SAR Application Checklist

Special Access Route (Named-Patient), HSA Singapore · Innorini Pte Ltd (UEN 202015523Z)

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Use this checklist to prepare the documents for a Named-Patient SAR application. Tick each item before the application is submitted.

Section 1: Prescribing doctor

- [ ] Patient diagnosis and medical history documented
- [ ] Clinical justification for the unregistered product written
- [ ] Reasons for not using registered alternatives stated
- [ ] Proposed dosage and duration specified
- [ ] Informed consent obtained from the patient (or guardian) and documented
- [ ] MOH compliance declaration signed
- [ ] SMC Ethical Code declaration signed
- [ ] HSA Signed Request Form (Named-Patient) completed and signed
- [ ] For investigational products: professional consensus from local peer clinician(s) obtained

Section 2: Clinic or hospital

- [ ] Institution licence verified and current
- [ ] Patient is under the care of a doctor at this institution
- [ ] Signed Request Form received from the doctor
- [ ] Product name, strength and formulation confirmed
- [ ] Estimated quantity needed (maximum 3 months' supply per patient per consignment)
- [ ] Delivery address and contact person confirmed

Section 3: Company applying on the institution's behalf

- [ ] HSA Importer's Licence current and valid
- [ ] HSA Wholesaler's Licence current and valid
- [ ] Qualified pharmacist named as Responsible Person
- [ ] Product source and manufacturer verified
- [ ] Product labels (outer, inner, package insert) in English, first application only
- [ ] SAR online application form (Sections A to E) completed
- [ ] Application submitted via Corppass
- [ ] 24-character HSA reference number recorded
- [ ] HSA clarification requests answered promptly

- [ ] Import and customs clearance arranged
- [ ] Cold chain maintained if required
- [ ] Product labelled with the patient's name
- [ ] Delivery to the licensed institution arranged

Section 4: Key facts at a glance

Named-Patient approval	Valid 6 months
Buffer Stock approval	Valid 12 months (essential medicines for hospital stock)
Maximum supply per consignment	3 months per patient (Named-Patient)
HSA target turnaround	14 working days, excluding clarification time
HSA fee	None
Submission	Online via Corppass
Controlled drugs	Additional import licence required
Ongoing supply	New application after the approval expires

HSA does not assess the safety, quality or efficacy of products supplied through SAR; the requesting doctor or dentist is fully responsible for their use. Innorini helps clinics prepare SAR documents and coordinate sourcing.

Reference only. Always check current requirements at hsa.gov.sg; this checklist is not medical or regulatory advice.
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