Wye Valley NHS
NHS Trust

PROCEDURE ON THE USE OF UNLICENSED MEDICINES AND THE USE OF LICENSED MEDICINES FOR UNLICENSED INDICATIONS

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Adapted from West Midlands Dispensary Managers Group Version 1 October 2014
by Jo Howe – Lead Technician Medicines Information.
Date: 07/09/2015
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Authorised by: Clinical Director of Pharmacy

Sources of Information and further reading:

1. Guidance for the Purchase and Supply of Unlicensed Medicinal Products – Notes for Prescribers and Pharmacists 3rd Edition June 2004.
NHS Pharmaceutical Quality Assurance Committee

2. The Supply of Unlicensed Relevant Medicinal Products For Individual Patients August 2006 **MHRA (formerly MCA) Guidance Note No 14**

3. The Purchase and Use of Unlicensed Medicines in Hospital – Guild of Healthcare Pharmacists Policy Statement.

4. "Good Medical Practice" 2001. General Medical Council.

5. "Consent to Treatment" 2001 Medical Defence Union.

6. Using Unlicensed and Off-label Medicines. 2002.
Nunn, A.J., Pharmacy Management, 18, 64-67.

7. "Medicines for Children", Royal College of Paediatrics and Child Health, and the Neonatal and Paediatric Pharmacists Group, 2nd Edition, August 2003

8. Statements on good professional practice, Royal Pharmaceutical Society of Great Britain

9. BNF for Children, Royal Pharmaceutical Society of Great Britain and the British Medical Association. 1st Edition, September 2005

10. Guidance for the purchase and supply of unlicensed medicinal products- Notes for prescribers and pharmacists. NHS Pharmaceutical QA committee, 2004

11. The British Pharmacopoeia 2008. www.pharmacopoeia.co.uk

12. Records Management: NHS Code of Practice. Annex D1: Health Record Retention Schedule.

Wye Valley NHS
NHS Trust

PROCEDURE ON THE USE OF UNLICENSED MEDICINES AND THE USE OF LICENSED MEDICINES FOR UNLICENSED INDICATIONS

CONTENTS PAGE

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1. INTRODUCTION AND SCOPE:

In order to ensure that medicines are safe, effective and of appropriate quality, manufacture, sale or supply is controlled by national and EU legislation. Accordingly, no medicinal product may be "placed on the market" unless a marketing authorisation (formerly a product licence) has been granted. However, in order to preserve prescribers' clinical freedom, the legislation gives some exemptions from full control. Thus, medicinal products that are not licensed may be prescribed in order to fulfil special needs in individual patients on the direct personal responsibility of the prescribing clinician.

Therefore for good clinical reasons the use of unlicensed medicines and the use of licensed medicines for an unlicensed indication is widespread in hospitals (and in primary care). Were this practice to be curtailed, the treatment of many patients would be impeded. It is therefore important that the Trust and its prescribers and pharmacists should be aware of the associated medico-legal implications. These include but are not limited to
the Consumer Protection Act 2015 -
http://www.legislation.gov.uk/ukpga/2015/15/contents/enacted
and product liability legislation –
https://www.gov.uk/guidance/product-liability-and-safety-law

Whilst licensed medicinal products are subject to stringent control by the Medicines and Healthcare Products Regulatory Agency (MHRA), neither prescriber nor pharmacist can make the same assumptions of quality, safety and efficacy about unlicensed products.

2. DEFINITIONS:

A **UK-licensed medicine** is one that has been granted a product licence (PL), now known as a marketing authorisation (MA), and can be marketed in the UK for the treatment of medical conditions as defined in its PL or MA (i.e. its licensed indications). The summary of Product Characteristics (SPC), previously known as the Product Data Sheet, also specifies the licensed indications (uses) of a medicinal product and how it is to be used (e.g. doses, frequency, route, form, reconstitution, dilution etc) and when it is not to be used (contra-indications) or used with caution (special precautions).

Off label-Sometimes medicines are used for a clinical indication or in a way that is not covered by the licence. This would constitute unlicensed use of a licensed medicine. In neonatal or paediatric medicine, drugs are often used "off label" (outside their licence limits) because the cost and ethical considerations for clinical trials in children discourage manufacturers from applying for a licence for use in children. Up to 80% of neonatal drug use can be unlicensed or "off label". Unlicensed drug use is also not uncommon in ITU clinical practice.

There are 3 reasons for products being unlicensed- No UK licence granted; medicines licensed in countries other than the UK; manufacturers "Specials".

No UK licence may have been issued because the product is waiting for a licence to be granted, or it is undergoing clinical trials, or is only manufactured for export or has been withdrawn from the UK market. Such medicinal products can often be obtained from the manufacturer on a "named patient / individual patient / compassionate supply basis".

Medicines available / licensed in a country other than the UK may be imported through specialist importers, and their UK use would also be unlicensed.

Some manufacturers specialise in the preparation of products for which demand does not justify commercial production and licensing. Some NHS pharmacy aseptic units and non-sterile manufacturing units are included in this group. They produce a medicinal product to the specification of an authorised purchaser, usually a pharmacist. Such products are often known as "specials", and as the products do not have a Product License (PL) or Marketing Authorisation (MA) they do not have a specified indication for use, recommended dose or SPC (Summary of Product Characteristics).

Two activities within Pharmacy can render a licensed product unlicensed. These are:

1. The use of a licensed drug, as an ingredient in preparing a medicine for a specified patient, in accordance with a prescriber's instructions, is known as extemporaneous dispensing and also includes parenteral nutrition (PN) compounding, preparation of intravenous additives, and cytotoxic drug reconstitution services. So long as best practice is used in the preparation process, and the plant, premises, processes and personnel are subject to audit and inspection, the risk involved in converting a licensed medicine to an unlicensed medicine in this way is small but justified if the clinical need cannot be met in another way.

2. Repackaging of a licensed medicinal product e.g. preparing 5 packs of 20 tablets for use as patient packs in an A & E department from a manufacturer's pack of 100 tablets would 'de-licence' the medicinal product. So long as the new packaging is appropriate to the product, the risk involved in converting a licensed pack to an unlicensed pack in this way is minimal and justified, if the operational need cannot be met in another way. MHRA guidelines exist to limit this activity to a small scale.

Certificate of Analysis /Conformity (COA/COC) (UK 'Specials') - This is the documentation associated with the particular unlicensed medicine batch. It states the ingredients, test constraints (if appropriate) and other information of note. The information included in this document will vary depending upon the product it describes but should contain test results with parameters used, ingredients, should be batch specific and should be signed by the person releasing the batch.

Transmissable Spongiform Encephalopathy (TSE) compliance - There should be a positive statement stipulating that the product is free from TSE (Transmissable Spongiform Encephalopathy). Although there is no mandatory requirement for information to be supplied with an unlicensed product, it is recognised as good practice.

1. RESPONSIBILITY AND ACCOUNTABILITY:

A **prescriber** who prescribes an unlicensed medicine or a licensed medicine in an unlicensed way is professionally accountable for his/her judgement in so doing, and may be called upon to justify his/her actions. However, it could be anticipated that such justification would be achievable if a body of peers would recognise the prescription as best practice.
Pharmacists are responsible for ensuring that prescribers are always aware that a medicine they have requested is only available as an unlicensed product, (e.g. formulary, intranet, newsletters etc.)
The pharmacist(s) who clinically check(s) the initial prescription and who signs the purchase authorisation will share responsibility as the purchaser of the product, particularly where this involves specifying the product to be purchased, or if their actions or omissions have contributed to harm. When an unlicensed medicine is to be ordered for the first time, there needs to be critical, evidence based risk assessment evaluation for its use, and should not automatically become a "formulary item". Where the brand is changed a further risk assessment of the product itself is needed.
The Trust and its clinical practitioners should be seen to have a 'good practice' obligation, though not a legal duty, to inform patients about the use of unlicensed medicines or of licensed medicines used 'off label' to such an extent that the patient can make an informed consent (or an informed choice to refuse such medication).
The Trust, through the Formulary Working Group (FWG), should approve such medicines and monitor, audit, evaluate and record their use.

2. LIABILITIES:

If a patient is harmed by a licensed medicine used for an unlicensed indication, or in an unlicensed way, and not because of any defect in the product itself, then the prescriber is liable for the harm, in the same way that they would be liable when a licensed medicine is used in accordance with its licence.

If a patient is harmed by a defective medicine, whether licensed or unlicensed, then the supplier of that medicine (normally a pharmacist) is liable for the harm. If the supplier can identify the manufacturer of the medicine, then the liability passes to the manufacturer. If the manufacturer can prove that the specification of the medicine, as provided by the pharmacist raising the order, contributed to its being defective, then the liability passes back to the pharmacist.

If a patient is harmed by a defective medicine which has been prepared by or under the supervision of a pharmacist, then that pharmacist is liable for the harm as the manufacturer of the medicine. If the medicine has been procured from a 'specials' manufacturer, then the pharmacist who placed the order is considered by law to be the 'manufacturer' and is therefore liable.

3. PATIENT CONSENT:

Healthcare professionals and The Trust respect the rights of patients or carers to participate in decisions on their healthcare treatment, and ensure that those decisions are properly informed. There is no statutory requirement to obtain more specific consent from a patient or carer in order to prescribe and supply an unlicensed medicine or to prescribe a medicine in an unlicensed way.

However, this would represent excellent professional practice, and patients should be given sufficient information by the prescriber, whenever possible, for them to be aware that they are being prescribed an unlicensed medicinal treatment, and for them to make an informed choice to consent. A suitable Patient Information Leaflet is attached as Appendix 5.

This practice may not be practicable in paediatric or neonatal care, because so large a proportion of medicines would require this information at the time of prescribing, that the patient or carer would be overwhelmed. Instead a leaflet titled 'Medicines for Children information for parents and carers – Unlicensed Medicines', accessed via the following: http://www.medicinesforchildren.org.uk/sites/default/files/content-type/leaflet/pdf/MfC_Unlicensed_medicines_PV2_2015-08-06.pdf, will be provided in advance, through the admissions or appointment letter, and the patient or carer invited to enquire when a medicine is prescribed, if they have specific concerns.

It is accepted that there are circumstances where involving patients in decisions on unlicensed drug use is inappropriate and impractical (e.g. clinical emergencies, unconscious patients, patients without the ability to comprehend). In those cases, it is considered that presenting for care constitutes consent to the use of unlicensed medicines if that constitutes 'best practice'.

6. PROCUREMENT: (See appendix 1, 2 & 3 for flow charts)

A DESIGNATED SENIOR PHARMACIST will be responsible for ensuring that all processes for the appropriate procurement and safe use of unlicensed medicines are followed. This will include:

a) initial consideration of requests from prescribers, ensuring no suitable UK licensed alternative product exists
b) risk assessing procurement of a suitable UK unlicensed alternative or a product licensed outside the UK where no UK licensed equivalent/alternative is available
c) advising on the process to be used to progress the request
d) ensuring pharmacy procedures for the procurement of unlicensed medicines are followed
e) ensuring that appropriate records are kept relating to the procurement of the unlicensed medicines, as detailed on the 'Request Form for Unlicensed Medicines' (appendix 4 - part 7)
f) ensuring that unlicensed medicines are identifiable from all licensed medicines at the point of access

g) review of the need for continued use of unlicensed medicines and transfer to a licensed preparation when available
h) passing the unlicensed medicine to Medicines Information for formal check and risk assessment .
i) quarantine of the unlicensed medicine until approved for use by the FWG.

7. MEDICINES INFORMATION:

The Lead Medicines Information Technician will be responsible for the formal risk assessment of the unlicensed product. This will include:

a) a visual inspection to determine that:
   - critical data can be easily read
   - the product is presented in packaging of an acceptable quality
   - shelf-life and storage requirements are easily identified.
b) a search using reputable reference sources, to collate available evidence, to support the use of the preparation for the proposed indication.
c) a review of the evidence
d) completion of the 'Unlicensed Medicine Risk Assessment Form' using the evidence sourced (appendix 4 – part 8)
e) to create an english Patient Information Leaflet (PIL), if no english translated leaflet exists
f) to submit the completed risk assessment form to Formulary Working Group (FWG), to determine suitability of use within Wye Valley NHS Trust.

8. DISPENSARY:

a) The pharmacist who clinically checks the prescription will share responsibility as the purchaser of the product, particularly where this involves specifying the product to be purchased, or if their actions or omissions contribute to harm
b) Clinical pharmacists will advise prescribers where appropriate of suitable licensed alternatives to unlicensed medicines
c) The dispensary manager will ensure that appropriate records are kept relating to supply to patients or wards/units for individual patient use (appendix 4 – part 10)

9. PRESCRIBERS will complete a 'Request form for Unlicensed Medicines' (appendix 4 – parts 1-6), to include published evidence to support the use of the unlicensed medicine, and any previous clinical experience with the medicine.

10. The DIRECTOR OF PHARMACY will be responsible for the content, implementation and review of this policy.

All records should be kept for 5 years to comply with Statutory Instrument SI1994/3144. With regard to children's records refer to the Records Management: NHS Code of Practice. Annex D1: Health Records Retention Schedule.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200139/Records_Management_-_NHS_Code_of_Practice_Part_2_second_edition.pdf

The British Pharmacopoeia (BP) (https://www.pharmacopoeia.com/) now describes the minimum quality standards for Unlicensed Medicines which became mandatory in 2008. There are monographs for specific unlicensed products and, where requested, the supplier should comply with these standards and be able to demonstrate compliance. These should be used in preference to alternatives not listed in the BP wherever possible.

11. ADVERSE DRUG REACTIONS & DEFECTIVE MEDICINES:

Adverse drug reactions and defective products are handled and reported in the same way as licensed medicines. Doctors or pharmacists should report serious adverse drug reactions to the Medicines and Healthcare Regulatory Agency using the Yellow Card System https://yellowcard.mhra.gov.uk/ (hard copies are available in the BNF, MIMS, and ABPI Compendium). A Trust incident form should be completed and a copy of this should also be submitted to the Formulary Working Group (FWG).

12. UNLICENSED MEDICINES PROVIDED AS WARD STOCK:

Unlicensed medicines are NOT to be supplied as stock, unless the Pharmacist in charge of an area, can see a reason why the service cannot run smoothly without it. For example Otocomb Otic ointment for use in ENT and Theatre, Indigo Carmine injection 40mg/5ml for use in Endoscopy. Refer to the SOP for 'Providing an Unlicensed Medicine as Ward Stock'.

13. OTHER RELATED DOCUMENTS:

- Standard Operating Procedure - Procurement and Risk Assessment of Unlicensed Medicines
- Standard Operating Procedure - Supply of Unlicensed Medicines as Ward Stock

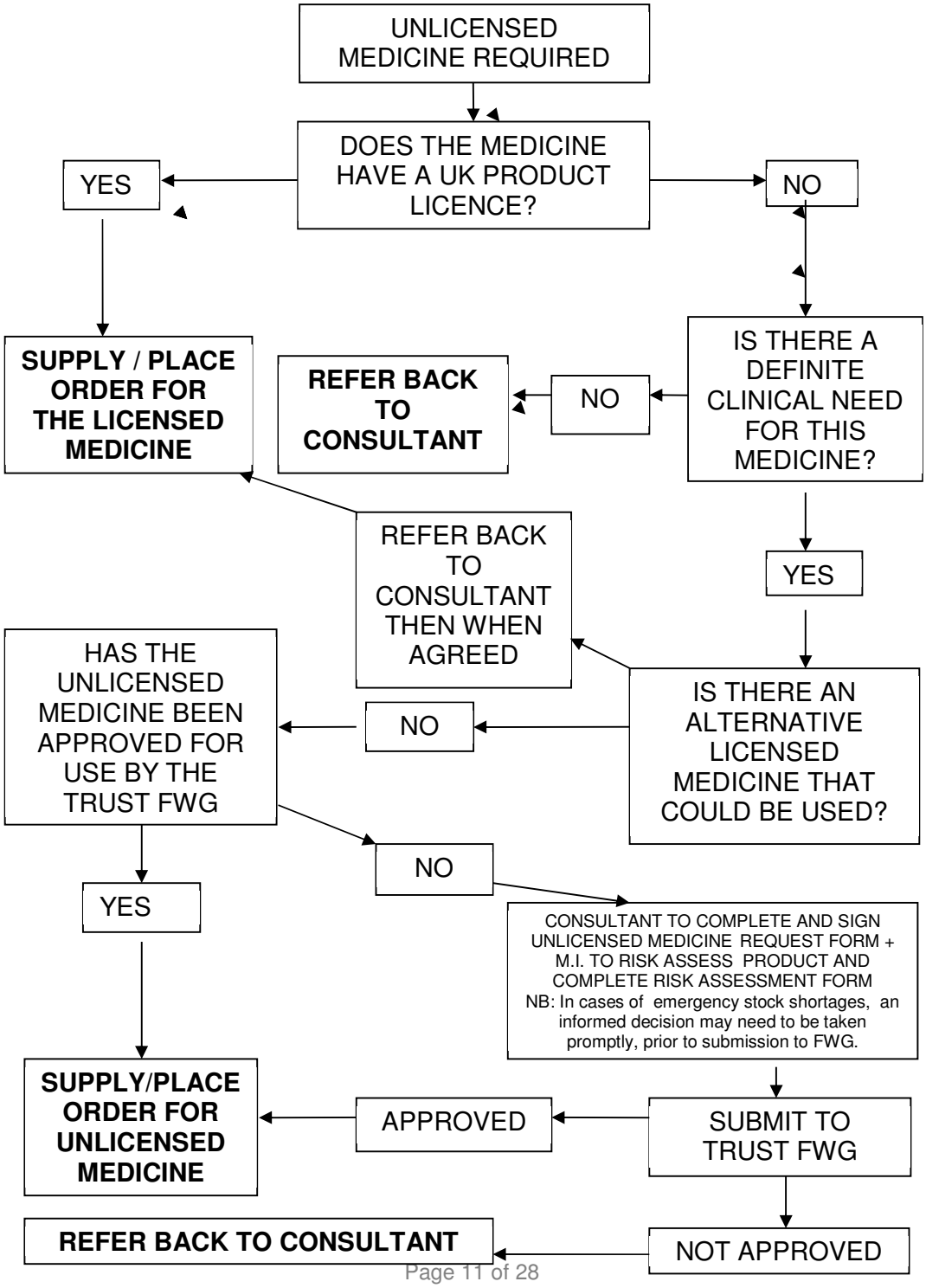
14. MONITORING:

Aspect of compliance or effectiveness being monitored	**Monitoring Method**	**Individual responsible for the monitoring**	**Frequency of the monitoring activity**	**Group/ committee which will receive the findings / monitoring report**	**Group / committee / individual responsible for ensuring that the actions are completed**
Computer records	On individual receipt	Lead Pharmacist Procurement and operational and Manager Medicines Procurement , provision and Homecare	Quarterly	Department of Pharmacy Senior Management Team	Quality Committee
Paper register	Stock check at every issue	Dispensary Manager	Quarterly	Department of Pharmacy Senior Management Team	Quality Committee

APPENDIX 1: Initial Request Decision tree

Wye Valley NHS Trust

UNLICENSED MEDICINES INITIAL REQUEST DECISION TREE FOR PRESCRIBERS, CLINICAL PHARMACISTS AND PHARMACY



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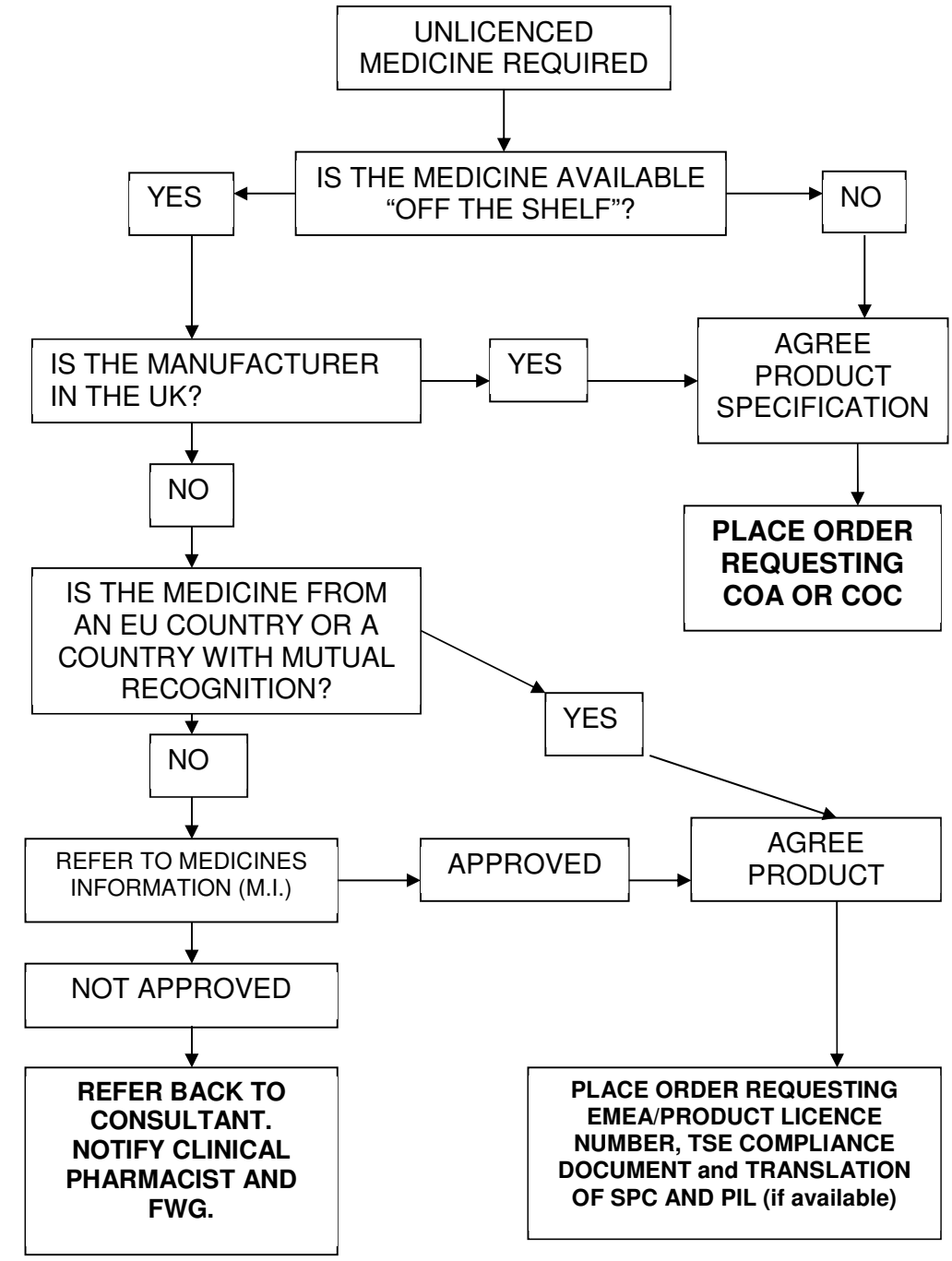
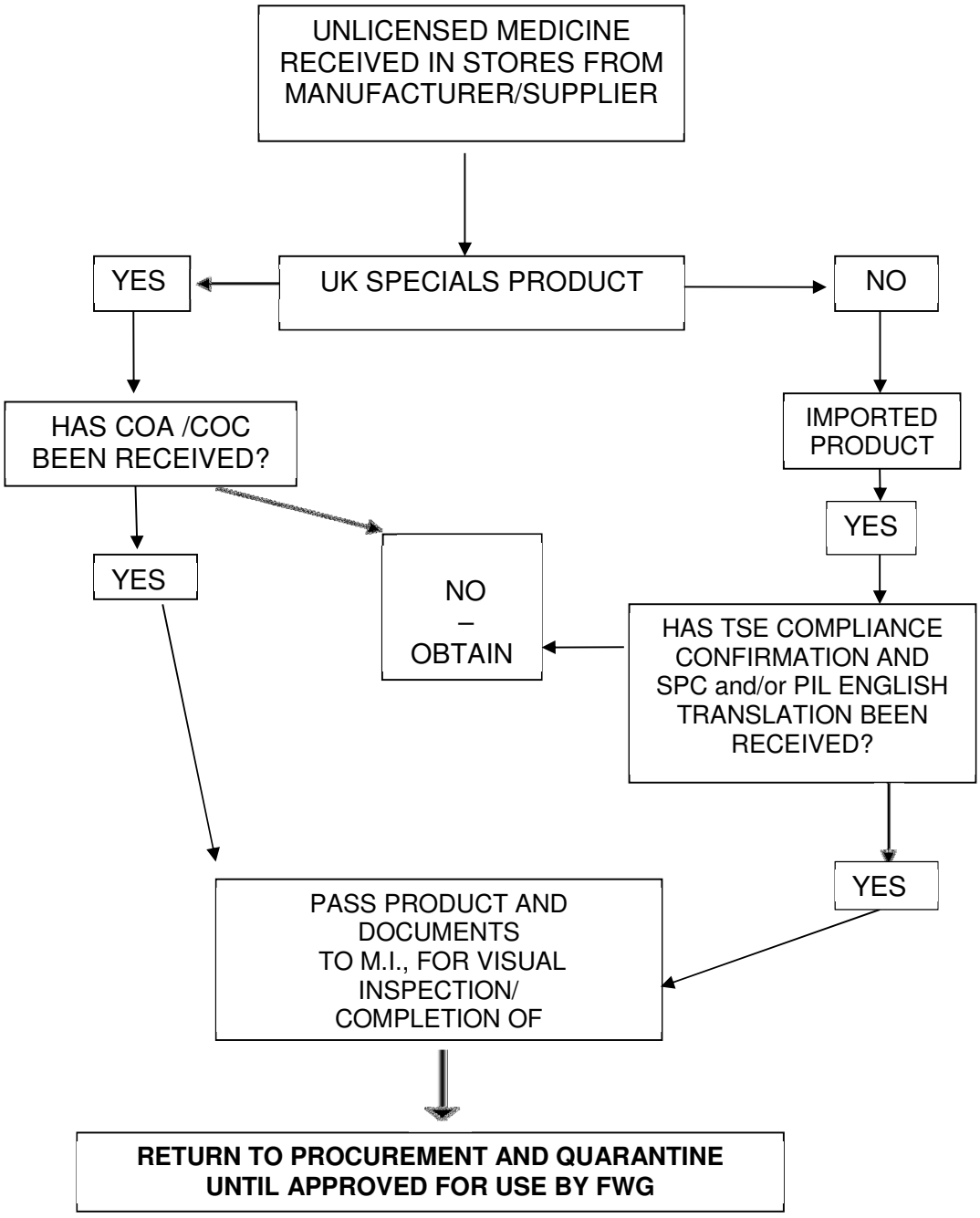
APPENDIX 2: UNLICENSED MEDICINES PROCUREMENT TREE FOR PROCUREMENT & PROVISION



Appendix 3: UNLICENSED MEDICINES RELEASE DECISION TREE FOR PROCUREMENT & PROVISION



Wye Valley NHS Trust

REQUEST FORM for Unlicensed Medicines

This form should be completed by the Consultant in conjunction with the Specialist (Clinical) Pharmacist each time a new unlicensed medicine is required. The completed form is to be submitted to the Formulary Working Group (FWG) as part of the submission for approval to use the product. Only in the case of urgent clinical need, may the Consultant and/or Senior Pharmacist (Band 8a or above) authorise the use of a new unlicensed medicine without a completed form at the time, but will be completed at a later date. This will be subject to formal ratification at the next Formulary Working Group (FWG) meeting. Before completing this form you must have read the Trust Policy on the Prescribing, Use and Supply of Unlicensed Medicines titled '*Procedure On The Use Of Unlicensed Medicines and The Use Of Licensed Medicines for Unlicensed Indications'*, and you must be aware of your responsibilities under this policy.

Parts 1-6 to completed by Consultant
Part 7 to be completed by Pharmacy (Procurement)
Part 8 to be completed by Pharmacy (Medicines Information)
Part 9 to be completed by FWG member
Part 10 to be completed by Pharmacy on issue to the patient/ward (Dispensary)

Part 1: Unlicensed Medicine Details

Approved Name:

Proprietary Name (if known):

Dose Form: Strength: Manufacturer (if known):

Part 2: Patient Details

Is this to be used for a single patient only? Yes / No

Single Patient Only

Number: Ward/Clinic:

Multiple Patients

Approximate number of patients per year:

Part 3: Clinical Details

Indication: Route:

Dose: Frequency:

Duration:

Why is an unlicensed medicine being considered?

1.	Pharmaceutically equivalent licensed product temporarily unavailable*
2.	Equivalent UK licensed product unavailable / unsuitable* (explain)
3.	Other* (give details)
* delete as appropriate	

Part 4: Clinical Evidence for Unlicensed Medicine

Is there any evidence to support its use for the proposed indication?	Yes / No
If not, is there any evidence to support its use for other indications?	Yes / No
Is there any evidence to support its proposed administration schedule?	Yes / No
Is the active drug currently in a licensed product for use via the same route?	Yes / No
Are other centres using this medicine?	Yes / No / Not Known If yes, name:

Please summarise below any published evidence to support the use of the unlicensed medicine and any previous clinical experience with the medicine:

Authors:	
Title:	
Journal / Issue No Volume / Year:	

Authors:	
Title:	
Journal / Issue No Volume / Year:	

What are the risks to the patient of NOT using this medicine?

Describe any monitoring required:

How will patient obtain further supplies?

Is there a need for a shared care protocol?

Yes / No

Part 5: Assessing the level of risk

The information contained in this form should now be used to assess the level of risk associated with using the unlicensed medicine. Using the Trust Risk Matrix (attached) calculate the level of risk by:

- Measuring the consequence / impact using the definitions given in table 1. You only need to identify the risk score under the first column 'Clinical / Health and Safety / Staff reaction'. The highest score determines the overall risk rating.
- Assessing the likelihood for occurrence or re-occurrence using table 2 and assigning a level of likelihood.
- Taking the risk rating from table 1 and the measure of likelihood as identified from table 2 and assigning a level of risk from table 3.

Risk Score (table 1):	
Measure of likelihood (table 2):	
Level of risk (table 3):	

Table 1 - Measure of consequence or impact

Risk Score	Descriptor	Clinical/Health and Safety Staff Reaction	Regulatory Breach Potential Litigation	Financial Loss/Disruption Costs Commercial Interests	Loss of Goodwill Management of Operations	IT systems
1	Insignificant	At worst, minor illness/injuries possible Dissatisfaction in one area,	Low financial loss Possible litigation Direct loss of <£10,000	Direct loss of <£10,000 Commercial value of <£10,000	Local loss of goodwill Inefficient short-term operation of one part of the organisation	No impact to business processes, services. Not for recovery
2	Minor	Minor illness/injury likely, dissatisfaction in some areas,	Medium financial loss Litigation penalties Direct loss of <£100,000	Direct loss of <£100, 000 Value to a competitor of up to £100,000	Impact felt in other areas Inefficient medium term operation management	Impact localised, does not effect critical business processes, no timescale for recovery
3	Moderate	More than minor injuries to limited numbers Significant impact on staff satisfaction	High financial loss Litigation/penalties Direct loss of <£1 million	Direct loss of <£1 million Value to a competitor of up to £5 million	Relations with public affected Development of organisation impeded	Impact on one or more business processes, impacts on services noticeable
4	Major	Major illness/injuries to limited numbers Threat of strike/ general non Co-operation	Major financial loss Litigation/penalties Direct losses of <£3 million	Direct losses of £3 million Substantially weaken the viability and competitiveness of the local organisation	Widespread adverse publicity Development of organisation seriously affected	Major impact on one or more business processes, major impact on ability to provide services, maintain legal compliance, maintain safety
5	Catastrophic	Death or likely to risk life with associated major injuries strike/ General non Co-operation	Huge financial loss Litigation certain Potential for multiple Criminal/civil suits	Long-term damage to the organisation Lasting loss of market share	Widespread adverse publicity, future strategies seriously affected Loss of credibility	Unavailability of IT system causes irreparable damage to capability to provide service and impacts directly on patient care

Table 2 - Measure of likelihood

Level	Descriptor	Description
A	Almost certain	Is expected to occur in most circumstance
B	Likely	Will probably occur in most circumstance
C	Possible	Might occur at some time
D	Unlikely	Could occur at some time
E	Rare	May occur only in exceptional circumstance

Table 3 - Risk analysis Matrix – level of Risk

Likelihood	Consequence				
	1	2	3	4	5
A Almost certain	Mod	High	Extreme	Ext	Ext
B Likely	Mod	High	High	Ext	Ext
C Possible	Low	Mod	High	Ext	Ext
D Unlikely	Low	Low	Mod	High	Ext
E Rare	Low	Low	Mod	High	High

Part 6: Details of person(s) completing form

Consultant Name:

Directorate / Speciality:

Contact Number:

Email address:

I have read the Trust Policy on the prescribing, use and supply of unlicensed medicines and accept full responsibility for use of this medicine.

Consultant Signature: Date:

Specialist (Clinical) Pharmacist Name:

Pharmacist Signature: Date:

Business Unit Manager:

Part 7: PROCUREMENT DETAILS to be completed by Pharmacy (Procurement)

Where is the medicine to be obtained from?	
Is the supplier an approved supplier of unlicensed medicines for the Trust? (see approved unlicensed medicines supplier list)	Yes / No
Is the manufacturer in the UK?	Yes / No
Describe any problems associated with continuity of supply:	
What is the cost of the product?	
List any additional costs involved in obtaining this medicine:	

Questions 1 to 13 below to be completed if manufacturer is not in the UK:

1	Name of Country	
2	Country within EU	Yes / No
3	If country not in EU does it have a mutual recognition agreement with the UK for the manufacture of medicinal products?	Yes / No
4	Is this product licensed in the country of origin	Yes / No
5	If licensed what is the product licence number?	
6	Name of Importer	
7	Is confirmation of TSE compliance available?	Yes / No
8	Quoted importation time	
9	Quantity to be imported	
10	Language on the packaging	
11	English translation of the SPC and or Patient Information Leaflet available	Yes / No
12	Translation provided by	
13	English translations certified By whom,	Yes / No

Questions 1 to 5 below to be completed for UK 'Specials':

1	What is the Manufacturer Licence Number?	
2	Is a Batch-Specific Certificate of Analysis available?	Yes/No
3	Is a Product Specification available? If yes attach a copy. NB: If there is no product specification already available one will need to be written	Yes/No
4	Is a Certificate of Conformity/Analysis available?	Yes/No
5	Is confirmation of GMP compliance available?	Yes/No

Below for completion on receipt:

Date:	
Product name:	
Strength:	
Formulation:	
Batch number:	
Quantity received:	
Prescribers name:	

Part 8: RISK ASSESSMENT OF THE UNLICENSED MEDICINE to be completed by Pharmacy-Medicines Information (M.I.)

Can critical data be easily read?	Yes/No

Is the product presented in packaging of an acceptable quality?

Yes /No

Can expiration and storage requirements be easily identified?

Yes/No

Details of contraindications and any other risks to the patient:

Pharmaceutical Precautions / Precautions in Use:

What side effects or toxic effects have been reported?

Are there any significant interactions?

Stability information / Manipulation in pharmacy re: Health & Safety/Storage conditions:

What are the costs involved in obtaining this drug?

Excipients:

RISK LEVEL ASSIGNMENT: SCORING GUIDELINES		
Supplier		
MHRA licensed importer with full Pharmacovigilance in QMS (IDIS)	1	
Known NHS Unit with QA managed by qualified person or pharmacist	1	
Other NHS Specials Unit (not local)	2	
Commercial Specials Manufacturer (UK)	2	
Supplier not manufacturer (e.g. wholesalers)	3	
Registered Pharmacist (extemporaneous preparation)	4	
Origin		
UK manufacturers with Specials licence	0	
EU / USA / Canada / Australia / NZ and licensed in country of origin	1	
Elsewhere - licensed in country of origin	3	
EU / USA / Canada / Australia / NZ and not licensed in country of origin	3	
UK - no Specials licence (Section 10)	HIGH	
Certification		
Full analytical report available	0	
Fully licensed product with EMEA / PL number (Imports)	1	
Certificate of Analysis and GMP compliance available (Specials	1	
Certificate of Conformity available product analysed (Specials)	2	
Certificate of Conformity but no product analysis (Specials)	3	
No Certificate available / no analysis carried out (Specials)	4	
Documentation		
Product TSE compliant with English-translated SPC	1	
Product TSE compliant with no English-translated SPC	2	
Packaging & Labelling		
English	0	
Foreign language but easy to read critical data	2	
Foreign language and not easy to read critical data	4	
Specification		
BP / EP / USP monograph product	0	
Other Pharmacopoeial monograph	1	
Manufacturer's specification available	2	
No external specification available	3	
Route of Administration		
Topical to intact skin (non-sterile)	0	
Mucous membranes, broken skin, oral (non-sterile)	1	
Sterile all routes except intrathecal	2	
Sterile intrathecal	3	
Therapeutic Agent		
Established therapeutic agent - no special problems	0	
Recognised therapeutic agent - minor problems or little experience of use	2	
Novel therapeutic agent of unusual use	4	
Unrecognised therapeutic agent with some supporting information for use	6	
Unrecognised therapeutic agent with no information available	HIGH	
Recognised therapeutic agent with known problems	HIGH	
Products containing material of animal or human origin	HIGH	
TOTAL SCORE		
LOW	0 to 5	
MEDIUM	6 to 14	
HIGH	15 to 26	
RISK LEVEL =		

Part 9: Outcome of Risk Assessment

Formulary Working Group approved?	Yes / No
Reasons if not approved:	
Restrictions on prescribing:	
Date of review: (Max 5 years)	
Name:	
Signed: (FWG member)	Date:

Part 10: DISPENSING DETAILS to be completed on issue by Pharmacy (Dispensary)

Drug name:
Brand/manufacturer:
Form:
Strength:
Quantity supplied:
Batch number:
Expiry date:
Patient name:
Hospital number (RLQ):
Ward:
Date:

APPENDIX 5

Department of Pharmacy

SPECIAL/UNLICENSED MEDICINES

Our goal is to provide EXCELLENT care. We hope that we have been able to exceed your expectations for care when you visited this hospital. If there was anything that we could have done better please tell us, your opinion is important to us.

Please contact the appropriate department but if you have any further comments, you can speak to the Patient Advice and Liaison Service on the number below.

Thank you for choosing Hereford Hospitals

This information leaflet is also available in Large Print (it is also available in Braille, other languages and on audio tape on request). Please contact PALS on
01432 372986

Date Written: Oct 2011
Reviewed Feb 2014. Next review due: 2016
Written by Joanne Howe (M.I.Technician)

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Special/Unlicensed Medicines

Information for Patients, Parents and Carers

Most medicines used in the UK are approved for use by the government's Medicines and Healthcare products Regulatory Agency (MHRA). These medicines are called 'Licensed Medicines'. Without such approval, manufacturers are unable to advertise and promote their medicines.

Why are medicines usually 'Officially Approved' (Licensed)?:
Approval by the MHRA helps to ensure that medicines:
- Are safe and effective
- Do not cause too many side-effects
- Are manufactured appropriately

Special/Unlicensed Medicines:
Sometimes doctors may prescribe medicines that have not gone through this approval process. These medicines are called 'Special Medicines' or 'Unlicensed Medicines'.

Your Special/Unlicensed medicine is called……..

and has been prescribed for (indication)……...

Special/Unlicensed medicines may be manufactured in the UK by a specials manufacturer or may be imported through specialist importers. Doctors and Pharmacists will only prescribe/supply 'Special/Unlicensed Medicines' when it is considered to be the most appropriate treatment and licensed alternatives are not available.

Does unlicensed mean unregulated? No, although the medicine is classed as unlicensed, a UK manufacturer must hold a 'Specials Licence'. The special (unlicensed) products in the UK must be manufactured in accordance with GMP (Good Manufacturing Practices) and are regulated and inspected by the MHRA.

The Department of Pharmacy at Wye Valley NHS Trust, only purchase imported unlicensed medicines through specialist importers who adhere to MHRA guidance. In addition, each product is risk assessed before being issued to the patient.

Why do doctors prescribe 'Special/Unlicensed Medicines'?
Some examples:

- Unlicensed formulations may be used because no suitable licensed product exists i.e. discontinued UK licensed product, temporary supply shortage of UK licensed product.

- Research may have shown that the special/unlicensed treatment is better than one that has been officially approved, but the manufacturer of the treatment may not have requested approval for this use or they may be waiting for approval.

- The product may be licensed in another country e.g. Germany, but not in the UK.

- The medicine may be licensed for use in adults, but doctors may have found that it is also suitable for use in children.

- A licensed medicine may not be available in a liquid formulation. A specially prepared liquid formulation may be required for adult patients with swallowing difficulties or for use in children.

What differences might be noticed, if prescribed/supplied with a Special/Unlicensed Medicine?

- The prescribing Doctor or Pharmacist may provide some separate information about the medicine. Please read this carefully and follow all instructions

- The manufacturer's information leaflet may not include information about the condition to be treated, use in the elderly or in children, or the dose may be different from that which the Doctor has prescribed.

What do I do if I want more information?
If you have concerns about any medicine, licensed or unlicensed, or you require further information and advice, please speak to your Doctor or the Medicines Information Department at Wye Valley NHS Trust.

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