Worcestershire Acute Hospitals NHS Trust

Animal derived medical products – trust guideline for patients who do not wish to receive medicines containing animal extracts.

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction

Certain faith groups discourage the taking of medicines which contain certain animal product. Likewise, those who exclude animal products from their diet may also not wish to take medicines that contain animal products. Often these medicines can be substituted for a different preparation. Where no alternative is available the risks/benefits of not having the medicine needs to be discussed with the patient.

This guideline is for use by the following staff groups:
All staff who prescribe and administer medicines

Lead Clinician(s)

Alison Smith	Lead Pharmacist Medicines Safety
Approved by Pharmacy Governance Committee on:	5th June 2024
Approved by Medicines Safety Committee on:	12th June 2024
This guideline should not be used after end of: This is most current document and should be used until a revised version is in place	5th June 2027

Key amendments to this guideline

Date	Amendment	By:
November 2013	New Guideline	
November 2015	Document extended for 12 months as per TMC paper approved on 22nd July 2015	TMC
Oct 16	Further extension as per TMC paper approved on 22ND July 2015	TMC
Oct 17	Document extended for further two years with no changes	Dr Crowther
Dec 17	Sentence added in at the request of the Coroner	
May 2020	New Version • Format updated • References added • Lead clinicians and contribution list updated • Text updated	R.Fletcher
July 23	Document extended whilst review is taking place	Medicines Safety Committee
13th September 2023	Document extended for 6 months whilst review is taking place	Medicines Safety Committee
June 24	Parenteral nutrition added to list (contains egg phospholipid and fish oils)	Alison Smith

Policy for patients who do not wish to receive medicines containing animal extracts

Introduction

Several medicines are derived from animals or contain animal products in their packaging or formulation. Uniformly all medicines will have been tested on animals during their development. A patient may not wish to take a product if it contains animal product. This may be for religious reasons (Islam and Judaism prohibit the taking of pork and some Buddhists and Hindus are vegetarian) or personal lifestyle choices (vegetarian and vegan).

If a patient does not wish to receive a certain medicine then alternatives should be offered. If there is no suitable alternative then they may wish not to receive that medicine. The patient should be fully informed of the risks of taking an alternative medicine or not taking a medicine at all. The Trust also has a responsibility to ensure that medicines prescribed take account of patient's choices, lifestyle, cultural and religious beliefs (CQC Outcome 9A.1)

Details of Guideline

Screening patients who are to receive a medicine containing an animal product
The majority of patients of the faiths that prohibit animal products are happy to receive medicines containing animal products as the medicine is seen as a necessity and not as a food. Most vegetarians and vegans will receive animal containing medicines. It is therefore reasonable to assume that patients or carers who do not raise the issue are happy to receive these products and discussing the issue with all patients is not necessary.

Information sheets for patients
An information sheet (see appendix 1) is available to give to patients who wish for more information on the issue. It has been endorsed by local religious leaders.

Medicines that contain animal products and possible alternatives
The following medicines contain animal products. There are alternatives for patients who do not want to receive these medicines. If a patient wishes to receive an alternative they must be fully counselled on any additional risks/benefits of the medicine. If there is no alternative and a patient wishes not to receive any treatment then they must be fully informed of the likely consequences. The results of any discussions/decisions must be documented in the notes. It may be appropriate to contact the Spiritual and Pastoral Care Team so that the patient can receive additional appropriate advice.

Heparins

All unfractionated and low molecular weight heparins in the UK are derived from pigs. The following alternatives can be used:

- Treatment of possible or confirmed deep vein thrombosis (DVT) or pulmonary embolism in patients with GFR>15mls/min – **Rivaroxaban, Apixaban or Edoxaban** – see WAHT-HAE-002 and WAHT-HAE-019
- Treatment of possible or confirmed deep vein thrombosis (DVT) or pulmonary embolism in patients with GFR>15mls/min where rivaroxaban, apixaban or edoxaban is contra-indicated – **Fondaparinux. Fondaparinux cannot be given with a GFR<15ls/min.**

- Treatment of possible or confirmed deep vein thrombosis (DVT) or pulmonary embolism in patients with GFR<15mls/min or where rapid reversal of anticoagulation is required – **no alternative to unfractionated heparin**
- Medical and surgical prophylaxis of DVT/PE – **Fondaparinux (at prophylactic dose)**
- Ensuring patency of central intravenous lines (see Guideline WAHT-INF-017) – **no alternative to unfractionated heparin as an anticoagulant but sodium chloride 0.9% flushes can be used**
- Ensuring patency of dialysis circuits – **no good alternative but sodium chloride 0.9% flushes and sodium citrate can be used**
- Treatment or prophylaxis of DVT or PE in pregnancy – **no medicine is licensed in pregnancy but there are case reports for the use of fondaparinux (using the same dosing as non-pregnant patients) therefore this can only be used after detailed discussion between the patient and the obstetrician. Fondaparinux is contra-indicated in breast feeding. Fondaparinux is renally excreted therefore care must be taken in renal impairment.**

Insulin
Some insulins are of porcine origin - human insulins can be used instead. The choice of insulin is usually made by the diabetic team.

Pancreatin
The only pancreatin preparation available is porcine.

Vaccines
- The measles mumps and rubella vaccine can contain both gelatin (from pigs) and egg protein, The Priorix® brand is free from gelatin.
- The shingles vaccine contains pork gelatin and currently no alternative is available.

The Fluenz Tetra® nasal spray vaccine for healthy children contains gelatin. There are injectable flu vaccines that do not contain pork gelatin, but these are expected to be less effective than Fluenz Tetra® in children.

Pulmonary surfactants
The two products available are both animal derived, beractant from cows and poractant from pigs.

Vitamin D preparations
Colecalciferol is usually derived from sheep's wool fat (lanolin) and although they may be acceptable to vegetarians they are not suitable for vegans. A small number of preparations are available that are considered suitable for vegans. Please contact Pharmacy for advice.

Parenteral nutrition
Contains egg phospholipid and fish oils

Capsules
Most capsules contain gelatin (porcine or bovine derived) as part of the capsule shell. Information on the gelatin content can be found in the Summary of Product Characteristics (SPC) and Patient Information Leaflets (PIL) for licensed medicines, which are usually available at https://www.medicines.org.uk. Usually there are alternative preparations of the medicine available e.g. tablets or syrup, or consideration given to an alternative medicine.

Excipients

As well as the active drug medicinal formulations will also contain other ingredients some of which may have animal origin e.g. lactose from cow's milk, cochineal and shellac from insects. If there is a concern about excipients being of animal origin then the manufacturer can be contacted directly or contact Pharmacy for advice.

Monitoring Tool

Due to the likely rarity of patients in whom this guideline is relevant there are no plans to monitor the compliance of this guideline. There are no defined standards. Complaints and incidents will be monitored by the Medicine Safety Committee.

STANDARDS	%	CLINICAL EXCEPTIONS

References

- Choosing an oral vitamin D preparation for vegetarians or vegans – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
- Choosing a calcium and vitamin D preparation for vegetarians or vegans – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
- UK Medicines Information. Medicines Q&A Excipients: What are the general considerations for vegan patients? Available from: www.sps.nhs.uk
- UK Medicines Information. Medicines Q&A What factors to consider when advising on medicines suitable for a Halal diet? Available from: www.sps.nhs.uk
- UK Medicines Information. Medicines Q&A Which oral vitamin D products are suitable for people with vegetarian or vegan diets? Available from: www.sps.nhs.uk
- Public Health England. Vaccines and Porcine Gelatine. Available from: www.gov.uk Vaccines and porcine gelatine - GOV.UK (www.gov.uk)

APPENIDIX 1 – PATIENT INFORMATION SHEET

Patient Information Leaflet with order code WR4523 (Double click to open as PDF).

CONTRIBUTION LIST

This key document has been circulated to the following individuals for consultation;

Name	Designation
Salim Shafeek	Consultant - Haematology
Alison Smith	Principal Pharmacist Medicines Safety
Laura Veal	Consultant - Obstetrics
Swapna George	Endocrinology Nurse

This key document has been circulated to the chair(s) of the following committee groups for comments;

Name	Committee / group
Tania Carruthers	Pharmacy Governance Committee
Christine Blanshard	Medicines Safety Committee

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

NHS Worcestershire Acute Hospitals NHS Trust

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	√	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	Rosemary Fletcher

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Alison Smith	Lead Pharmacist Medicines Safety	alison.smith105@nhs.net
Date assessment completed	05/07/2023		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:** Animal derived medical products – trust guideline for patients who do not wish to receive medicines containing animal extracts.			
What is the aim, purpose and/or intended outcomes of this Activity?	To provide guidance on treating patients who do not wish to receive medicines containing animal extracts.			
Who will be affected by the development & implementation of this activity?	❑ √ √	Service User Patient Carers Visitors	❑ ❑ ❑ ❑	Staff Communities Other _____

Is this:	√ Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	Information from SPS, UKMi and Gov.uk
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	Representatives from maternity and haematology and endocrinology
Summary of relevant findings	

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		√		Not applicable
Disability		√		Not applicable
Gender Reassignment		√		Not applicable
Marriage & Civil Partnerships		√		Not applicable
Pregnancy & Maternity		√		Not applicable
Race including Traveling Communities		√		Not applicable
Religion & Belief	√			Provides information
Sex		√		Not applicable
Sexual Orientation		√		Not applicable

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		√		Not applicable
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		√		Not applicable

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
		.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)				

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Alison Smith
Date signed	05/07/2023
Comments:	
Signature of person the Leader Person for this activity	Alison Smith
Date signed	05/07/2023
Comments:	

Supporting Document – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	Yes – requires printing of information sheets
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval