NPD Pathways Service

Your expert-led pathway to a market-ready, TGA-compliant supplement — turning an idea into a validated, production-ready product.

Prevention is better than cure.

DE-RISK YOUR LAUNCH

Bringing a new supplement to market is exciting — but the path from concept to compliant, shelf-ready product is full of technical, regulatory and commercial decisions. The **AWS360 NPD Pathways Service** takes that weight off your shoulders. Our team assesses your idea from every angle and hands you a clear blueprint for launch.

01 What is the NPD Pathways Service?

It's a structured, front-loaded assessment of your product concept — carried out by our technical, regulatory and manufacturing specialists before you commit to production. Rather than discovering problems late (and expensively), we surface them early and design around them.

The service culminates in a comprehensive **NPD Brief** — your single source of truth covering formulation, evidence, packaging, regulatory pathway, manufacturing feasibility and next steps. It's the document you take to your board, your investors, or simply your own decision to proceed.

Assess
Feasibility, ingredients & route to market

De-risk
Regulatory, evidence & compliance up front

Blueprint
A complete NPD Brief to launch from

02 Who it's for

Start-ups & emerging brands

Especially those navigating **Australian TGA compliance** for the first time. We translate a complex regulatory landscape into clear, actionable steps — so you can move forward with confidence instead of guesswork.

International brands

Established brands **entering the Australian market** who need locally-compliant, registered products. We adapt your existing range to Australian requirements and map the fastest compliant route to shelf.

03 Why the Australian market is different

Australia's Therapeutic Goods Administration (TGA) regulates supplements as therapeutic goods — one of the most rigorous frameworks in the world. Getting it right is essential; getting it wrong is costly. Our service is built around it.

- **Listed Medicines (AUST L)** — most supplements are listed via self-assessment through the TGA Business Services portal.
- **Permitted ingredients & indications** — only approved ingredients and low-risk claims may be used; we check every one.
- **Evidence obligations** — sponsors must hold evidence to support their claims; we outline exactly what's required.
- **Labelling & advisory statements** — strict rules govern what appears on-pack; we build these into artwork from the start.

04 What you receive — the NPD Brief

A detailed, confidential document prepared specifically for your product. It covers eight areas:

1 Product Overview
Format, pack, market, channel and target consumer.

2 Summary & Recommendation
Our expert view and recommended pathway.

3 Formulation & Ingredients
Proposed actives, forms, doses and rationale.

4 Efficacy Evidence Summary
Evidence behind each ingredient and claim.

5 Dosage Form & Packaging
Recommended format, packaging and shelf-life.

6 Regulatory Compliance
Classification, indications and labelling.

7 Manufacturing Feasibility
MOQs, lead times, stability and supply notes.

8 Next Steps Roadmap
A clear route from brief to production.

05 How the pathway works

1. **NPD Brief sign-off** — you confirm the formulation, indications and pack format.
2. **Manufacturing quotation & sign-off** — a firm quotation covering unit cost, packaging, freight and lead time. No further commitment until you accept.

3. **NPD phase** — prototype samples produced, tested and tasted, with the formulation fine-tuned to an approved master formulation.
4. **Artwork development** — label and packaging artwork developed to TGA labelling requirements, with your written sign-off.
5. **TGA listing submission** — AUST L self-assessment lodged via the TGA Business Services portal. We can support this or refer a preferred consultant.
6. **Purchase order & production** — production slot confirmed and your product is made, ready for freight and delivery.

The NPD Brief does not constitute a manufacturing quotation, a regulatory opinion, or a guarantee of product performance or marketability. Final formulation and indications are confirmed at quotation stage; regulatory outcomes are subject to TGA assessment.

Start your NPD Brief

Tell us about your product idea — even a rough one — and we'll begin mapping your pathway to a compliant, market-ready launch.

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AWS360 *Prevention is better than cure.*

NPD Pathways Report

SAMPLE REPORT

The following pages are a worked example of an NPD Pathways Report — the blueprint AWS360 prepares for every new product concept. It's the platform from which you take the next concrete steps: an accurate manufacturing quotation, sample development, and preparation of your regulatory dossier, among others.

Prevention is better than cure.

WORKED EXAMPLE

New Product Development Brief

SAMPLE NPD BRIEF — ILLUSTRATIVE PURPOSES ONLY

DOCUMENT DETAILS

Document Reference:	AWS360-NPD-2024-001
Prepared by:	AWS 360 New Product Development Team
Date:	April 2024
Status:	Draft for Client Review
Client:	[Client Company Name]
Confidentiality:	Strictly Confidential — For Named Recipient Only

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New Product Development Brief

SAMPLE NPD BRIEF — ILLUSTRATIVE PURPOSES ONLY

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New Product Development Brief

SAMPLE NPD BRIEF — ILLUSTRATIVE PURPOSES ONLY

1. PRODUCT OVERVIEW

Working Title	VitaCharge Effervescent
Dosage Form	Effervescent tablet
Pack Format	20 tablets per tube, (20-day supply at recommended dose)
Intended Market	Australia
Sales Channels	Pharmacy, Supermarket, Online, E-commerce, Social Media
Regulatory Classification	Australia: TGA, Listed Medicine (Aust-L)
Target Consumer	Male & Female 20+, active lifestyle, health-conscious
Target Consumer Price	$15

2. SUMMARY

The proposed formulation is designed to support energy metabolism, immune function, and daily hydration in active adults. The ingredient selection reflects both clinical evidence and consumer demand for clean-label, no-swallow formats.

The effervescent tablet format is recommended for this product based on its technical suitability, market positioning opportunity, and alignment with the target consumer's lifestyle and preferences.

All proposed ingredients are permitted for use in Listed Medicines under the Therapeutic Goods Act 1989. The recommended regulatory pathway is AUST L (Listed Medicine) via self-assessment.

3. FORMULATION & INGREDIENTS

The table below sets out the proposed formulation. All ingredients are commercially available and permitted for use in Australian Listed Medicines under the TGA permitted ingredients list.

INGREDIENT	FORM	DOSE	RATIONALE
Vitamin C	Ascorbic acid	500mg	Immune support; antioxidant; TGA permitted indication
Magnesium	Magnesium citrate	150mg	Muscle function, energy metabolism; high bioavailability form
Zinc	Zinc gluconate	10mg	Immune function; cofactor for 300+ enzymatic reactions
Vitamin B6	Pyridoxine HCl	10mg	Energy metabolism; nervous system support
Vitamin B12	Methylcobalamin	500mcg	Energy; neurological function; preferred active form
Sodium	Sodium bicarbonate	200mg	Electrolyte replenishment; effervescent base component
Natural flavour	Orange	q.s.	Palatability
Sweetener	Stevia	q.s.	Low-calorie; natural positioning

Doses are per serving (one effervescent tablet dissolved in 200–250ml water). q.s. = quantity sufficient for formulation/palatability purposes.

4. EFFICACY EVIDENCE SUMMARY

Vitamin C (500mg)

Well-established evidence supporting immune function and antioxidant activity at this dose. Supports TGA-permissible indication: 'helps support immune system health.' Ascorbic acid is the standard form for effervescent applications due to its stability and solubility.

Magnesium citrate (150mg)

Citrate form demonstrates superior bioavailability over magnesium oxide. Evidence supports roles in energy production (ATP synthesis), muscle function, and reduction of fatigue. Dose is within recommended daily intake range and well-tolerated in effervescent base.

Zinc gluconate (10mg)

Robust evidence base for immune support. Gluconate form is well-tolerated in effervescent applications. Dose aligns with TGA guidelines for listed indications. No adverse interactions with other proposed ingredients.

Vitamin B6 (10mg) & B12 (500mcg)

Established roles in energy metabolism via the citric acid cycle. Methylcobalamin (B12) is preferred over cyanocobalamin for bioavailability. Both support TGA-permissible energy indications and are stable in effervescent tablet format.

Combination assessment

No known adverse ingredient interactions identified. The combination is consistent with comparable products currently listed on the ARTG and aligns with consumer expectations for an energy and immunity effervescent supplement.

Note

This summary is not sufficient for a TGA evidence package. These Evidence Guidelines specify the type of evidence required to support indications made for listed medicines (excluding sunscreens and disinfectants) and help sponsors understand their regulatory obligations in relation to holding that evidence.

TGA Evidence package quotations are available on request. Evidence package costs vary according to number of ingredients, intended claims and regulatory classification. Typical fees range between $5,000 - $15,000.

5. DOSAGE FORM & PACKAGING

Recommended Dosage Form

The effervescent tablet format is optimal for this formulation for the following reasons:

– Magnesium citrate and sodium bicarbonate are core components of the effervescent reaction base, making this a technically clean and commercially proven formulation for this delivery form

– The no-swallow format aligns with the target consumer's preference for convenient, on-the-go nutrition and functional hydration

– The format commands a price premium in the Australian market relative to standard tablets or capsules and is visually distinctive at point of sale

– AWS360's affiliate manufacturers in Germany and Australia have deep effervescent tablet expertise and validated equipment for this format

Recommended Packaging

Polypropylene or Biobase plastic tubes containing 10, 15 or 20 tablets, based on standard tablet size and weight. Biobase tubes are a more sustainable option, being derived from renewable resources (e.g. sugar cane, potato starch), whereas standard polypropylene tubes are derived from crude oil. Biobase tubes typically add 5-10% to the total manufacturing cost.

Tube closure with tamper proof seal and in-built desiccant (silica-molecular sieve) optimised for hot and humid climates.

Shelf-Life Target

24 months at 25°C or 30°C / 60% RH.

25°C is standard for Australia, New Zealand, USA, and Europe.

30°C is standard for most Southeast Asian countries.

Our recommendation is to aim for product stability at 30°C to allow for opportunities to market your product in these countries.

6. REGULATORY COMPLIANCE

Recommended classification

AUST L (Listed Medicine)

All proposed ingredients are permitted for use in Listed Medicines. The intended indications fall within TGA low-risk permitted indications and do not require clinical evidence review at the Listed Medicine level. This product is suitable for self-assessment via the TGA Business Services portal.

Proposed indications (subject to final TGA review):

- Helps support immune system health
- Supports energy levels and reduces fatigue
- Supports electrolyte balance and hydration

Labelling considerations:

- Required advisory: 'Always read the label and follow the directions for use'
- Not recommended for children under 12 without medical advice
- Pregnancy and lactation advisory to be assessed at artwork stage
- Country of origin declaration required
- Ingredient list to comply with TGA labelling requirements (Order 98)

7. MANUFACTURING FEASIBILITY

Manufacturing Notes

Effervescent tablets require controlled-humidity manufacturing conditions, specialist compression equipment and formulation know-how. AWS 360's affiliate manufacturer is a large-scale specialist effervescent tablet manufacturing site located in Germany, GMP-certified and TGA-approved.

Ingredient Availability

All proposed ingredients are commercially available and are readily held in stock. No additional raw material MOQs are applicable. No supply chain concerns identified at this stage.

ITEM	DETAIL	NOTES
Bulk MOQ	200,000 tablets	Effervescent format minimum
Finished goods MOQ	10,000 units	Based on 20-tablet tube
Packaging MOQ	n/a	For high volume items with annual forecast, bulk packaging is potentially available subject to costs and write-off costs.
Raw Material MOQ	n/a	
Lead time – 1st order including artwork setup	18-20 weeks	From receipt of Purchase Order and Artwork Files
Lead time – Re-orders	14-16 weeks	From receipt of Purchase Order
Shelf-life target	24 months	At 25°C - 30°C / 60% RH
Stability testing	Quoted separately	Required for AUST L registration

8. NEXT STEPS ROADMAP

01 **NPD Brief sign-off**

Client confirms formulation, indications, and pack format. Any material changes to the brief at this stage may require a revised brief and additional fee.

02 **Manufacturing quotation and sign-off**

AWS 360 issues a firm quotation based on the approved brief, covering unit cost, packaging, freight, and lead time. No further commitment is required until the quotation is accepted.

03 **NPD Phase**

Let the magic begin! Now we really roll the sleeves up by producing proto-type samples, testing and tasting the product, fine tuning the formulation, to end up with an approved final master formulation ready for production..

04 **Artwork development**

Label and packaging artwork developed to TGA labelling requirements. Client review and written sign-off required before print-ready files are submitted.

05 **TGA listing submission**

AUST L self-assessment lodged via TGA Business Services portal. AWS 360 can support this process or refer to a preferred regulatory consultant.

06 **Purchase order & production**

Upon quotation acceptance, purchase order issued and production slot confirmed with the relevant affiliate manufacturer. Standard lead time 14–18 weeks from PO.

IMPORTANT NOTICE

This NPD Brief is prepared for the exclusive use of the client named on the cover page. All formulation, regulatory, and commercial information contained herein is confidential and may not be shared with third parties without the written consent of AWS 360 Pty Ltd.

This document does not constitute a manufacturing quotation, a regulatory opinion, or a guarantee of product performance or marketability. Final formulation and indications are subject to confirmation at manufacturing quotation stage. Regulatory outcomes are subject to TGA assessment and cannot be guaranteed.

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