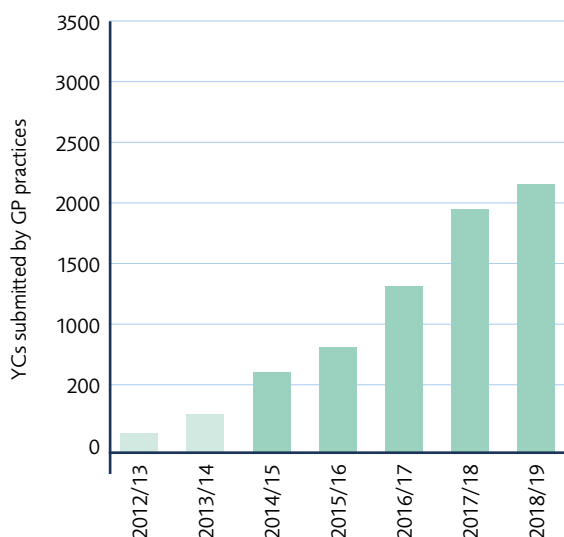
Yellow Cards

Adverse drug reactions (ADRs) are a significant clinical problem, increasing morbidity and mortality. Approximately 6.5% of hospital admissions in adults and 2.1% in children are attributed to ADRs.

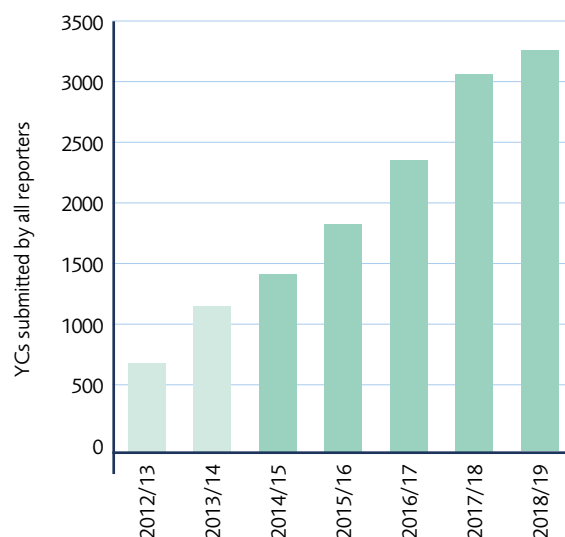
The number of Yellow Cards submitted by GPs and health boards has increased substantially since the NPI was introduced in 2014.

As of 2018–2019, the NPI has also monitored the number of yellow cards submitted by secondary care, members of the public and community pharmacists. Compared to 2017–2018, the number of yellow cards submitted by secondary care and community pharmacists has decreased, while the number of submissions from members of the public has increased. See Appendix 1 on page 33 for detailed NPI data.

Yellow Cards – GPs



Yellow Cards – all reporters



Stewardship

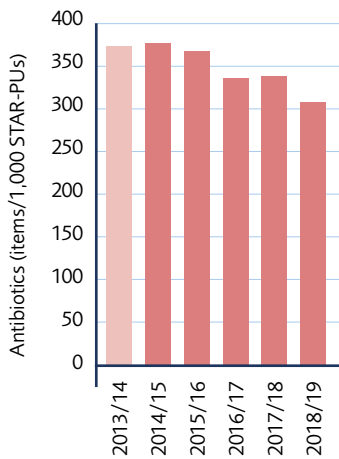
Antimicrobial Stewardship

The widespread and often excessive use of antimicrobials is one of the main factors contributing to the increasing emergence of antimicrobial resistance.

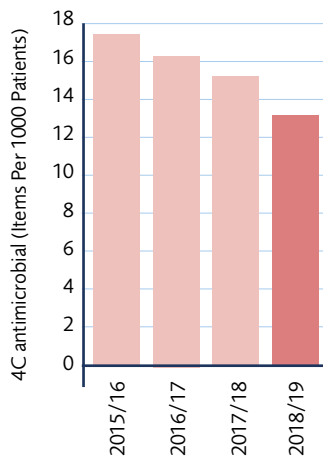
Antimicrobial prescribing in primary care

Total antibiotic prescribing (items per 1,000 STAR-PU) and 4C antimicrobial (co-amoxiclav, cephalosporins, fluoroquinolones and clindamycin) prescribing (as items per 1,000 patients and as a percentage of total antibiotic prescribing) have all decreased in line with the aim of the NPIs.

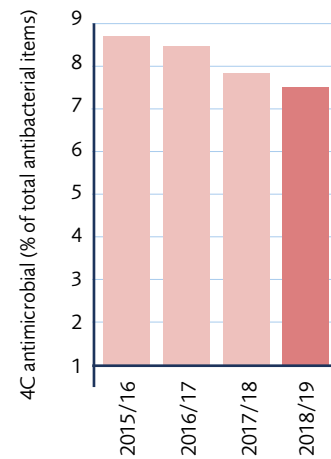
Total Antibiotics



4C antimicrobial (items per 1,000 patients)



4C antimicrobial (% of total items)

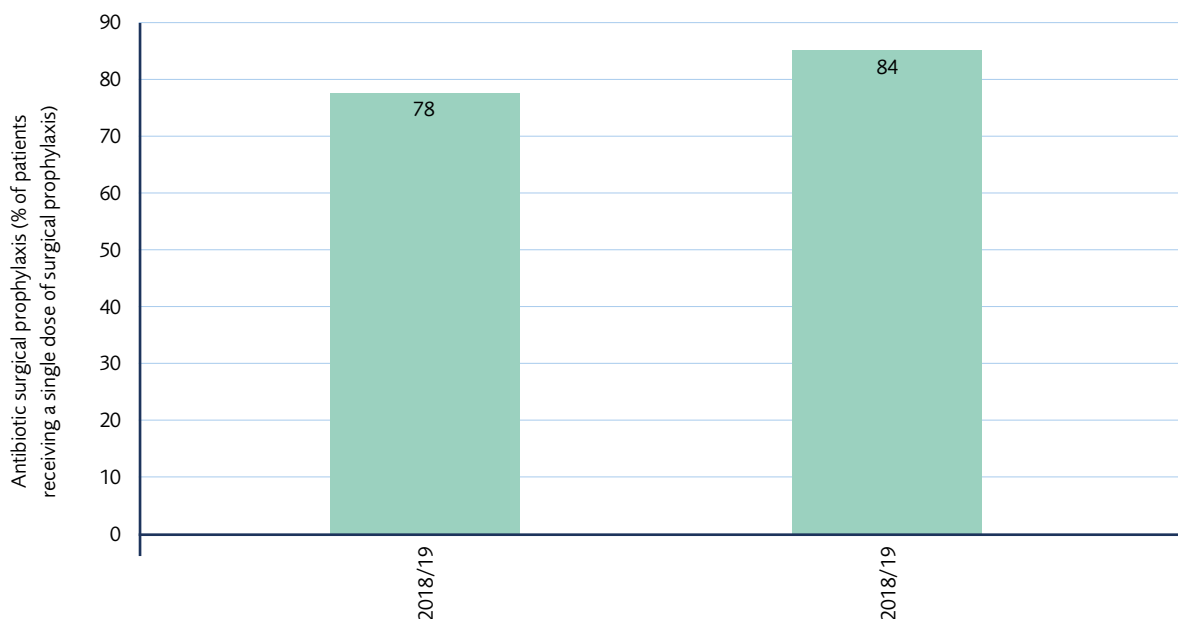


Antibiotic prophylaxis in colorectal surgery

Advice from national organisations, including Public Health Wales, Scottish Intercollegiate Guidelines Network (SIGN) and National Institute for Health and Care Excellence (NICE), recommends that antibiotic prophylaxis for surgical patients should be a single therapeutic dose of intravenous antibiotics in the majority of cases.

Data for this NPI show an increase in the proportion of patients receiving a single dose of antibiotics for surgical prophylaxis, in line with the aim of the NPI.

Antibiotic surgical prophylaxis



Our work this year – Prescribing monitoring and analysis *continued*

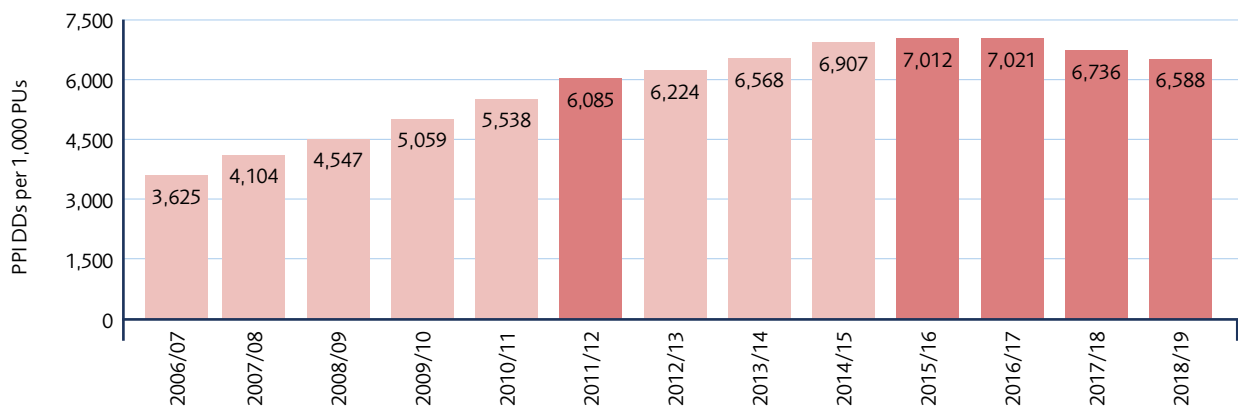
Efficiency

Proton pump inhibitors (PPIs)

Although PPIs are generally well tolerated, there is increasing evidence that long-term PPI use may be linked with an increased risk of adverse effects.

PPIs are monitored (using DDDs per 1,000 prescribing units [PUs]) with the aim of encouraging appropriate and cost-effective prescribing.

Prescribing of PPIs has decreased in the last two years, in line with the aim of the NPI.



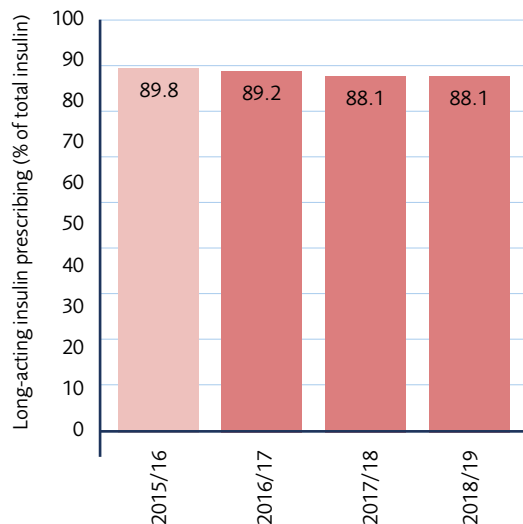
Insulin

This NPI aims to ensure long-acting analogue insulin prescribing in type 2 diabetes mellitus is in line with NICE guidance to maximise cost-effective prescribing within Wales.

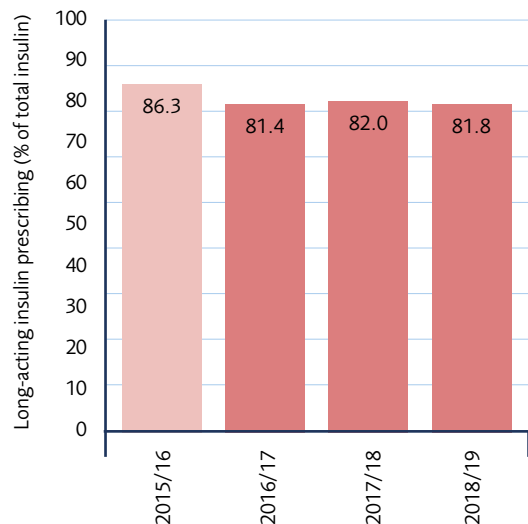
Figures for primary care prescribing are included here to capture ongoing prescribing that may have been initiated in secondary care.

Compared to the previous year, prescribing has remained static in primary care and decreased slightly in secondary care, in line with the aim of the NPI.

Insulin analogues Primary care



Insulin analogues Secondary care



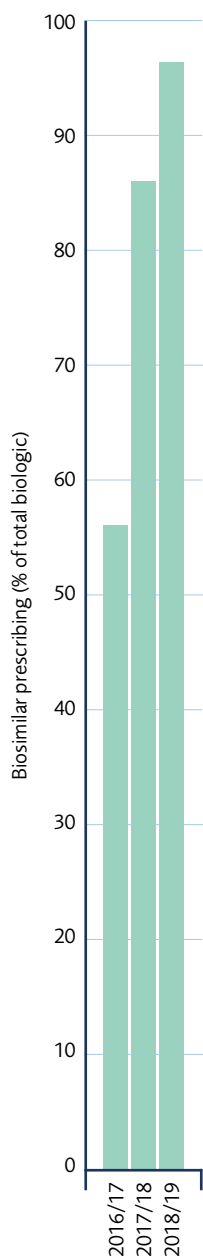
Biosimilars

The purpose of this NPI is to ensure prescribing of biosimilar medicines is in line with AWMSG guidance to support quality and cost-effective prescribing in Wales.

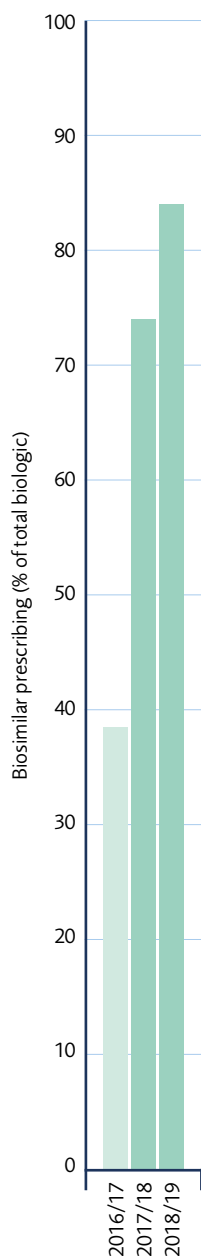
All five monitored biosimilars have shown an increase in prescribing as a percentage of total biologic medicine, in line with the aim of the NPI.

Figures for primary care prescribing are also included for those biologic medicines which show usage.

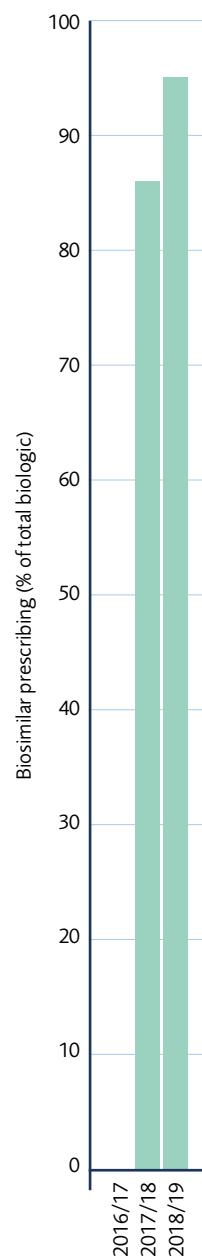
Infliximab



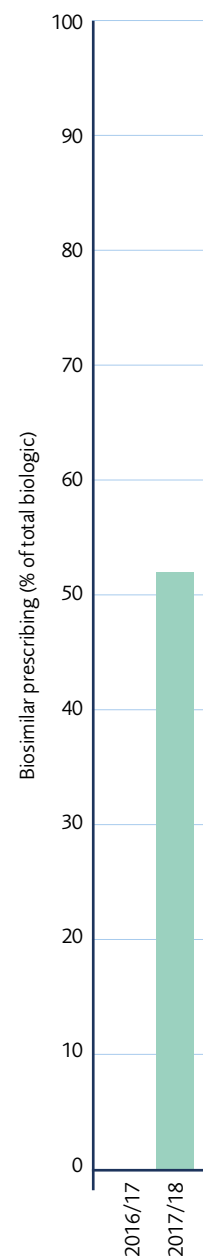
Etanercept



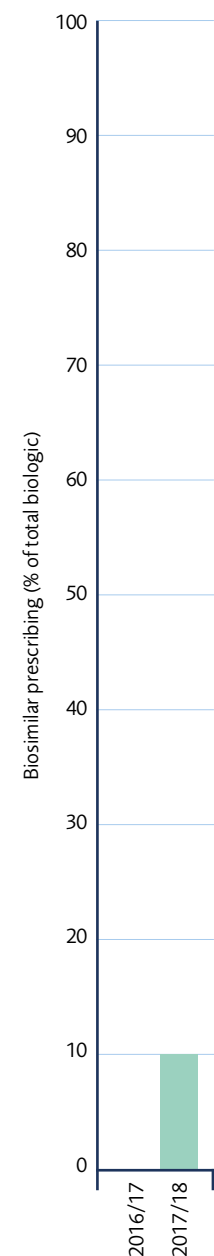
Rituximab



Trastuzumab



Adalimumab



Our work this year – Prescribing monitoring and analysis *continued*

Baseline data for the Prescribing Safety Indicators

The Prescribing Safety Indicator NPI was introduced in 2018–2019 and is monitored via Audit+. Historical data is not available for these indicators but March 2019 figures are provided below:

Prescribing Safety Indicator description		Data for Quarter ending March 2019
1	Number of patients with a peptic ulcer who have been prescribed NSAIDs without a PPI, as a percentage of all patients.	0.01%
2	Number of patients with asthma who have been prescribed a beta-blocker, as a percentage of all patients.	0.24%
3	Number of patients with concurrent prescriptions of verapamil and a beta-blocker, as a percentage of all patients.	0.01%
4	Number of female patients with a past medical history of venous or arterial thrombosis who have been prescribed combined hormonal contraceptives, as a percentage of all female patients.	0.01%
5	Number of female patients with a current prescription of oestrogen-only hormone replacement therapy without any hysterectomy READ/SNOMED codes, as a percentage of all female patients.	0.22%
6	Number of patients with concurrent prescriptions of warfarin and an oral NSAID, as a percentage of all patients.	0.01%
7	Number of patients under 12 with a current prescription of aspirin, as a percentage of all patients.	0.003%
8	Number of patients aged 65 years or over prescribed an NSAID plus aspirin and/or clopidogrel but without gastroprotection (PPI or H2 receptor antagonist), as a percentage of all patients aged 65 years or over.	0.12%
9	Number of patients aged 65 years or over prescribed an antipsychotic, as a percentage of all patients aged 65 years or over.	1.47%
10	Number of patients aged 75 and over with an Anticholinergic Effect on Cognition (AEC) score of 3 or more for items on active repeat, as a percentage of all patients aged 75 and over.	7.19%
11	Number of patients on the CKD register (CKD stage 3–5) who have received a repeat prescription for an NSAID within the last 3 months, as a percentage of all patients on the CKD register.	1.61%
12	Number of patients who are not on the CKD register but have an eGFR of < 59 ml/min and have received a repeat prescription for an NSAID within the last 3 months, as a percentage of all patients who are not on the CKD register but have an eGFR of < 59 ml/min.	2.70%

NPIs 2019–2020

The NPIs for 2019–2020 were endorsed by AWMSG at their February 2019 meeting along with the Supporting Information for Prescribers and Healthcare Professionals. These documents are available on the AWMSG website accompanied by an educational slide set.



Our work this year

– Health Technology Assessment

The All Wales Medicines Strategy Group (AWMSG) advises Welsh Government on whether new medicines should be made available for use in NHS Wales. New medicines are appraised against currently available medicines to compare:

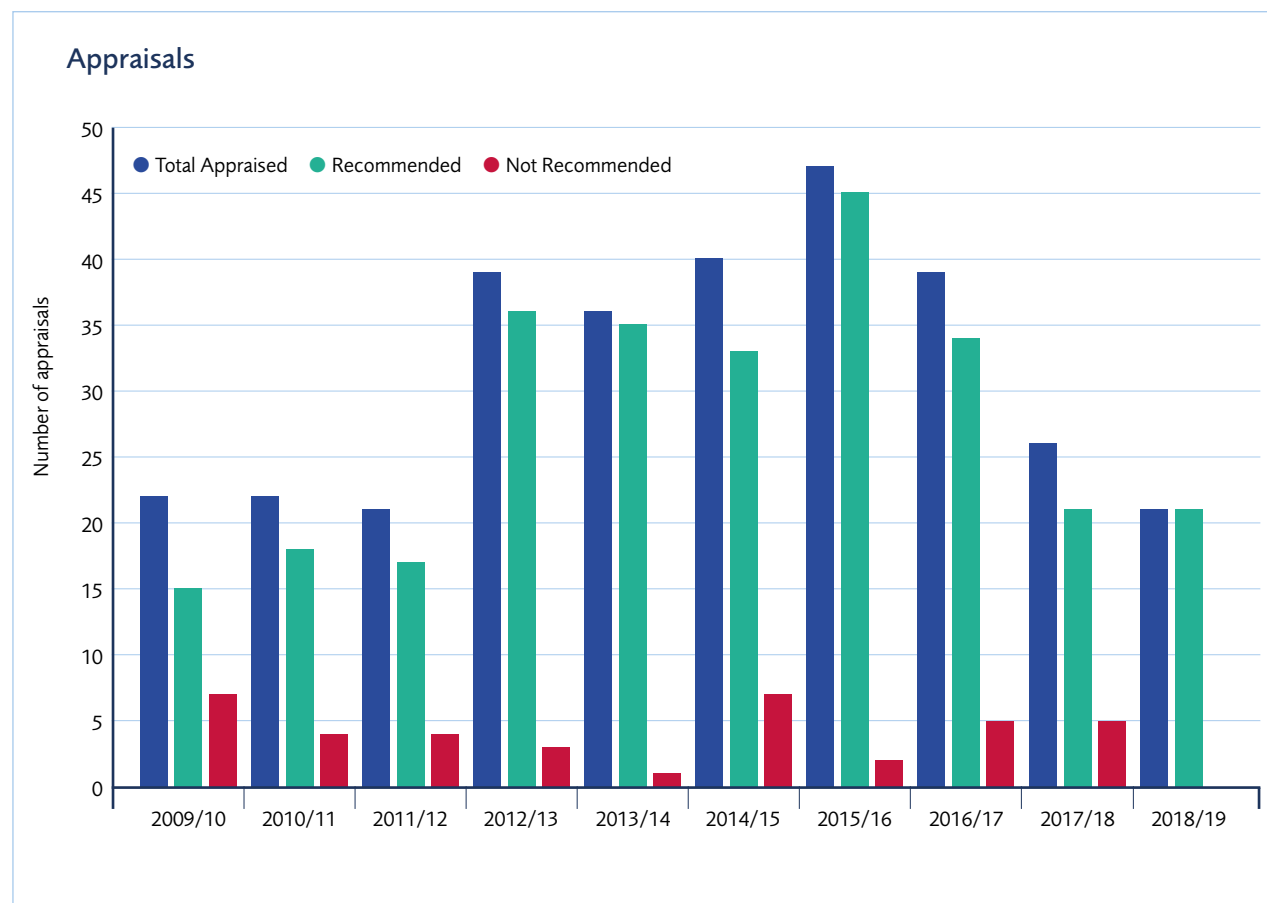
- ▶ how well they work in the real world (clinical effectiveness)
- ▶ how cost-effective they are
- ▶ which patients they would benefit the most.

Up to 31 March 2019, AWMSG has advised Welsh Government on 21 medicines, all of which received a positive recommendation and were made available within NHS Wales.

Advice issued in 2018–2019

Medicines appraisals	21
– Recommended	15
– Recommended for 'optimised' use*	6
– Not recommended	0
Statements of Advice issued on non-appraised medicines to NHS Wales	31
Total number of medicines on which advice provided to NHS Wales	52

*Medicine recommended for use in a smaller subset of patients than originally stated by the marketing authorisation. These medicines are also referred to in Wales as being recommended for 'restricted use'.

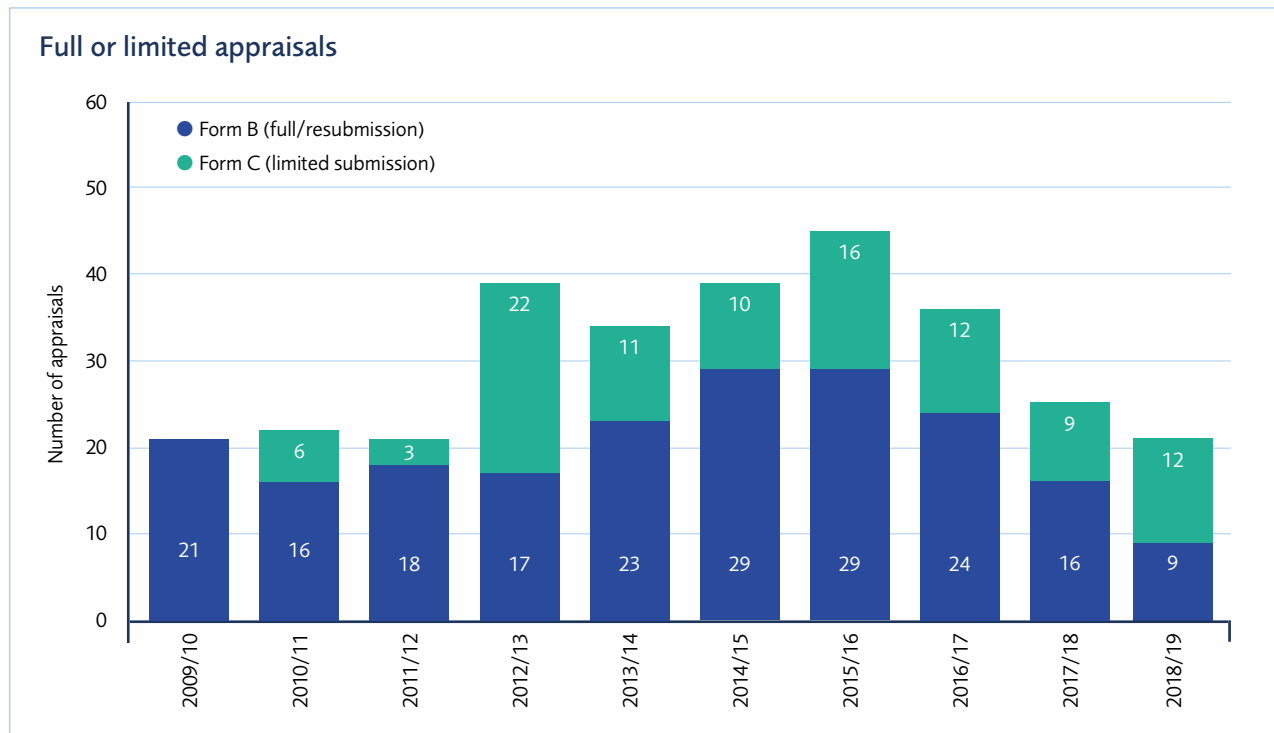


Our work this year – Health Technology Assessment *continued*

Limited submissions

A limited submission (Form C) may be appropriate for new formulations or minor licence extensions of existing products, where the anticipated usage in NHS Wales is considered to be of minor budget impact, or where estimated difference in cost compared with the

appropriate comparator(s) is small. The limited submission process has been associated with a significant increase in the number of appraisals since it was introduced in 2010–2011.



Wales Patient Access Scheme

A patient access scheme (PAS) enables the manufacturer of a medicine to offer a discount, rebate or variation on the list price. There are two types of scheme – simple discount and complex. Both types of scheme aim to improve the case for cost-effectiveness of a medicine and increase the chance of a positive appraisal recommendation.

In July 2010, AWMSG noted that the lack of a PAS process in Wales was leading to non-submission to AWMSG of medicines not on the NICE work programme and therefore delays in the availability of new treatments for patients in Wales. Therefore, the Patient Access Scheme Wales Group (PASWG) was established in October 2011. PASWG’s remit is to consider the feasibility and acceptability of Wales Patient Access Schemes (WPAS) within NHS Wales and to provide relevant advice to Welsh Government on these issues.

Schemes are approved if they are deemed clinically and financially robust, plausible, appropriate and

auditable. They must also be operationally manageable for NHS Wales; without unduly complex monitoring, disproportionate additional associated costs or bureaucracy. A “simple” scheme (e.g. a simple discount at one point of purchase) is the preferred option, and it applies to all licensed indications of the product. A “complex” or outcome-based scheme can be specific to a single indication; it is a scheme where the discount is not applied on the original invoice and an internal process/mechanism has to be implemented to allow potential cost avoidance to be realised (e.g. a dose-cap, rebate, free stock or outcome-based rebate).

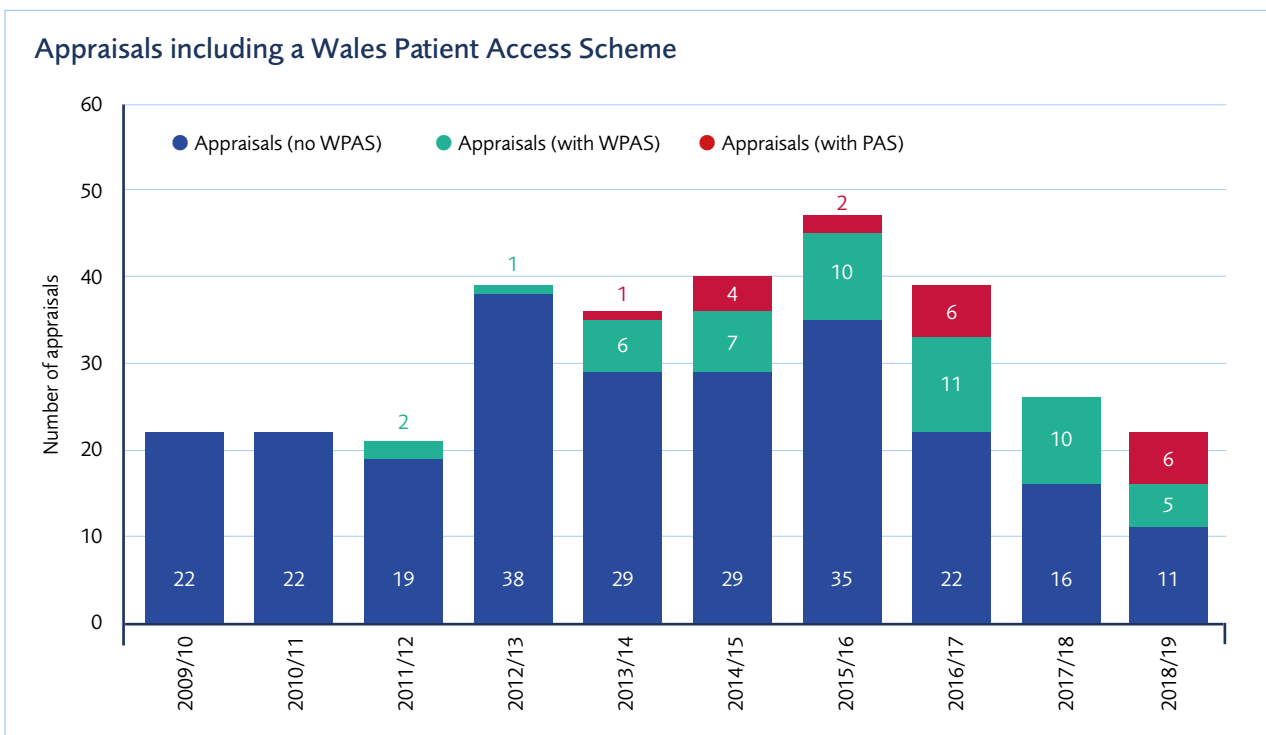
Some AWMSG-appraised medicines will incorporate a Department of Health-approved PAS which will have already been implemented in England and Wales for a previously approved NICE-appraised medicine.

Up to 31 March 2019, a total of 57 WPAS proposals were submitted for review. The largest proportion (72%)

of WPAS submissions have been for simple schemes (n=41), with 40 of these considered feasible to implement by PASWG and 1 resubmitted as a complex scheme. Up to 31 March 2019, 16 complex WPAS proposals were submitted, with 9 of these considered feasible for implementation by PASWG. Of the remaining 7 submissions, 3 were not considered feasible, and 4 were withdrawn (2 of which were resubmitted as simple schemes). The inclusion of a WPAS in the company

submission to the AWMMSG appraisal process has facilitated patient access to 43 medicines in Wales.

Ongoing review and development of the WPAS submission and implementation process, along with monitoring of schemes to ensure effective working and maximum financial return, is necessary to ensure the greatest efficiencies for NHS Wales, while still ensuring timely access to clinically effective and cost-effective medicines for patients (see page 11 for 'Invest to Save' project).



Membership

AWMSG

Post	Member	Deputy
Interim Chairman	Prof John Watkins	
Consultant in Public Health Medicine	Prof Stephen Monaghan	
Welsh Health Specialised Services Committee	Prof Iolo Doull	Dr Sian Lewis
Health Economist	Prof Dyfrig Hughes	Dr Pippa Anderson
Association of the British Pharmaceutical Industry (ABPI) Wales	Mr Rob Thomas	Mr Bill Malcolm Mr Farhan Mughal
Lay representative	Mr Cliff Jones	
Community Pharmacist	Mr Stefan Fec	Mr Ryan Dillon
Assistant Medical Director	Dr Mark Walker	
GP with prescribing lead role	Dr Jeremy Black	Dr Rebecca McGee
Senior Primary Care Pharmacist	Mrs Susan Murphy	Mrs Alison Hughes
Director of Finance	Mr Stuart Davies	Mr Hywel Purnell
Senior Hospital Pharmacist Representative	Mr John Terry	Mr Stuart Rees
Senior Nurse	Mrs Louise Williams	Mrs Mandy James
Other healthcare professionals eligible to prescribe not already represented	Dr Anwen Cope	Mrs Cathy Wynne Mr Aled Falvey
Clinical Pharmacologist	Dr Balwinder Bajaj	Dr John Thompson Dr Alison Thomas
Hospital Consultant	Dr Catherine Bale	

AWPAG

Post	Member	Health Board	Deputy
Chairman/Clinical Director of Pharmacy, Betsi Cadwaladr	Mrs Louise Howard-Baker		Dr Sue Jeffs Dr Laurence Gray
Doctor from each health board reflecting different roles			
Hospital Consultant	Dr Sue Jeffs	Aneurin Bevan	Dr Atir Khan (Hywel Dda) Dr David Pyle (Powys)
National Clinical Lead for Value Based Care	Dr Sally Lewis	All Wales	
General Practitioner	Dr Becky McGee	Aneurin Bevan	
General Practitioner	Dr Lisa Adams	Abertawe Bro Morgannwg	
Hospital Consultant/General Practitioner	Awaiting nomination	Betsi Cadwaladr	
Hospital Consultant/General Practitioner	Awaiting nomination	Cwm Taf	
Hospital Consultant	Dr Laurence Gray	Cardiff and Vale	
General Practitioner	Dr Richard Brown	Hywel Dda	
Hospital Consultant	Dr Anders Skarsten	Powys	
Hospital Consultant	Dr Craig Barrington	Velindre	
Pharmacist from each health board reflecting different roles			
Formulary and Interface Pharmacist	Mr Alan Clatworthy	Abertawe Bro Morgannwg	Awaiting nomination
Prescribing Advisor	Mr Mike Curson	Aneurin Bevan	Mr Hywel Jones
Hospital Head of Pharmacy	Mrs Louise Howard-Baker	Betsi Cadwaladr	Mr Ben Woodhouse
Prescribing Advisor	Ms Fiona Walker / Mrs Clare Clement	Cardiff & Vale	Ms Katie Morris/ Miss Karen May
Prescribing Advisor	Mrs Bev Woods	Cwm Taf	Miss Kate Spittle
Prescribing Advisor	Mrs Sarah Isaac / Mr Ross Davies	Hywel Dda	Mrs Sue Beach/ Mrs Jenny Pugh-Jones
Community Pharmacy	Mr Dylan Jones	Powys	Mr Steve Simmonds (Community)/ Mr Sudhir Sehwat (Community)
Chief Pharmacist	Mrs Bethan Tranter	Velindre	Mrs Sophie Harding/ Mr Usman Malik
Pharmacist	Ms Lynette James	Cardiff & Vale	
Lay member			
	Mrs Jane Barnard Mr David Barnard		Awaiting nomination
Healthcare professional eligible to prescribe			
	Mr Aled Falvey	Powys	Ms Cathy Wynne (Betsi Cadwaladr)
Nurse			
	Neil Thomas		Awaiting nomination
Public Health Wales			
	Ms Sian Evans		Awaiting nomination
Association of the British Pharmaceutical Industry (ABPI) Wales			
	Ms Robyn Miles		Miss Lee-Ann Farrell
Non-voting members			
Director ABPI Cymru Wales	Dr Rick Greville		
Director British Generic Manufacturers Association	Mr Paul Fleming		Mr Warwick Smith
Representatives from Welsh Government, AWTTTC and AWMSG may also attend as non-voting members			

NMG

Post	Member	Deputy
Chairman	Dr Saad Al-Ismael Dr James Coulson	
Vice Chairman	Mr Scott Pegler	
Pharmacist 1	Mr Brian Eadon Ms Suzanne Davies	Mr Usman Ali Malik Mrs Judith Green Mrs Teena Grenier
Pharmacist 2	Mrs Sue Beach	
Pharmacist 3	Mr Trevor Batt	
Doctor 1 Clinical Pharmacologist	Dr Alison Thomas Dr Emma Mason	Dr John Thompson Dr Manjeet Singh
Doctor 2 Hospital Consultant	Dr Satish Kumar	Dr Gareth Roberts Dr Ian Campbell
Doctor 3 General Practitioner	Dr David Whyler	Dr Avkash Das Jain
Professions allied to medicine or eligible to prescribe	Ms Cathy Wynne	Mr Aled Falvey
Public Health/Epidemiologist	Prof Stephen Monaghan Awaiting nomination	Awaiting nomination
Health Economist	Ms Philippa Anderson	Prof Deborah Fitzsimmons
Association of the British Pharmaceutical Industry (ABPI) Member	Mr Steven Lister Mr Sandeep Kiri Mr Alex Slowley	Attendance is rotated between the three named individuals
Welsh Health Specialised Services Committee	Dr Andrew Champion	Dr Sian Lewis
Lay Member	Mr Cliff Jones Mr Christopher Palmer	Mr Robert Henley
Nurse	Mr Neil Thomas	Dr Carolyn Middleton Mrs Susan Newport

Appendix 1. National Prescribing Indicators (NPIs) data 2002-2019

The table below shows the current NPIs and also the former NPI generic medicines as a percentage of all medicines. Underlined numbering indicates years in which the area was an NPI. Figures in the table are taken from the quarter ending March of each financial year, except Yellow Card figures, which show data for the full financial year. Figures show primary care prescribing, except where otherwise stated.

National Prescribing Indicators		2002-2003	2003-2004	2004-2005	2005-2006	2006-2007	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019																						
Generic medicines (% of items)		74	77	79	81	83	84	85	84	84	84	84	83	84	83	82	82	82																						
Prescribing Safety Indicators		See page 26																																						
Hypnotics and anxiolytics (ADOs/1,000 STAR-PU _s)		3,905																																						
Tramadol (DDD _s /1,000 patients)		741																																						
Opioid patches (as a % of opioids)		12.31																																						
Gabapentin and pregabalin (DDD _s per 1,000 patients)		116																																						
GP practices		627																																						
Secondary care		627																																						
Health boards		649																																						
Members of the public		290																																						
Community pharmacies		75																																						
Antibiotics (items/1,000 STAR-PU _s)		374																																						
4C items per 1,000 patients		340																																						
4C items as a percentage of total antibacterial items		17.7																																						
Antibiotic surgical prophylaxis in secondary care (% of patients receiving a single dose antimicrobial for surgical prophylaxis)		8.56																																						
Proton pump inhibitors (PPIs) (DDD _s /1,000 PU _s)		3,625			4,104			4,547			5,059			5,538			6,085			6,224			6,568			6,907			7,012			7,021			6,736			6,588		
Long-acting insulin prescribing (% of long and intermediate acting insulin)		89.8																																						
Biosimilar prescribing in secondary care (% of total biologic)		86.3																																						
Etanercept		38.3																																						
Infliximab		55.8																																						
Rituximab		0																																						
Trastuzumab		0																																						
Adalimumab		0																																						

Prescribing performance

Prescribing performance moving at odds with the aim of the indicator

Prescribing performance moving in line with the aim of the indicator

No change

4C = co-amoxiclav, cephalosporins, fluoroquinolones and clindamycin; PU = prescribing unit; DDD = defined daily dose; ADO = average daily quantity; STAR-PU = specific therapeutic group age-sex related prescribing unit.

* The measure for the Yellow Card indicator is number of reports submitted per practice and per health board, in addition to secondary care, members of the public and community pharmacies per health board. However, for consistency, the data shown here are for all Wales.

