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**POSITION PAPER ON THE USE OF  
SWARNABHASMA/SWARNAKALPA AS AN “IMMUNE  
BOOSTER” IN INFANTS AND CHILDREN OF NEPAL**

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**USE OF GOLD AS IMMUNE BOOSTER IN CHILDREN**



**POSITION PAPER-IV**

Position Paper on the use of Swarnabhasma/Swarnakalpa as an “Immune Booster.” In Infants and Children of Nepal. Endorsed by Nepal Paediatric Society (NEPAS)

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# Position Paper on the use of Swarnabhasma/ Swarnakalpa as an “Immune Booster” in Infants and Children of Nepal

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**Subject:** Use of “Gold” salt and Honey in small children

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## EXECUTIVE SUMMARY

**Position:** NEPAS does not recommend routine administration of *Swarnabhasma/Suvarnakalpa* to infants or children for “immune boosting,” whether through public programs or in private practice.

### Why.

1. No proven benefit: The only randomized controlled trial (RCT) in infants found no superiority of Swarnakalpa (gold + ghee + honey) over ghee + honey alone on immunologic outcomes.
2. Age-specific hazard: Most Swarnabhasma formulas contain honey, which is contraindicated in infants <12 months due to infant botulism risk.
3. Gold risk: Gold is a non-essential heavy metal. Medicinal gold exposure has documented contact allergies and systemic toxicities (cytopenia, nephrotic syndrome, hepatitis, pneumonitis, stomatitis/diarrhoea).
4. Product quality: Independent surveys show a substantial minority of Ayurvedic products contain lead/mercury/arsenic; paediatric lead-poisoning clusters have been linked to such medicines.
5. Biology ≠ “boosting”: Reviews of gold compounds/nanoparticles show context-dependent (sometimes suppressive) immune effects, not reliable enhancement in healthy children.
6. Regulatory clarity lacking: Public verification of Department of Drug Administration (DDA) registration and lot-wise Certificates of Analysis (COAs) for the product being rolled out has not been presented alongside the launch.

**Consensus:** The majority of NEPAS members do not agree to giving Swarnabhasma/Swarnakalpa to children.

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## HEADLINE RECOMMENDATION TO GOVERNMENT

Announce an immediate moratorium on population-level distribution; consider use only inside registered, independent clinical trials with third-party product testing and active safety monitoring.

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## SCOPE & AUDIENCE

This paper informs:

- Government of Nepal (MoHP), Department of Drug Administration (DDA), provincial and local authorities
  - Practising paediatricians and child-health providers in Nepal
  - Public health partners and the media
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## BACKGROUND

- Swarnabhasma (Suvarna/Svarna bhasma): calcined gold preparation used in Ayurveda.
- Swarnakalpa: oral “electuary” traditionally mixing Swarnabhasma with ghee (ghṛita) and honey; given as drops [Electuary-Medicinal substance mixed with honey or another sweet substance].
- Program context in Nepal: Public announcements indicate intent to provide Swarnabhasma to children (often cited 6–59 months) through Ayurveda facilities; parallel reporting raises questions about registration/renewal of the specific product(s) with DDA.

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## EVIDENCE OF EFFECTIVENESS

### 1) Infants (0–12 months)

- Design: Single-blind RCT; Swarna bhasma + ghee + honey vs ghee + honey for 4 weeks; 8-week follow-up.
- Outcome: Both groups showed within-group IgG rises, but no significant between-group difference in IgG or other immunologic markers.
- *Interpretation: Adding gold did not outperform the carrier (ghee + honey).*

### 2) Toddlers/preschoolers (2–5 years)

- Design: Open-label, single-arm interventional study (n≈30, 8 weeks).
- Outcome: Within-group changes in immunoglobulins/complements and symptom scores; no control group; authors acknowledge small sample and limited endpoints.
- *Interpretation: Cannot establish efficacy.*

### 3) Reviews

- Ayurveda-focused review (2025): Collates small, heterogeneous studies; suggests possible benefit but explicitly notes methodological weaknesses and immunosuppression signals from some gold literature.

**Overall conclusion:** *There is no high-quality clinical evidence that Swarnabhasma reduces infections, hospitalizations, or improves growth/neurocognition. The only infant RCT is negative for superiority.*

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## SAFETY, ADVERSE EFFECTS & CONTRAINDICATIONS

### A) Honey in infants

- Do not give honey to infants <12 months: risk of infant botulism from *Clostridium botulinum* spores.  
Program implication: Any honey-containing Swarnabhasma is contraindicated in babies under one year.

### B) Gold exposure (heavy-metal and drug experience)

- Contact allergy to gold: common in patch-test populations (~14% pooled).
- Systemic toxicities noted with auranofin/injectable gold in rheumatology include:
  - Hematologic: thrombocytopenia, leukopenia/other cytopenia
  - Renal: proteinuria, membranous glomerulonephritis (nephrotic syndrome)
  - Hepatic: hepatitis
  - Pulmonary: interstitial pneumonitis
  - Mucocutaneous/GI: stomatitis, diarrhoea

This mandates close monitoring and frequent drug discontinuation.

*Note:* Doses/forms differ from bhasma, but these data show biologically plausible organ/immune toxicities from systemic gold.

- Gold nanoparticles (AuNPs): Preclinical work shows organ accumulation (liver/spleen; sometimes kidney/brain) and bidirectional immune effects depending on size/coating/dose—not a basis for prophylactic “immune boosting” in healthy children.

### C) Product quality / contamination

- Market surveys of Ayurvedic medicines (online and retail) found ~20% with lead, mercury, and/or arsenic; paediatric lead-poisoning clusters have been linked to Ayurvedic products.

*Program implication: Without lot-wise independent testing, contamination is a credible harm pathway.*

### D) Contraindications & precautions

- Absolute: Infants <12 months (if any honey is present).
- Relative/medical: Prior gold allergy; history of gold-therapy reactions; renal/hepatic disease; concurrent metal-containing or unverified herbal products (additive exposure).

*If ever used in research: baseline and interval CBC, urinalysis (protein), LFTs in sentinel cohorts; stop if abnormalities or clinical reactions occur.*

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## GOLD AS A HEAVY METAL-PAEDIATRIC CONSIDERATIONS

- Classification: By common usage (density >5 g/cm<sup>3</sup>), gold (19.3 g/cm<sup>3</sup>) is a heavy metal.
- Nutrition: Gold is not an essential human nutrient; there is no physiological requirement.
- Children’s vulnerability: higher dose per kg, developing organs/immune system → lower tolerance for avoidable metal exposures.

*Principle: Avoid giving non-essential heavy metals to healthy children for unproven indications.*

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## PRODUCT IN USE (AS PER PHOTOGRAPHED IMAGE IN NEPAL)

- Trade name on pack: “Suvarna (Svarna) Bhasma — Premium Quality Suvarnakalpa.”
- Manufacturer: Shree Dhootapapeshwar Ltd. (India).
- Gold content: Independent literature shows wide variability across brands/lots (~32–98% Au by mass). One Dhootapapeshwar-sourced batch (industry-funded paper) reported ~98% Au by ICP-AES.

*Implication: Each lot intended for paediatric use in Nepal must have independent, third-party assays (Au %, and Pb/Hg/As, plus microbiology) with public COAs.*

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## REGULATORY CONTEXT IN NEPAL

- DDA is the authority for medicine registration, import/manufacture permission, and labelling.
- Media reports describe plans to distribute Swarnakalpa through Ayurveda facilities and, separately, allege lack of active DDA registration/renewal for the product/active now in use.
- NEPAS request: Before any paediatric use, MoHP/DDA should publish on an official page:
  - Registration certificate numbers (product and active), validity dates, indication/age, dosage form/pack
  - Import/manufacture authorization for the exact brand/lot
  - Lot-wise independent COAs (Au %, Pb/Hg/As within limits, microbiology)
  - Age warning: “Not for infants <12 months (contains honey)” where applicable

## MARKETED CLAIMS & NEPAS REBUTTAL (FOR CLINICIANS & REGULATORS)

COMMON CLAIMS	NEPAS REBUTTAL
“Boosts immunity”	The infant RCT shows no added benefit over ghee + honey; Au/AuNP literature shows context-dependent, not reliably beneficial, immune effects.
“Safe for 0–16 years / ‘Ayush/GMP certified’ ”	Honey makes it unsafe <12 months; GMP/AYUSH marks do not prove efficacy or lack of contamination; medicinal gold history shows serious adverse reactions.
“Improves memory/IQ/complexion/lifespan”	No blinded, controlled paediatric trials support these outcomes; small, uncontrolled studies cannot establish causality.
“Tiny 24K gold so harmless”	Dose & form matter; AuNPs can accumulate; gold drugs demonstrate organ/immune toxicities.
“Authorised in India → OK for Nepal”	Nepal’s DDA registration and lot testing are required for use in Nepal, especially in children.

## RECOMMENDATIONS

### A) To the Government of Nepal (MoHP)

1. Announce a moratorium on routine paediatric use of Swarnabhasma/Swarnakalpa.
2. Publish DDA registration details and lot-wise COAs (Au %, Pb/Hg/As, microbiology) for any product proposed for children.
3. If evaluation is desired, commission independent, registered RCTs comparing gold + carrier vs carrier (ghee + honey), powered for clinical outcomes (infection incidence/hospitalization), with DSMB oversight, pre-specified stop-rules, and active pharmacovigilance.
4. Exclude infants <12 months from any honey-containing preparation; require explicit age warnings on labels and in communications.
5. Prioritise proven child-health measures: exclusive breastfeeding, on-time immunisation, vitamin A, zinc for diarrhoea, nutrition and WASH.

### B) To the Department of Drug Administration (DDA)

1. Verify and publicly list: Registration certificate numbers/validity, indications/age groups, dosage forms, importer/manufacture for the exact brand/lot used.
2. Mandate & publish independent batch testing for Au %, Pb/Hg/As, and microbiology before any paediatric dispensing.
3. Enforce truthful advertising; prohibit unsubstantiated paediatric claims (“immunity,” “IQ,” “complexion,” “lifespan”).

### C) To members of NEPAS & Practising Paediatricians

1. Do not prescribe or endorse Swarnabhasma/Swarnakalpa as an immune enhancer.
2. Counsel families: no proven added benefit; honey unsafe <12 months; potential for gold-related AEs and contamination.
3. Report suspected adverse events linked to metal-containing/Ayurvedic products to the national pharmacovigilance system and NEPAS.

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## IF GOVERNMENT PROCEEDS DESPITE ADVICE (HARM-REDUCTION GUARD-RAILS)

- Exclude <12 months outright if any honey remains in the formula.
- Require lot-wise independent COAs (Au %, Pb/Hg/As, microbiology) published online prior to release.
- Implement active pharmacovigilance: sentinel cohort CBC, urinalysis (protein), LFTs; symptom monitoring for rash/eczema, stomatitis, eosinophilia/cytopenias, proteinuria, elevated LFTs, respiratory symptoms; stop-rules and referral pathways.
- Register any distribution as a clinical trial with DSMB/NHRC; pre-define endpoints (e.g., infection incidence/hospital days), analysis plan, and transparency commitments.

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## COMMUNICATION TOOLKIT (FOR CLINICS & PARENTS)

- “There is no proven added benefit of gold over ghee + honey in infants; the best trial showed no superiority.”
- “Honey is unsafe for babies under 12 months because of infant botulism.”
- “Gold is a non-essential heavy metal; some forms can accumulate, and medicinal gold has known toxicities.”
- “For strong immunity: exclusive breastfeeding, on-time vaccines, good nutrition (vitamin A where indicated), clean water/sanitation, and prompt care-seeking.”

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## CONCLUSION

**Until clear, public proof of DDA registration and lot-wise quality testing is provided, and in light of no proven clinical benefit and credible safety risks (including honey <12 months), NEPAS and its members oppose the routine administration of Swarnabhasma/Swarnakalpa to infants and children in Nepal and urges an immediate moratorium pending proper regulatory compliance and high-quality trials.**

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