

Appendix 4 Unlicensed Medicine Evaluation (UME) form (Pharmacy to complete)

Complete for all products:	
Product Name and strength: (rINN, including salt and Brand name)	Acarizax 12 SQ-HDM oral lyophilisate
Pack Size:	30
Route of administration:	Oral
Manufacturer (name & contact details):	[REDACTED]
Supplier (name & contact details):	[REDACTED]
Country of Origin:	[REDACTED]
Storage Conditions:	No special storage conditions
Shelf Life:	4 years
Cost: (include how long price is held)	[REDACTED] oral lyophilisates
Delivery lead time: (with / without Certification)	72 hours once initial documentation is complete
Imported Product – contact supplier / manufacturer to obtain the following details:	
Supplier: Has the company got the appropriate licence to import medicines into the UK?	Yes
Origin: Is product licensed in country of origin? <input checked="" type="checkbox"/> Yes / No (Circle as appropriate) If yes, record licence number: PA1255/010/001	Licensed in ROI - UK use this stock.
Is product licensed in: <input checked="" type="checkbox"/> EU <input checked="" type="checkbox"/> USA <input checked="" type="checkbox"/> Canada <input checked="" type="checkbox"/> NZ <input checked="" type="checkbox"/> Australia <input checked="" type="checkbox"/> Japan <input checked="" type="checkbox"/> Yes / No (Circle as appropriate). State country: Austria, Belgium, Croatia, Czech Republic, Denmark	Finland, France, Germany, Hungary, Ireland, Italy, Luxembourg, Malaysia, Netherlands, Hong Kong, Israel, Japan, Norway, Philippines, Poland, Romania, Russia, Saudi Arabia, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, United Arab Emirates.
Certification: Is certificate of analysis / conformity available? <input checked="" type="checkbox"/> Yes / No (Circle as appropriate).	
Packaging & labelling: Is product package English labelled? <input checked="" type="checkbox"/> Yes / No (Circle as appropriate)	
Is English SmPC & PIL available? Yes If yes, obtain copy of English SmPC & PIL and attach	Attach SmPC & PIL Attached
Product sourced from NHS / Non-NHS Specials Licensed Manufacturer in UK:	
Manufacturer's Licence No:	n/a
Is Stability data available Yes / No If yes, obtain specification and attach	Attach specification
Is product specification available Yes / No If yes, obtain specification and attach	Attach specification
Is product analysed using Physical / Chemical / Microbiological tests before release. If yes, obtain written confirmation stating the types of tests applied and attach.	Attach confirmation
Is certificate of analysis/conformity available? Yes / No State type of certificate: If yes, obtain written confirmation stating the product analysis applied and attach.	
Completed by: Niamh Tyrie	Date: 05.01.21

Attach completed form to papers for D&T submission