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Cardiff and Vale UHB Biological Medicines Value Optimisation Policy

Policy Statement

To ensure the Health Board delivers its aims, objectives, responsibilities and legal requirements transparently and consistently, we will:

- Prescribe the best value brand of a biological medicine for all ‘new’ patients (i.e., those who have not previously received any brand of the specific biological medicine).
- Prescribe the best value brand of a biological medicine for ‘existing’ patients (those currently receiving a less cost-effective brand of the specific biological medicine) as better value brands become available, and we will not continue to prescribe less cost-effective brands of biological medicines to patients solely for reasons of patient preference.
- Inform patients that the brand of biological medicine they receive may change over time to ensure best value. We will communicate clearly and consistently to support patient understanding and confidence in treatment. We will always inform patients when a brand change is going to take place.
- Avoid prescribing a different brand of a specific biological medicine for a patient within 12 months of their last brand change.
- Not routinely revert to prescribing a less cost-effective brand if a patient experiences loss of disease control or adverse effects following a change of treatment to the best value brand.
- Not change brands of biological medicines at the point of dispensing (known as substitution)
- Always prescribe biological medicines by their brand name.

Policy Commitment

To maximise the value available from biological medicines across the organisation, while maintaining clinical standards and patient-centred care.

Supporting Procedures and Written Control Documents

This Policy describes the following:

- Use of brands of biological medicines

Other supporting documents are:

- UHB 389 Medicines Code

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Scope	
This policy applies to all of our staff in all locations including those with honorary contracts	
Equality Impact Assessment	An Equality Impact Assessment (EqIA) has been completed and this found there to no impact.
Health Impact Assessment	A Health Impact Assessment (HIA) has been and this found there to no impact.
Policy Approved by	Quality Committee
Group with authority to approve procedures written to explain how this policy will be implemented	Medicines Implementation and Governance Group
Accountable Executive or Clinical Board Director	Medical Director
<u>Disclaimer</u>	
If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate .	

Summary of reviews/amendments			
Version Number	Date Review Approved	Date Published	Summary of Amendments
1	Quality Committee on 03/03/2026	10/03/2026	<i>New Document</i>

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1. Purpose

This policy sets out a transparent and equitable approach to ensure the sustainable use of biological medicines across Cardiff and Vale University Health Board.

2. Scope

This policy applies to:

- All clinical specialties prescribing biological medicines.
- All patients who are receiving or for whom there is a plan to commence treatment with biological medicines.
- All clinicians, multidisciplinary teams (MDTs) and pharmacy team members involved in the prescribing and supply of biological medicines.

3. Definitions

3.1 Biological medicines

Biological medicines offer treatment options for patients with chronic and often disabling conditions such as diabetes, autoimmune disease and cancers.

These medicines contain active substances from a biological source, such as living cells or organisms (human, animals and microorganisms such as bacteria or yeast) and are often produced by cutting-edge technology.

Most biological medicines in current clinical use contain active substances made of proteins. These can differ in size and structural complexity, from simple proteins like insulin or growth hormone to more complex ones such as coagulation factors or monoclonal antibodies.

3.2 Reference product* (or originator product)

A biological medicine reference product (also known as an originator product) is the original biological medicine that was first granted marketing authorisation, serving as the basis for the approval of subsequent biosimilar medicinal products.

*This policy uses the term reference product.

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3.3 Biosimilar medicine

A biosimilar medicine is a highly similar copy of its reference product. Since it is not possible to replicate biological medicines exactly, a small degree of variation is expected and accepted so long as the biosimilar has no clinically meaningful differences from its reference product.

3.4 Interchangeability

Once authorised by the Medicines and Healthcare products Regulatory Agency (MHRA), a biosimilar product is considered to be interchangeable with its reference product, which means a prescriber can choose the biosimilar medicine over the reference product (or vice versa) and expect to achieve the same therapeutic effect.

Likewise, a biosimilar product is considered interchangeable with another biosimilar of the same reference product.

As a result of interchangeability, prescribing changeovers from one brand to another brand of a biological medicine (reference product or biosimilar) has become clinical practice. The decision rests with the prescriber in consultation with the patient, in line with the principles of shared decision making; both need to be aware of the brand name of the biological medicine prescribed.

3.5 Substitution

The practice of dispensing one medicine instead of another equivalent medicine at the pharmacy level without consulting the prescriber.

3.6 Nocebo effect

The nocebo effect is the opposite of the placebo effect. It describes a situation where a negative outcome occurs due to a belief that the intervention will cause harm.

For adverse reactions to medicines, nocebo implies that patients are more likely to experience an adverse effect if they expect or are worried about the adverse effect. The adverse effects may be physically experienced by the patient and are often clinically diagnosable. An example of the nocebo effect is the severe adverse effects experienced by patients taking a placebo during a clinical trial.

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The nocebo effect in relation to biosimilar medicines is defined as the development of negative, subjective, and non-pharmacological side effects or symptoms caused by a patient's negative expectations or anxieties, rather than the drug's actual, equivalent pharmacological action. It is a significant clinical challenge during brand changeovers that has the potential to cause treatment discontinuation, often triggered by misinformation or negative perceptions.

4. Responsibilities

Role	Responsible for:
Executive Medical Director	<p>(a) Supporting and championing the use of best value biological medicines within the UHB.</p> <p>(b) Ensuring that all prescribers within the UHB adhere to this policy.</p>
Clinical Board Triumvirate	<p>(a) Providing capacity to implement prescribing of best value biological medicines in clinical teams within their clinical board.</p> <p>(b) Supporting and championing the use of best value biological medicines within their clinical board.</p> <p>(b) Ensuring that all clinicians within their clinical board adhere to this policy.</p>
Director of Pharmacy & Medicines Management	<p>(a) Ensuring the cost-effective use of biosimilar medicines; and the governance framework for the use of these medicines.</p> <p>(b) Ensuring accurate high-cost drug data is supplied to finance for invoicing/cross charging.</p> <p>(c) Ensuring that Pharmacy team members adhere to this policy.</p>

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5. Policy Statements

5.1 We will prescribe the best value brand of a biological medicine for all 'new' patients (i.e., those who have not previously received any brand of the specific biological medicine).

In line with the All Wales Medicines Strategy Group document "*Maximising the opportunity presented by biosimilar medicines: A national strategy for Wales*", the best value brand of a biological medicine must be identified for use within a speciality.

The best value brand will be identified by an assessment undertaken by a multidisciplinary group that will include the following as a minimum: Speciality Clinical Lead, Directorate Pharmacist and Medicines Procurement Lead & Homecare Manager.

While acquisition cost will be a major factor in identifying the best value brand, other criteria will be included in the decision-making process:

- Brand product range, presentation (e.g., pre-filled syringe), and stability.
- The robustness of the manufacturer's supply chain.
- Consideration of homecare service provision, if applicable.
- The total cost of treatment, including delivery and administration costs.
- Any negative or positive effects on patient adherence to the medicine (consider patient factors)

There may be more than one best-value brand for a given indication within a specialty. If the lowest-cost brand is not available in all required pharmaceutical presentations, it cannot be considered the best-value option for patients who need a specific presentation to enable administration. For example, if Brand X has the lowest acquisition cost but is not available as a pre-filled pen, it is not the best-value brand for patients who require that presentation.

The availability of new brands and the loss of exclusivity of reference products must be included in horizon scanning activities undertaken by the pharmacy directorate and the prescribing advisory branch of the Primary and

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Community Integrated Care Board (PCIC). The likely impact of prescribing the best value brand must be factored into financial forecasting where contract prices and timelines for availability in Wales are able to be confirmed by NHS Wales Shared Services or the Medicines Value Unit (also based in Shared Services).

Existing Health Technology Appraisal advice for the reference products, published by the AWMSG or NICE, automatically apply to biosimilar brands of medicines licensed for the same indication as the reference product.

5.2 We will prescribe the best value brand of a biological medicine for ‘existing’ patients (those currently receiving a less cost-effective brand of the specific biological medicine) as better value brands become available, and we will not continue to prescribe less cost-effective brands of biological medicines to patients solely for reasons of patient preference.

The responsible prescriber, in consultation with the patient, will decide whether to initiate, continue, or change the brand of a biological medicine, taking into account clinical appropriateness, patient-specific factors, and the organisation’s formulary and commissioning arrangements. Biological medicines are prescribed by brand name; brand selection is guided by the organisation’s formulary and is not determined by patient preference.

Prescribing changeovers from one biological brand to another brand of the same biological (reference product or biosimilar) is established clinical practice.

There is no scientific rationale to expect different clinical outcomes when changing between brands of the same reference product and this is supported by real-world data. Biological medicines show a small degree of expected variation within their molecular structures. This occurs even between batches of the same product and is due to the variability of biological systems and manufacturing processes. Due to this variation, there is no reason to suspect that prescribing a different brand of a biological medicine would introduce more variability than the natural variation that occurs between batches of a reference product.

To ensure a robust implementation process for brand changeovers is followed in secondary care, the ‘Best Value Brand Implementation Checklist’ (Appendix II) must be followed. Prescribing brand changeovers originating in primary care must follow the ‘Medication Switches Standard Operating Procedure’.

No patient will be exempt from a prescribing changeover from a less cost-effective biological brand to the best value brand. In extreme circumstances, a

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changeover may be delayed by a maximum of 6 months only (12 months for pregnancy related requests) once approval from the CAV Biological Medicines Brand Oversight Group, a sub-group of the Medicines Implementation and Governance Group (MIGG), is provided. To request a delay to a brand changeover, a '[Biological Medicines — Exceptional Request to Defer Brand Changeover or Revert to an Alternative \(Non-Best-Value\) brand](#)' must be completed and sent to: Formulary.Enquiries.cav@wales.nhs.uk.

On expiry of the approved delay (6 months; 12 months for pregnancy-related requests), the prescribing team must implement the brand changeover to the current best-value brand for the next prescription, unless a new clinical contraindication has arisen. No further supplies of less cost-effective brand will be authorised following the expiry of the approved delay.

Where a new reason for a delay arises for the same patient, a new request (with supporting evidence) must be submitted to the CAV Biological Medicines Brand Oversight Group.

5.3 We will inform patients that the brand of biological medicine they receive may change over time to ensure best value. We will communicate clearly and consistently to support patient understanding and confidence in treatment. We will always inform patients when a brand change is going to take place.

From the date of policy implementation, we will provide information to patients:

- At initiation of treatment: All patients starting therapy with a biological medicine must be advised that brand changes are likely to occur during their treatment journey.
- For existing patients: Those already receiving biological medicines should be informed during routine care discussions, such as follow-up appointments or medication reviews.

We will provide key messages to patients:

- We must explain that brand changes are driven by cost-effectiveness and NHS sustainability, not by differences in quality or efficacy.
- We must reassure patients that all biosimilars undergo rigorous regulatory approval and are clinically equivalent to the reference product.
- We must use positive framing: emphasizing that switching supports wider patient access and NHS resource optimization.

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Adjustments for Protected Characteristics and Additional Support:

- Communication strategies must be adapted for patients with protected characteristics (e.g., disability, age, language barriers, cognitive impairment) to ensure understanding and reduce anxiety.
- Patients who may need the most support include those with mental health conditions (such as anxiety), learning disabilities, sensory impairments, or limited health literacy. These groups are at higher risk of experiencing the nocebo effect and should receive tailored explanations, accessible materials, and additional reassurance.

Documentation Requirements:

- Confirmation that this information has been provided must be recorded in the patient's clinical record.

All patients must be advised that a brand changeover is taking place and must be made aware of the name of the new brand they are to receive. The method of patient communication selected to inform the patient of the brand changeover will be decided in partnership between the clinical team and the relevant supporting pharmacy team.

Patients must be informed of the brand name they are receiving due to traceability and pharmacovigilance reporting purposes (many biosimilars carry a black triangle ▼) if there are any suspected safety issues relating to the reference products or biosimilar medicines.

A record of all communications with the patient about the brand changeovers must be retained within the patient record.

5.4 We will avoid prescribing a different brand of a biological medicine for a patient within 12 months of their last brand change.

To preserve patient stability in their treatment regimen and confidence, we will not look to change brands of specific biological medicines prescribed more frequently than every twelve months.

Where patients have changed brands by a separate health organisation in the prior 12 months prior to their treatment being taken over by a Cardiff and Vale UHB prescriber, they will be prescribed the best value biological medicine upon transition to Cardiff and Vale UHB.

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5.5 We will not routinely revert to prescribing a less cost-effective brand of a biological medicine if a patient experiences loss of disease control or adverse effects following a change to the best value brand.

Systematic reviews of brand changeovers, whether from reference products to biosimilars or between biosimilar brands have consistently shown no major loss of efficacy or increase in adverse events. [1-3]

If a patient's disease symptoms worsen, clinicians should include the following factors when assessing the likely cause:

Nocebo effect: Patient expectations or anxiety about changing brands may lead to perceived or real worsening of symptoms.

Natural disease fluctuation: symptom severity of some chronic conditions vary over time, independent of treatment changes.

In extreme circumstances, a clinician can request permission for a patient to revert to a less cost-effective brand of a biological medicine from the CAV Biological Medicines Brand Oversight Group. A ['Biological Medicines — Exceptional Request to Defer Brand Changeover or Revert to an Alternative \(Non-Best-Value\) brand'](#) must be completed and sent to: Formulary.Enquiries.cav@wales.nhs.uk.

5.6 We will not change brands of biological medicines at the point of dispensing (known as substitution)

Substitution – the practice of dispensing one medicine instead of another equivalent medicine at the pharmacy level without consulting the prescriber – is not permitted for biological medicines, including substitution between biosimilar medicines.

5.7 We will always prescribe biological medicines by their brand name

In line with MHRA guidance all biological medicines (including biosimilar medicines) must be prescribed by brand name.

In the post-authorisation phase as a result of manufacturing, product variability over time within and across products with similar active substances is possible. Therefore, a key requirement for pharmacovigilance of biosimilars is the need to ensure continuous product and batch traceability in clinical use to support detection of any important safety issues that may be product- or batch-specific.

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As biosimilar medicines often use the same international non-proprietary name (INN) as their reference product, an important way to ensure substitution does not take place is through brand name prescribing.

Brand name prescribing must be adhered to by all prescribers of biological medicines, including biosimilars, and is in line with recommendations from the MHRA and NICE.

6. Governance

6.1 Complaints/Concerns

Patients wishing to raise a concern about not being able to remain on their favoured brand of a particular biological medicine will be issued a standard response by the UHB Concerns team – Appendix III.

6.2 Medicines Formulary

Formulary requests for biological medicines will follow the [Formulary Application Procedure for New Medicines](#).

6.3 Pharmacovigilance

At market entry, all biosimilar medicines carry a black triangle ▼.

The black triangle signifies that there is **less information available** about its long-term safety, so any suspected adverse reactions should be reported, even if they are minor.

Suspected adverse drug reactions (ADRs) must be reported via the Yellow Card Scheme.

6.4 Financial monitoring

The implementation of biosimilar medicines will be monitored via Medicines Implementation and Governance Group (MIGG) and via the NHS Wales Value & Sustainability delivery group.

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7. References

1. Barbier L, Ebbers HC, Declerck P, et al. The efficacy, safety, and immunogenicity of switching between reference biopharmaceuticals and biosimilars: a systematic review. *Clin Pharmacol Ther.* 2020;108:734–755
2. Cohen HP, Blauvelt A, Rifkin RM, et al. Switching reference medicines to biosimilars: a systematic literature review of clinical outcomes. *Drugs.* 2018;78:463–478.
3. Cohen HP, Hachaichi S, Bodenmueller W, et al. Switching from One Biosimilar to Another Biosimilar of the Same Reference Biological: A Systematic Review of Studies. *BioDrugs.* 2022 Jul 26;36(5):625–637

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Appendix I: [Biological Medicines — Exceptional Request to Defer Brand Changeover or Revert to an Alternative \(Non-Best-Value\) Brand](#)

PART 1: DETAILS OF CLINICIAN SUBMITTING REQUEST

Details of Clinician making request <i>(must be the responsible prescriber for the biological medicine who is currently prescribing for the patient)</i>			
Name:			
Job Title:			
NHS Health Board, Trust or GP Practice:			
Correspondence address:			
Tel:			
Email:			
Secretary's Name:		Tel:	
Secretary's Email:			

PART 2: DETAILS OF PATIENT

Details of Patient			
Forename:		Surname:	
Address: <i>(including postcode)</i>		Postcode:	
NHS Number:			
Date of Birth: <i>(dd/mm/yy)</i>		M or F:	
Registered GP or GDP Name and Practice:			

PART 3: URGENCY

How urgent is the request and why? <i>(tick as applicable)</i>	Urgent: 24 – 48 hours	Soon: within 3 wks	Non-urgent: 4 – 6 wks

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<p>If the request is urgent or soon clinical reasons must be provided. Administrative reasons will not be considered.</p>	
Points to Consider	<ul style="list-style-type: none"> Applies to working days only (not weekends or bank holidays). If application is 'urgent' contact department before submitting application to notify them that an application will be sent in.

PART 4: DIAGNOSIS AND PATIENT'S CURRENT CONDITION RELATED TO REQUEST

Diagnosis:					
Has this been discussed by the MDT?	YES		No		If Yes, please provide a copy of the minutes to support the discussion
Relevant Medical History:					
Please summarise the current status of the patient in terms of quality of life, symptoms etc:					

PART 5: BIOLOGICAL MEDICINE AND BRAND DETAILS

Name of biological medicine	
Name of brand currently receiving	
Name of best value brand for this indication	

PART 6: JUSTIFICATION FOR DELAY OF BRAND CHANGEOVER / OR REQUEST TO REVERT TO LESS COST-EFFECTIVE

Provide a concise summary of the justification for delaying the brand changeover or reverting to less cost-effective brand	
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Appendix II: Best Value Biologic Implementation Checklist

Clinical Board: _____ Best Value Biologic Brand: _____

Phase 1: Pre-All Wales Secondary Care Contract Award					
No.	Task/Action	Person/Team Responsible	In Progress (Date)	Comments/Updates/Decisions	Completed (Date)
1	Identify and appoint a dedicated implementation lead and consultant clinical champion (can be other HCP profession if felt appropriate by team).				
2	Engage and seek input from across all clinical specialties within the board where the originator is currently used.				
3	Identify number of patients currently being treated with the current brand used and how they are supplied (e.g. homecare, hospital pharmacy, OPD, WP10HP).				
4	Identify number of patients initiated on the current brand each month				
5	Review and agree which patients will be eligible for the new biosimilar and				

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	which will require completion of “Biological Medicines — Exceptional Request to Defer Brand Changeover or Revert to an Alternative (Non–Best-Value) Brand”				
6	Liaise with homecare providers to understand their processes for managing the prescribing changeover (whether you plan to stay with current provider or move providers).	Pharmacy Procurement Lead & Homecare manager			
7	Consider how patients will be informed about the change in prescribing. Use template letters if available and supporting materials if available (SPS, AWTTTC, WMAS). Provision must be made to identify patients who will need additional support and tailored communication as per section 5.3 of policy.				
8	Prepare patient information and agree how this will be distributed.				
9	Manage stock of current brand held in hospital pharmacy				
10	Review SPS guidance and available information (contact NWSSP Medicines Procurement) on biosimilars being launched				

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Phase 2: Post- All Wales Secondary Care Contract Award – Pre-Contract Availability Start date					
No.	Task/Action	Person/Team Responsible	In Progress (Date)	Comments/Updates/Decisions	Completed (Date)
1	Review Contract award documentation to understand prices and presentations offered by each supplier.				
2a	Clinical teams to agree on chosen brand (consider cost, formulation, presentation, QA assessment, supply route)				
2b	Agree whether prescribing changeover will happen at the same time for all indications or specific indications.				
3	For homecare patients, consider whether bundled or unbundled services will be most appropriate and cost effective.				
4	Contact (NWSSP) All Wales procurement to notify them of patient numbers and confirm they have capacity (and can supply from anticipated switch date).				
5a	Inform chosen homecare provider of decision and agree mechanism and timeline for the prescribing changeover				

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	ensuring minimal delay based on delivery frequencies (request exit data if moving providers).				
5b	Ensure service level agreement with homecare provider is in place.				
6	Engage with patients ahead of the switch by informing them of potential changes to their medication and/or home care services to maintain patient trust. Provide additional support and tailored communication to patients (as per section 5.3 of policy) who have been identified as requiring this.				
7a	Ensure brand is available on the CAV drug formulary				
7b	Ensure brand is available on pharmacy systems (including for homecare and OPDs if required)				
8	Ensure stock and drug files for current brand are managed to run down existing stock				
9	Communicate appropriately with all stakeholders (clinical teams, pharmacy teams, OPDs etc) so that they are aware of the change in product and commencement date.				

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Phase 3: Post-Contract Availability Start date					
No.	Task/Action	Person/Team Responsible	In Progress (Date)	Comments/Updates/Decisions	Completed (Date)
1	Order stock of best value brand presentations into hospital pharmacy or outpatient providers if required.				
2	Manage drug files on pharmacy systems to reduce/remove minimum reorder levels if appropriate				
3	Work with homecare providers and clinical teams to progress brand prescribing changeover to agreed mechanism and timelines				
4	Monitor patients for adverse events and ensure regular follow up				
5	Report to clinicians, finance and Pharmacy Director about the ongoing brand changeover progress				

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Appendix III: The brand of your medicine is changing

We want to let you know that the brand of your medicine – **[name of biological medicine]** – will be changing to a biosimilar called **[name of biosimilar]**.

What is happening?

- We're letting you know the new brand name on your medicine box. You should not notice any difference. It works the same and is just as safe and effective as your previous brand.
- Your hospital doctor has agreed that you can be prescribed a biosimilar (new brand) of your medicine.
- The new brand will be delivered by a different **homecare service provider** – will be changing from **[former homecare provider]** to **[new homecare provider]**
- You will continue to receive the same care from your doctor, nurse, or pharmacist.

Why is this happening?

- The NHS in Wales needs to reduce spending.
- The Welsh Government has asked Health Boards to save money in ways that do not harm patient care.
- One way to do this is to use biosimilars instead of costly original brands, as they work just as well.

What is a biosimilar medicine?

- Biosimilars are carefully checked by experts before they are used.
- In the UK, the **MHRA** (the medicines regulator) confirms that biosimilars are **just as safe and effective** as the original medicine.
- They work the same way in your body.
- They may look different, but they do the same job.
- They cost less for the NHS.

Why this matters

- Switching to biosimilars saves the NHS in Wales **millions of pounds every year**.
- This helps the NHS spend money on other important care.

We understand

- We know you might feel unsure about this change.
- Please be reassured: your new medicine is still the right one for your condition.
- **Patient safety and good treatment remain our top priorities.**

What will happen next

- **[To be completed by clinic]**
- To include reference to nursing assistance with training on the new device

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Have Questions?

If you have questions, please contact us:

- **[Exact name clinic managing care] – Clinic Contact number**

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Appendix IV: Your Medicine Has Changed (Concerns team response)

Thank you for contacting the **Concerns Team**.

We want to explain why your medicine has changed to a **biosimilar**.

What is happening?

- Your hospital doctor has agreed to you being prescribed a biosimilar version of your medicine.
- You will still get the same care from your doctor, nurse, or pharmacist. We will make sure the new medicine works well for you.

Why is this happening?

- The NHS in Wales is spending too much money.
- The Welsh Government has asked Health Boards to save money in ways that do not harm patient care.
- One way to save money is to stop using costly brands biologic medicines when a biosimilar is just as good

What is a biosimilar medicine?

- Experts check biosimilar medicines very carefully before anyone uses them. In the UK, the MHRA (a group that makes sure medicines are safe) says biosimilars are just as good as the original ones.
- It works the same way in your body.
- It is safe and effective.
- It may look different, but it does the same job.
- It costs less money for the NHS.

Why this matters

- Changing to biosimilars saves the NHS in Wales millions of pounds every year.
- This helps the NHS spend money on other important care.

We understand

- We know you might feel unsure about this change.
- But we want to reassure you: your new medicine is still the right one for your condition.
- Patient safety and good treatment are still our top priorities.

Thank you

We are sorry if this change has caused any worry.

Thank you for understanding

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Equality & Health Impact Assessment for

Cardiff and Vale UHB Biological Medicines Value Optimisation Policy

Please read the Guidance Notes in Appendix 1 prior to commencing this Assessment

Please note:

1. The completed Equality & Health Impact Assessment (EHIA) must be
 1. Included as an appendix with the cover report when the strategy, policy, plan, procedure and/or service change is submitted for approval
 2. Published on the UHB intranet and internet pages as part of the consultation (if applicable) and once agreed.
2. Formal consultation must be undertaken, as required¹
3. Appendices 1-3 must be deleted prior to submission for approval

Please answer all questions:-

	For service change, provide the title of the Project Outline Document or Business Case and Reference Number	Not applicable
	Name of Clinical Board / Corporate Directorate and title of lead member of staff, including contact details	Clinical Diagnostics & Therapeutics Directorate: Pharmacy & Medicines Management Lead author: David McRae Contact details: David.mcrae@wales.nhs.uk

¹http://nww.cardiffandvale.wales.nhs.uk/portal/page?_pageid=253,73860407,253_73860411&_dad=portal&_schema=PORTAL

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	<p>Objectives of strategy/ policy/ plan/ procedure/ service</p>	<ol style="list-style-type: none"> 1. Establish a clear, equitable, and sustainable approach for the use of biological medicines across Cardiff and Vale UHB. 2. Maximise value from biological medicines while maintaining clinical standards and patient-centred care. 3. Ensure cost-effectiveness by prescribing the best value brand for: <ul style="list-style-type: none"> • New patients (those not previously on a biological medicine). • Existing patients (switching from less cost-effective brands as better value options become available). 4. Promote transparency and consistency in prescribing decisions and implementation. 5. Support shared decision-making by informing patients about potential brand changes and ensuring traceability for pharmacovigilance. 6. Prevent unnecessary variability by: <ul style="list-style-type: none"> • Avoiding frequent brand changes (minimum 12-month interval). • Prohibiting substitution at the point of dispensing. • Mandating brand name prescribing for all biological medicines. • Align with national strategy (AWMSG guidance) and regulatory requirements (MHRA, NICE).
	<p>Evidence and background information considered. For example</p> <ol style="list-style-type: none"> 1. population data 2. staff and service users data, as applicable 3. needs assessment 4. engagement and involvement findings 5. research 6. good practice guidelines 7. participant knowledge 8. list of stakeholders and how stakeholders have engaged in the development stages 	<p>Good Practice Guidance:</p> <p>Understanding biological and biosimilar medicines – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice</p>

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	<p>9. comments from those involved in the designing and development stages</p> <p>Population pyramids are available from Public Health Wales Observatory² and the UHB's 'Shaping Our Future Wellbeing' Strategy provides an overview of health need³.</p>	
	<p>Who will be affected by the policy</p>	<p>This policy applies to all of our staff in all locations including those with honorary contracts.</p> <p>This policy applies to all patients being treated with biological medicines.</p>

² <http://nww2.nphs.wales.nhs.uk:8080/PubHObservatoryProjDocs.nsf>

³ <http://www.cardiffandvaleuhb.wales.nhs.uk/the-challenges-we-face>

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11. EQIA / How will the strategy, policy, plan, procedure and/or service impact on people?

Questions in this section relate to the impact on people on the basis of their 'protected characteristics'. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
6.1 Age For most purposes, the main categories are: <ol style="list-style-type: none"> 1. under 18; 2. between 18 and 65; and 3. over 65 	Older adults (>65): Higher rates of frailty, dexterity/vision challenges and polypharmacy may make device changes harder, increase error risk, or heighten anxiety about brand change.	Older adults: large-print materials, and check of dexterity/vision screening before switch; offer home visits or video support for those with mobility issues. Already part of clinic and homecare offerings.	Section 5.3
6.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes	Sensory loss (hearing/vision): Risk of inaccessible letters, missed deliveries, or device misuse without adapted training. Learning disability/neurodiversity:	Apply All-Wales Accessible Communication Standards: provide BSL, braille, audio, large print, easy-read, and communication passports as needed; record the format in patient record. Additional support and communication required.	Section 5.3

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How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
	<p>Anxiety and nocebo risk; difficulties understanding switch rationale or device steps.</p> <p>Mental health: Heightened switch anxiety; potential adherence drop after changeover.</p>	<p>Simple and reassuring phrasing in all patient conversations/materials required.</p>	
<p>6.3 People of different genders: Consider men, women, people undergoing gender reassignment</p> <p>NB Gender-reassignment is anyone who proposes to, starts, is going through or who has completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender</p>	<p>No negative or positive impacts identified</p>		

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How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
6.4 People who are married or who have a civil partner.	No negative or positive impacts identified.		
6.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding. They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	Pregnancy and breastfeeding can heighten anxiety; clinicians may prefer stability during perinatal periods.	Use the exceptional 12-month delay pathway for pregnancy-related requests; set timed review with automatic changeover on expiry unless contraindicated.	Section 5.2: operationalise 12-month delay and timed review.
6.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies/travellers, migrant workers	Language barriers can lead to misunderstanding, or non-adherence; travelling communities may need flexible delivery points. Not a risk introduced by policy.	Provide translated letters and telephone interpreting, record language preference in patient record. No mitigation for the need for flexible delivery points.	Section 5.3
6.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief	No negative or positive impacts identified	Provide product excipients/source information where relevant. Standard Clinical Practice	

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How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
6.8 People who are attracted to other people of: <ol style="list-style-type: none"> 1. the opposite sex (heterosexual); 2. the same sex (lesbian or gay); 3. both sexes (bisexual) 	No negative or positive impacts identified		
6.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design Well-being Goal – A Wales of vibrant culture and thriving Welsh language	English-only materials reduce understanding and trust; lack of Active Offer may disadvantage Welsh speakers.	Provide bilingual letters/leaflets and an Active Offer for Welsh; publish easy-read versions in Welsh; audit parity of response times and access.	Section 5.3 Appendix III and switch letters to be bilingual (Welsh).
6.10 People according to their income related group: Consider people on low income, economically inactive, unemployed/workless, people who are unable to work due to ill-health	No negative or positive impacts identified		

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How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
6.11 People according to where they live: Consider people living in areas known to exhibit poor economic and/or health indicators, people unable to access services and facilities	No negative or positive impacts identified		
6.12 Consider any other groups and risk factors relevant to this strategy, policy, plan, procedure and/or service	Low health literacy	Additional communication and reassurance required.	5.3

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4. HIA / How will the strategy, policy, plan, procedure and/or service impact on the health and well-being of our population and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people and on the impact on our population. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
<p>7.1 People being able to access the service offered: Consider access for those living in areas of deprivation and/or those experiencing health inequalities</p> <p>Well-being Goal - A more equal Wales</p>	<p>Using best-value biological medicines typically expands access by freeing resources and stabilising supply, while brand-name prescribing and planned switch governance protect safety. The main risks to access (communication barriers, device changes, and provider transitions) are manageable with the actions embedded in the policy.</p>		<p>Section 5.3</p>
<p>7.2 People being able to improve /maintain healthy lifestyles: Consider the impact on healthy lifestyles, including healthy eating, being active, no smoking /smoking cessation, reducing the harm caused by alcohol and /or non-prescribed drugs plus</p>	<p>No negative or positive impacts identified</p>		

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How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
<p>access to services that support disease prevention (eg immunisation and vaccination, falls prevention). Also consider impact on access to supportive services including smoking cessation services, weight management services etc</p> <p>Well-being Goal – A healthier Wales</p>			
<p>7.3 People in terms of their income and employment status: Consider the impact on the availability and accessibility of work, paid/ unpaid employment, wage levels, job security, working conditions</p> <p>Well-being Goal – A prosperous Wales</p>	<p>No negative or positive impacts identified</p>		
<p>7.4 People in terms of their use of the physical environment:</p>	<p>No negative or positive impacts identified</p>		

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How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
<p>Consider the impact on the availability and accessibility of transport, healthy food, leisure activities, green spaces; of the design of the built environment on the physical and mental health of patients, staff and visitors; on air quality, exposure to pollutants; safety of neighbourhoods, exposure to crime; road safety and preventing injuries/accidents; quality and safety of play areas and open spaces</p> <p>Well-being Goal – A resilient Wales</p>			
<p>7.5 People in terms of social and community influences on their health: Consider the impact on family organisation and roles; social support and social networks; neighbourliness and sense of belonging; social isolation; peer</p>	<p>No negative or positive impacts identified</p>		

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How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
<p>pressure; community identity; cultural and spiritual ethos</p> <p>Well-being Goal – A Wales of cohesive communities</p>			
<p>7.6 People in terms of macro-economic, environmental and sustainability factors: Consider the impact of government policies; gross domestic product; economic development; biological diversity; climate</p> <p>Well-being Goal – A globally responsible Wales</p>	<p>The policy should have a net positive impact on macro-economic, environmental and sustainability factors—by releasing cash for care, strengthening supply resilience, and aligning procurement and delivery with Net Zero and Well-being of Future Generations (Wales) Act duties. The main risks is supply-chain concentration.</p>	<p>Supplier concentration: A “best-value first” model could narrow supplier diversity if not balanced with open frameworks and clear supplier roadmaps. NWSSP are responsible for ensuring supplier diversity, so outside the scope of the policy.</p>	

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Please answer question 8.1 following the completion of the EHA and complete the action plan

<p>1. Please summarise the potential positive and/or negative impacts of the strategy, policy, plan or service</p>	<p>Overall, the net impact is positive if the policy is implemented as written: it should improve value, standardise safe practice, and support equitable access, while recognising and mitigating foreseeable risks around patient experience, device/presentation needs, homecare transitions, and supplier concentration.</p> <p>Potential positive impacts</p> <ul style="list-style-type: none"> • Better value and service sustainability Best-value first prescribing for new and existing patients is expected to release savings for care, supported by structured horizon scanning and multi-criteria brand selection (cost, presentations, stability, supply robustness, homecare) to avoid false economies. • Consistency and safety in practice Mandating brand-name prescribing, prohibiting dispensing substitution, and keeping a minimum 12-month interval between brand changes reduces unintended variation and supports continuity of care. • Stronger pharmacovigilance & traceability Brand-name prescribing, explicit recording of brand changes, and Yellow Card reporting for black-triangle biosimilars enhance batch/brand traceability and safety monitoring. • Evidence-based brand changes Cites systematic reviews showing no meaningful loss of efficacy/safety on switching; embeds a governance pathway for planned brand changeovers rather than ad-hoc substitution. • Clear governance and oversight Use of an Implementation Checklist (Appendix II), and an Oversight Group
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	<p>to manage exceptional delays (6 months; 12 months for pregnancy) provide transparent, auditable decision-making.</p> <ul style="list-style-type: none"> • Patient communication & involvement Standard patient letters (Appendix III/IV), shared-decision statements, recorded communications and support for understanding and adherence. • Equity and Welsh-language commitments The EHIA builds in actions for accessible formats, support for sensory loss, learning disability, and pregnancy. • Alignment with national guidance Aligns with AWMSG/NICE positions on biosimilars and the requirement to prescribe biologics by brand; sets out local formulary processes and financial/benefits monitoring via MIGG and Value & Sustainability. <p>Potential negative impacts / risks</p> <ul style="list-style-type: none"> • Patient experience & adherence risks Anxiety about switching and nocebo effects may reduce confidence and adherence without careful communication and follow-up. The policy acknowledges and mitigates this but the risk remains. • Operational risk during homecare transitions Switching brands and, in some cases, changing homecare provider carry onboarding/delivery risks (missed deliveries, data errors) that could briefly interrupt supply if not closely managed. • Equity risks if mitigations lapse Without consistent application of accessible formats and tailored communication and support including: translation/interpreting, device training, for people with sensory loss, limited literacy and health literacy, non-English/Welsh language needs may face barriers.
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	<ul style="list-style-type: none"> • Supplier concentration Focusing on a single best-value option could narrow supplier diversity over time; the EHIA flags this as a macro-economic risk requiring NWSSP procurement controls. • Expectation management A clear statement that patient preference alone does not determine brand choice may generate complaints if communication is not handled sensitively and consistently. <p>Built-in mitigations (already in the policy/EHIA)</p> <ul style="list-style-type: none"> • Support for patients most in need: requirement to support citizens with protected characteristics and those most likely to require additional reassurance and communication. • Exceptional delay pathway: up to 6 months (or 12 months in pregnancy), with Oversight Group approval and automatic changeover at expiry unless contraindicated, balancing governance with individual circumstances. • Horizon scanning & selection criteria: consider cost, presentation range, supply chain robustness, homecare service provision and total cost of treatment—reducing the chance of picking a brand that undermines usability or supply. • Monitoring & accountability: progress and finances monitored via MIGG and Value & Sustainability; communications recorded in the patient record; pharmacovigilance via Yellow Card.
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Action Plan for Mitigation / Improvement and Implementation

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	Action	Lead	Timescale	Action taken by Clinical Board / Corporate Directorate
<p>2. What are the key actions identified as a result of completing the EHIA?</p>	Additional and tailored communication required for patients with certain protected characteristics and those most likely to experience the nocebo effect.	DM	Complete	5.3
<p>3. Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment required?</p> <p>This means thinking about relevance and proportionality to the Equality Act and asking: is the impact significant enough that a more formal and full consultation is required?</p>	No			

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<p>4. What are the next steps?</p> <p>Some suggestions:-</p> <ol style="list-style-type: none"> 1. Decide whether the strategy, policy, plan, procedure and/or service proposal: <ol style="list-style-type: none"> 1. continues unchanged as there are no significant negative impacts 2. adjusts to account for the negative impacts 3. continues despite potential for adverse impact or missed opportunities to advance equality (set out the justifications for doing so) 4. stops. 1. Have your strategy, policy, plan, procedure and/or service proposal approved 2. Publish your report of this impact assessment 3. Monitor and review 	<p>Policy to proceed unchanged.</p>			
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Appendix 1

Equality & Health Impact Assessment

Developing strategies, policies, plans and services that reflect our Mission of 'Caring for People, Keeping People Well'

Guidance

The University Health Board's (the UHB's) Strategy 'Shaping Our Future Wellbeing' (2015-2025) outlines how we will meet the health and care needs of our population, working with key partner organisations to deliver services that reflect the UHB's values. Our population has varied and diverse needs with some of our communities and population groups requiring additional consideration and support. With this in mind, when developing or reviewing any strategies, policies, plans, procedures or services it will be required that the following issues are explicitly included and addressed from the outset:-

1. Equitable access to services
2. Service delivery that addresses health inequalities
3. Sustainability and how the UHB is meeting the requirements of the Well-being of Future Generations (Wales) Act (2015)⁴

This explicit consideration of the above will apply to strategies (e.g. Shaping Our Future Strategy, Estates Strategy), policies (e.g. catering policies, procurement policies), plans (e.g. Clinical Board operational plans, Diabetes Delivery Plan), procedures (for example Varicella Zoster - chickenpox/shingles - Infection Control Procedure) and services /activity (e.g. developing new clinical services, setting up a weight management service).

Considering and completing the Equality & Health Impact Assessment (EHIA) in parallel with development stages will ensure that all UHB strategies, policies, plans, procedures or services comply with relevant statutory obligations and responsibilities and at the same time takes forward the UHB's Vision, 'a person's chance of leading a healthy life is the same wherever they live and whoever they are'. This process should be proportionate but still provide helpful and robust information to support decision making. Where a more detailed consideration of an issue is required, the EHIA will identify if there is a need for a full impact assessment.

Some key statutory/mandatory requirements that strategies, policies, plans, procedures and services must reflect include:

⁴ <http://thewaleswewant.co.uk/about/well-being-future-generations-wales-act-2015>

1. All Wales Standards for Communication and Information for People with Sensory Loss (2014)⁵
1. Equality Act 2010⁶
2. Well-being of Future Generations (Wales) Act 2015⁷
3. Social Services and Well-being (Wales) Act 2015⁸
4. Health Impact Assessment (non statutory but good practice)⁹
5. The Human Rights Act 1998¹⁰
6. United Nations Convention on the Rights of the Child 1989¹¹
7. United Nations Convention on Rights of Persons with Disabilities 2009¹²
8. United Nations Principles for Older Persons 1991¹³
9. Welsh Health Circular (2015) NHS Wales Infrastructure Investment Guidance¹⁴
10. Welsh Government Health & Care Standards 2015¹⁵
11. Welsh Language (Wales) Measure 2011¹⁶

This EHIA allows us to meet the requirements of the above as part of an integrated impact assessment method that brings together Equality Impact Assessment (EQIA) and Health Impact Assessment (HIA). A number of statutory /mandatory requirements will need to be included and failure to comply with these requirements, or demonstrate due regard, can expose the UHB to legal challenge or other forms of reproach. This means showing due regard to the need to:

1. eliminate unlawful discrimination, harassment and victimisation;
2. advance equality of opportunity between different groups; and
3. foster good relations between different groups.

EQIAs assess whether a proposed policy, procedure, service change or plan will affect people differently on the basis of their 'protected characteristics' (ie their age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion, sex or sexual orientation) and if it will affect their human rights. It also takes account of caring responsibilities and Welsh Language issues.

⁵ <http://gov.wales/topics/health/publications/health/guidance/standards/?lang=en>

⁶ <https://www.gov.uk/guidance/equality-act-2010-guidance>

⁷ <http://gov.wales/topics/people-and-communities/people/future-generations-act/?lang=en>

⁸ <http://gov.wales/topics/health/socialcare/act/?lang=en>

⁹ <http://www.wales.nhs.uk/sites3/page.cfm?orgid=522&pid=63782>

¹⁰ <https://www.equalityhumanrights.com/en/human-rights/human-rights-act>

¹¹ <http://www.unicef.org.uk/UNICEFs-Work/UN-Convention>

¹² <http://www.un.org/disabilities/convention/conventionfull.shtml>

¹³ <http://www.ohchr.org/EN/ProfessionalInterest/Pages/OlderPersons.aspx>

¹⁴ <http://www.wales.nhs.uk/sites3/Documents/254/WHC-2015-012%20-%20English%20Version.pdf>

¹⁵ <http://gov.wales/topics/health/publications/health/guidance/care-standards/?lang=en>

¹⁶ <http://www.legislation.gov.uk/mwa/2011/1/contents/enacted>

They provide a systematic way of ensuring that legal obligations are met and are a practical means of examining new and existing policies and practices to determine what impact they may have on equality for those affected by the outcomes.

HIAs assess the potential impact of any change or amendment to a policy, service, plan, procedure or programme on the health of the population and on the distribution of those effects within the population, particularly within vulnerable groups. HIAs help identify how people may be affected differently on the basis of where they live and potential impacts on health inequalities and health equity. HIA increases understanding of potential health impacts on those living in the most deprived communities, improves service delivery to ensure that those with the greatest health needs receive a larger proportion of attention and highlights gaps and barriers in services.

The **EHIA** brings together both impact assessments in to a single tool and helps to assess the impact of the strategy, policy, plan, procedure and/or service. Using the EHIA from the outset and during development stages will help identify those most affected by the proposed revisions or changes and inform plans for engagement and co-production. Engaging with those most affected and co-producing any changes or revisions will result in a set of recommendations to mitigate negative, and enhance positive impacts. Throughout the assessment, 'health' is not restricted to medical conditions but includes the wide range of influences on people's well-being including, but not limited to, experience of discrimination, access to transport, education, housing quality and employment.

Throughout the development of the strategy, policy, plan, procedure or service, in addition to the questions in the EHIA, you are required to remember our values of *care, trust, respect, personal responsibility, integrity and kindness* and to take the Human Rights Act 1998 into account. All NHS organisations have a duty to act compatibly with and to respect, protect and fulfil the rights set out in the Human Rights Act. Further detail on the Act is available in Appendix 2.

Completion of the EHIA should be an iterative process and commenced as soon as you begin to develop a strategy, policy, plan, procedure and/or service proposal and used again as the work progresses to keep informing you of those most affected and to inform mitigating actions. It should be led by the individual responsible for the strategy, policy, plan, procedure and/or service and be completed with relevant others or as part of a facilitated session. Some useful tips are included in Appendix 3.

For further information or if you require support to facilitate a session, please contact Susan Toner, Principal Health Promotion Specialist (susan.toner@wales.nh.uk) or Keithley Wilkinson, Equality Manager (Keithley.wilkinson@wales.nhs.uk)

Based on

1. Cardiff Council (2013) Statutory Screening Tool Guidance
2. NHS Scotland (2011) Health Inequalities Impact Assessment: An approach to fair and effective policy making. Guidance, tools and templates¹⁷
3. Wales Health Impact Assessment Support Unit (2012) Health Impact Assessment: A Practical Guide¹⁸

¹⁷ <http://www.healthscotland.com/uploads/documents/5563-HIIA%20-%20An%20approach%20to%20fair%20and%20effective%20policy%20making.pdf> (accessed 4 January 2016)

¹⁸ <http://www.wales.nhs.uk/sites3/page.cfm?orgid=522&pid=63782> (accessed on 4 January 2016)

Appendix 2 – The Human Rights Act 1998¹⁹

The Act sets out our human rights in a series of ‘Articles’. Each Article deals with a different right. These are all taken from the European Convention on Human Rights and are commonly known as ‘the Convention Rights’:

1. Article 2 Right to life. NHS examples: the protection and promotion of the safety and welfare of patients and staff
2. Article 3 Freedom from torture and inhuman or degrading treatment. NHS examples: issues of dignity and privacy, the protection and promotion of the safety and welfare of patients and staff, the treatment of vulnerable groups or groups that may experience social exclusion, for example, gypsies and travelers, issues of patient restraint and control
3. Article 4 Freedom from slavery and forced labour
4. Article 5 Right to liberty and security. NHS examples: issues of patient choice, control, empowerment and independence, issues of patient restraint and control
5. Article 6 Right to a fair trial
6. Article 7 No punishment without law
7. Article 8 Respect for your private and family life, home and correspondence. NHS examples: issues of dignity and privacy, the protection and promotion of the safety and welfare of patients and staff, the treatment of vulnerable groups or groups that may experience social exclusion, for example, gypsies and travelers, the right of a patient or employee to enjoy their family and/or private life
8. Article 9 Freedom of thought, belief and religion. NHS examples: the protection and promotion of the safety and welfare of patients and staff, the treatment of vulnerable groups or groups that may experience social exclusion, for example, gypsies and travelers
9. Article 10 Freedom of expression. NHS examples: the right to hold and express opinions and to receive and impart information and ideas to others, procedures around whistle-blowing when informing on improper practices of employers where it is a protected disclosure
10. Article 11 Freedom of assembly and association
11. Article 12 Right to marry and start a family

¹⁹ <https://www.equalityhumanrights.com/en/human-rights/human-rights-act>

12. Article 14 Protection from discrimination in respect of these rights and freedoms. NHS examples: refusal of medical treatment to an older person solely because of their age, patients presented with health options without the use of an interpreter to meet need, discrimination against UHB staff on the basis of their caring responsibilities at home
13. Protocol 1, Article 1 Right to peaceful enjoyment of your property
14. Protocol 1, Article 2 Right to education
15. Protocol 1, Article 3 Right to participate in free elections
16. Protocol 13, Article 1 Abolition of the death penalty

Appendix 3

Tips

1. Be clear about the policy or decision's rationale, objectives, delivery method and stakeholders.
2. Work through the Toolkit early in the design and development stages and make use of it as the work progresses to inform you of those most affected and inform mitigating actions
3. Allow adequate time to complete the Equality Health Impact Assessment
4. Identify what data you already have and what are the gaps.
5. Engage with stakeholders and those most affected early. View them as active partners rather than passive recipients of your services.
6. Remember to consider the impact of your decisions on your staff as well as the public.
7. Record which organisations and protected characteristic groups you engaged with, when you engaged with them and how you did so (for example, workshop, public meeting, written submission).
8. Produce a summary table describing the issues affecting each protected group and what the potential mitigations are.
9. Report on positive impacts as well as negative ones.
10. Remember what the Equality Act says – how can this policy or decision help foster good relations between different groups?
11. Do it with other people! Talk to colleagues, bounce ideas, seek views and opinions.