

## Risk Assessment Form for an Unlicensed Medicine

Product Name:

Manufacturer/

Strength/Form/

Code:

Supplier:

Pack size:

<b>RISK ASSESSMENT (RA): SCORING</b>		
<b>Supplier</b>		
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 <b>not</b> manufacturer (e.g. wholesalers)	5	
Registered Pharmacy (extemporaneous preparation)	10	
<b>Origin</b>		
UK manufacturers with Specials licence	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 <b>not</b> licensed in country of origin	3	
Elsewhere e.g. China, India and <b>not</b> licensed in country of origin	10	
UK Registered Pharmacy (extemporaneous preparation)	10	
<b>Certification</b>		
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 <b>no</b> product analysis (Specials)	5	
No Certificate available / no analysis carried out (Specials / Section 10)	10	
<b>Documentation</b>		
Product TSE compliant with English-translated SPC	1	
Product TSE compliant with <b>no</b> English-translated SPC	2	
UK manuf. Special/ Section 10 – product TSE compliant with no product information	2	
No product TSE compliance certification	10	
<b>Packaging &amp; Labelling</b>		
English	0	
Foreign language but easy to read critical data	5	
Foreign language and <b>not</b> easy to read critical data	10	
<b>Specification</b>		
BP / EP / USP monograph product	0	
Other Pharmacopoeial monograph	1	
Manufacturer's specification available	2	
No external specification available	5	
<b>Route of Administration</b>		
Topical to intact skin (non-sterile)	0	
Mucous membranes, broken skin, oral (non-sterile)	1	
Sterile all routes except intrathecal	2	
Sterile intrathecal	3	
<b>Therapeutic Agent</b>		
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	
<b>Total Score</b>		
<b>LOW</b>	<b>0 to 8</b>	
<b>MEDIUM</b>	<b>9 to 16</b>	
<b>HIGH</b>	<b>17 to 44</b>	

RA Signed Off by (Print name):

Signature:

Date:

Designation: