Appendix 2

Pharmaceutical Services

Risk assessment tool for use with unlicensed medicinal products.

This risk assessment tool must be used to risk assess all unlicensed products used within SFT in accordance with the Trust policy on unlicensed medicines. Each product will receive an overall risk rating of either HIGH or LOW which will be determined by considering both the level of potential risk posed by the product itself and the level of potential risk posed by the actions of the product on or within the body.

Risk assessments will be carried out by pharmacy staff and submitted to the Drugs and Therapeutics Committee for approval. The level of risk will determine the conditions of use of the product – see unlicensed medicines policy.

Product	Risk rating:

PRODUCT INFORMATION			
Product name, form, strength			
Details of manufacture & supply (give both if different)			
Intended therapeutic use		Product type: Drug / Dressing / Food Supplement /Other…….	
Reason required			
Proposed distribution (e.g. named patient/ ward stock etc)		Specialty/ Client group	
Level of clinical need for product (est. usage pa)			
Does the Manufacturer hold a specials license for item? (note no.)	YES/NO License No;		
In which country is the item manufactured?			
Is the product licensed in any country? If so where ?	YES NO Where Licensed:		
Is a batch specific Certificate of Analysis (CofA) available?	YES/NO	Is a batch specific Certificate of Conformity available?	YES/NO
Is there a specification available?	YES/NO	Where is specification available from ?	
Does labeling format conform to UK standards?	YES/NO	Is label legible?	YES/NO
Is label information unambiguous?	YES/NO	Does label contain all necessary information?	YES/NO
Is a PIL available?	YES/NO	Is any other product info available?	YES/NO
Has any info been translated from another language?	YES/NO	Are special storage conditions required? (i.e. refrigeration)	YES/NO
Is the packaging satisfactory?	YES/NO		
Other information / comments:			

Risk assessment score for product		
Supplier;		
Local unit with QA managed by Regional QA Lab	0	
Commercial Specials Manufacturer (UK)	0	
Other NHS licensed specials unit (not local)	1	
Supplier **not** manufacturer (importers etc)	2	
Origin;		
UK manufacturer with specials license	0	
EU/USA/Canada/NZ and licensed in country of origin	1	
EU/USA/Canada/NZ and **NOT** licensed in country of origin	2	
Elsewhere – licensed in country of origin	3	
Elsewhere – **NOT** licensed in country of origin	4	
UK – no specials license	15	
Certification;		
Full analytical report available	0	
Batch specific Certificate of Analysis available	0	
Batch specific Certificate of Conformity available	2	
No certificate available (fully licensed product in country of origin)	3	
No certificate available	4	
Specification;		
BP/EP/USP monograph product	0	
Other Pharmacopoieal monograph	1	
Manufacturers specification available	2	
No external specification available	3	
Sub-total risk score for product		
Risk assessment score for actions of product		
Route of administration;		
Topical to intact skin (non-sterile)	0	
Mucous membranes or 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 or unusual use	4	
Unrecognised therapeutic agent with some supporting evidence for use	6	
Unrecognised therapeutic agent with no information available	15	
Recognised therapeutic agent with known problems	15	
Products containing material of animal or human origin	15	
Sub-total risk score for actions of product		

Total score = sub-total for product + sub-total for actions of product:
Products scoring a total of 0 - 14, = LOW risk rating Products scoring a total of 15 or above = HIGH risk rating **OVERALL RISK RATING FOR THIS PRODUCT: HIGH/LOW** (delete as appropriate)

Risk assessment carried out by: Date:
Risk assessment checked by: Date:
Risk assessment agreed by DTC: Date: