Probiotic Adverse Event — Documentation Checklist

Tick every item before you submit any AE report. Missing strain, lot, or timing data is the single most common reason a probiotic AE report is rejected by FDA MedWatch, EU national authorities, MHRA Yellow Card, RASFF, or a manufacturer's pharmacovigilance team. Use alongside the full AE Report Template (PDF/CSV).

1 — Reporter & patient

- [ ] Report date and internal report ID assigned
- [ ] Reporter name, role, institution, contact
- [ ] Patient ID (de-identified)
- [ ] Age, sex, weight, pregnancy status
- [ ] Care setting at time of event (clinic / ED / inpatient / ICU)
- [ ] Consent / privacy reviewed per local policy

2 — Product identification (REQUIRED for any escalation)

- [ ] Brand name AND manufacturer captured
- [ ] NDC / GTIN / EAN recorded
- [ ] Lot / batch number — photographed if possible
- [ ] Expiry date
- [ ] CFU per dose as printed on the label
- [ ] Dosage form (capsule / sachet / liquid / chewable)
- [ ] Storage at point of use (ambient / refrigerated / cold chain breach?)
- [ ] Remaining product retained and quarantined

3 — Strain-level detail (every strain on the label)

- [ ] Genus and species written in full for each strain
- [ ] Strain designation (e.g. CNCM I-745, ATCC 53103, DSM 17938)
- [ ] CFU contribution per strain if multi-strain product
- [ ] Country of purchase / market authorisation jurisdiction

4 — Dose & exposure window

- [ ] Indication for use (and prescribed vs self-initiated)
- [ ] Dose per administration and frequency (BID / TID / etc.)
- [ ] Route (PO / NG / vaginal / topical)
- [ ] Total daily CFU calculated
- [ ] Date of FIRST dose
- [ ] Date of LAST dose
- [ ] Total duration of use (days)
- [ ] Doses missed / adherence noted
- [ ] Co-administered antibiotics, supplements, drugs

5 — Risk factors at exposure

- [ ] Central venous catheter (in situ or planned)
- [ ] Severe immunosuppression / neutropenia
- [ ] Prosthetic heart valve
- [ ] Short bowel syndrome
- [ ] Severe acute pancreatitis
- [ ] Preterm / NICU patient
- [ ] Active GI mucosal injury / mucositis
- [ ] Age ≥ 75, pregnancy, infant < 12 months
- [ ] Chronic steroids / biologics / chemotherapy

6 — Event timeline (timestamps, not just dates)

- [ ] Date AND time of symptom onset
- [ ] Time from first dose to onset
- [ ] Time from last dose to onset
- [ ] Date / time the product was stopped (dechallenge)
- [ ] Date / time medical care was sought
- [ ] Resolution date and dechallenge response (improved / unchanged / worsened)
- [ ] Rechallenge attempted? Outcome documented
- [ ] Outcome: resolved / ongoing / sequelae / fatal

7 — Symptoms, severity & seriousness

[ ] Symptom list with onset, character, and severity 1–10

[ ] Vital signs at presentation (T, HR, BP, SpO2)

[ ] Seriousness criteria ticked: death / life-threatening / hospitalisation / disability / congenital / other-important

[ ] Free-text narrative attached

8 — Diagnostics & microbiology

[ ] CBC, CRP / procalcitonin, basic chemistry

[ ] Blood cultures (paired peripheral + line)

[ ] Catheter tip culture if line removed

[ ] Stool culture / PCR if GI signs

[ ] Imaging (echo / CT / US) if indicated

[ ] Strain ID method (MALDI / 16S / WGS) recorded

[ ] ANI vs re-isolated product colony (≥ 99.9% = identity)

[ ] Resistance gene scan: vanA/B, ermB, tetM/W, aac(6′)-aph(2″)

9 — Management

[ ] Probiotic stopped — date / time and dechallenge response

[ ] Empiric antimicrobials (drug, dose, route, duration)

[ ] Vancomycin AVOIDED for Lactobacillus (intrinsic resistance) — noted in chart

[ ] Source control performed (line removal, drainage, surgery)

[ ] Supportive care / ICU interventions documented

10 — Causality assessment

[ ] WHO-UMC category selected (certain / probable / possible / unlikely / unassessable)

[ ] Plausible time relationship documented

[ ] Alternative explanations considered and excluded

[ ] Dechallenge / rechallenge evidence captured

[ ] Strain identity confirmed (or not) by ANI

11 — Reporting submitted

[ ] FDA MedWatch (3500 / 3500B) — reference ID

[ ] FDA Safety Reporting Portal (mandatory ≤ 15 days for serious AE)

[ ] RASFF alert (EU contamination signal)

[ ] EU national competent authority — reference ID

[ ] MHRA Yellow Card (UK)

[ ] Livsmedelsverket / Läkemedelsverket (SE)

[ ] Manufacturer pharmacovigilance — reference ID

[ ] Internal escalation: pharmacy / IPC / AMR stewardship

[ ] EARS-Net (EU) or CDC AR Lab Network (US) for resistance gene findings

12 — Post-report actions

[ ] Allergy-style EHR flag added naming the strain mix

[ ] Hard stop / no-rechallenge order entered

[ ] Patient counselled on what happened and why

[ ] Patient handout provided (red-flag symptoms + reporting routes)

[ ] Lot quarantined for ≥ 12 months or until case closure

[ ] Case scheduled for pharmacovigilance review meeting

Final sign-off: Reporter signature _____ Date _____ Pharmacovigilance reviewer _____ Date _____