

Appendix 8 – Hospital Pharmacy Risk Assessment Form for an Unlicensed Medicine

Product Name:

Manufacturer:

Strength/Form:

Code:

Supplier:

Pack Size:

Risk Assessment (RA): Scoring			
Supplier	Score	Pharmacy Action	
MHRA licensed importer with full pharmacovigilance in QMS (e.g. IDIS/Durbin/ULM)	1		
NHS Specials Unit with QA managed by qualified person or pharmacist	1		
Commercial Specials Manufacturer (UK)	2		
Supplier not manufacturer (e.g. wholesalers)	5		
Registered Pharmacy (extemporaneous preparation)	10		
Origin			
UK manufacturers with Specials license	1		
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		
Elsewhere e.g. China, India and not licensed in country of origin	10		
UK Registered Pharmacy (extemporaneous preparation)	10		
Certification			
Full analytical report available	0		
Fully licensed product with EMEA/PL number (imports)	1		
Certificate of Analysis and Good Manufacturing Practice (GMP) compliance available (Specials)	1		
Certificate of Conformity available product analysed (Specials)	2		
Certificate of Conformity but no product analysis (Specials)	5		
No Certificate available/no analysis carried out (Specials/Section 10)	10		
Documentation			
Product TSE compliant with English-translated SPC	1		
Product TSE compliant with no English-translated SPC	2		
UK manufactures Special/Section 10 - product TSE compliant with no product information	2		
No product TSE compliance certification	10		
Packaging and Labelling			
English	0		
Foreign language but easy to read critical data	5		
Foreign language and not easy to read critical data	10		
Specification			
BP/EP/USP monograph product	0		
Other Pharmacopoeial monograph	1		
Manufacturer's specification available	2		
No external specification available	5		
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	HIGH	HIGH	
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	10		
Recognised therapeutic agent with known problems	10		
Products containing material of animal or human origin	10		
Total Score			
LOW	0 to 8		
MEDIUM	9 to 16		
HIGH	17 to 44		
Risk Category Signed off by:	Date:		