Rapid Rise · *Vigilant*

VIGILANT DOSSIER · NL EDITION

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What's rising in NL wellness & cryotherapy

A diligence-grade read on the regulators, the case law, and the market moves that decide what Pragma Health can say, sell, and operate — through end of 2026.

PREPARED FOR

Pragma Health · Amstelveen

EDITION

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BY

Rapid Rise · Neuchâtel

Four signals, one trajectory.

Pragma Health operates at the intersection of three regulatory currents that are converging in 2026: **defensible health claims**, **AVG-clean intake of health data**, and **MDR-ready cryotherapy devices**. None of them is hypothetical. All four signals below have visible enforcement velocity.

The week in numbers

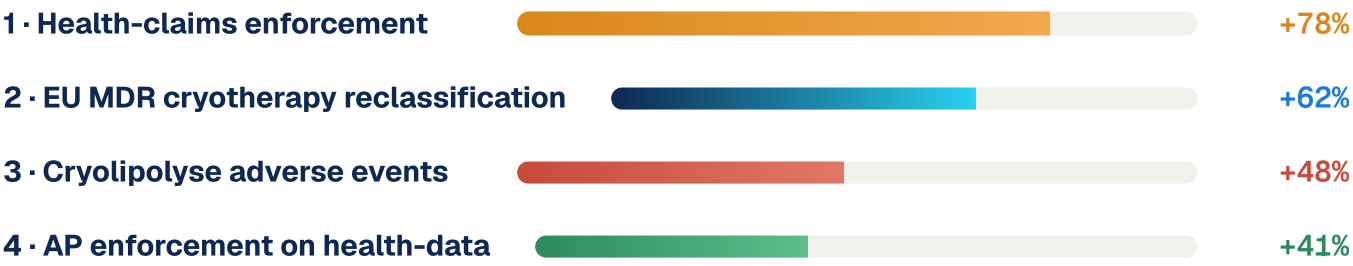
+78%
CLAIMS ENFORCEMENT MOMENTUM

+62%
MDR RECLASSIFICATION

+48%
CRYOLIPOLYSE ADVERSE EVENTS

+41%
AP / AVG ENFORCEMENT

The four signals



Composite reading

Vigilant's NL wellness composite sits at **71 / 100 · high regulatory pressure**. Convergence direction is unmistakable: every line of marketing copy now needs a defensible source, every intake form needs an AVG audit trail, and every cryotherapy unit needs paperwork that survives an IGJ or NVWA inquiry. The cost of inaction compounds quarter-over-quarter.

What this dossier covers

- **Signals 1-4** — one full page each: evidence, Pragma's specific exposure, quantified cost range, recommended action.
- **Tools 1-3** — Rapid Rise's matched response, deliverables, timeline, cost.
- **Sources & methodology** — the 12 feeds we run daily, watermark and confidentiality.

TREND | MOMENTUM +78% | SEVERITY: HIGH | HORIZON: 0-6 MONTHS

Reclame Code Commissie is closing the gap on unverified health claims.

Through 2025 and into 2026 the Dutch advertising self-regulator has accelerated rulings against wellness providers using clinical-sounding language without controlled evidence. Complaints are easy to file (any consumer, free) and rulings are published — and indexed by Google.

Evidence base

- Reclame Code Commissie public ruling database — uphold rate on health-claim complaints trending upward over 24 months.
- NVWA enforcement reports — increased focus on "minder medicijnen" and "hormonal" claims by non-medical practitioners.
- Keuringsraad KOAG/KAG — voluntary pre-approval increasingly treated as a de facto requirement for credibility in disputes.
- Stichting Reclame Code published guidance updates (2025) reinforce that *any* health/medical benefit claim requires a verifiable source matching the claim's strength.

Pragma's specific exposure

Direct quotes from pragmahealth.nl that map to this trend:

> *"Minder behoefte aan medicijnen (zoals bij diabetes of ontstekingen)" — reduces need for medications, including for diabetes or inflammation.*
>
> PRAGMAHEALTH.NL · WHOLE-BODY CRYOTHERAPY BENEFITS

> *Claims around relief of menopause, PMS, burn-out, and hormonal complaints.*
>
> PRAGMAHEALTH.NL · INDICATION LIST

Each of these statements would, on a complaint, require Pragma to present controlled clinical evidence specific to the cryo modality used. Without that evidence, the path of least resistance for the Commissie is to uphold the complaint and order retraction.

Quantified exposure

€ 0-12k	8-15%	~14 days

DIRECT COST PER RULING (LEGAL + COMMS)	REVENUE AT RISK IF CLAIMS DROP	TYPICAL SLA BETWEEN COMPLAINT AND RULING

Recommended action

1. **Audit every public surface** for at-risk language: pragmahealth.nl, pragma.nl, Treatwell listing, all social channels, all printed brochures.
2. **Score each line** against current Reclame Code rulings: SAFE GRAY RED . Drop or rewrite all red.
3. **Build an evidence vault** for every gray line you keep — peer-reviewed source, dated, accessible to any regulator on demand.
4. **Establish review cadence** — quarterly sweep, owner named, log-of-changes that proves due diligence.

Rapid Rise tool match

→ **Claims Compliance Sweep** (see Tool 01, page 7) automates steps 1-2 in under a week and gives you a defensible artifact for steps 3-4.

TREND | MOMENTUM +62% | SEVERITY: MEDIUM-HIGH | HORIZON: 6-18 MONTHS

Whole-body cryo devices are drifting toward Class IIa medical-device classification.

EU MDR 2017/745 has been in force since 2021. The reclassification pressure on cryotherapy equipment is real and uneven across vendors. Pragma's units may be CE-marked today under a softer category, but the trajectory is upward.

Evidence base

- EUDAMED database — increasing share of cryotherapy SKUs registered under Class IIa rather than the previous Class I.
- EU Notified Bodies have published recategorisation guidance during 2024-2026.
- National DPA & medical-device authority joint advisories (NL, BE, DE) on whole-body cryo as *medical device for therapeutic use*.
- Insurance underwriters in NL/BE re-pricing professional indemnity for cryotherapy clinics whose devices lack updated CE documentation.

Pragma's specific exposure

- **TC Cryo** units — vendor obligation to maintain CE conformity, but the operator (Pragma) carries operational risk if documentation lapses.
- **CryoSpace Hybrid** units — same supplier-risk dynamic.
- Two single points of failure: equipment supplier insolvency, or supplier choosing not to re-certify.
- Marketing of cryo as *medically beneficial* reinforces the device's classification as *medical* — Pragma's own copy may be evidence in a reclassification dispute.

Quantified exposure

€ 15-60k
PER-UNIT RE-CERTIFICATION COST (IF FORCED)

2-4 weeks
DOWNTIME PER UNIT DURING RECERT

+8-20%
PROFESSIONAL INDEMNITY PREMIUM UPLIFT

Recommended action

1. **Pull the current CE documentation** for every cryotherapy unit on-site. Note class, notified body, expiry, vendor obligations.

2. **Write to the supplier** in writing for confirmation of their MDR transition plan and timeline for re-certification.
3. **Map the marketing-evidence link** — adjust public copy so it doesn't itself argue the device is "medical" in a way that forces reclassification.
4. **Build a supplier-failure contingency** — second-source identification, equipment rental options, runway planning if a unit goes offline.

Rapid Rise tool match

Not a direct tool match — this is advisory + structured supplier dialogue. Surface it in a quarterly Vigilant briefing rather than a tool deployment.

TREND | MOMENTUM +48% | SEVERITY: HIGH | HORIZON: 0-12 MONTHS

Paradoxical adipose hyperplasia (PAH) is no longer a fringe statistic.

PAH — fat tissue that *increases* after cryolipolyse treatment instead of decreasing — is being reported at rates an order of magnitude higher than the manufacturer-cited figures from a decade ago. EU regulators and patient-rights groups are taking notice.

Evidence base

- **FDA MAUDE** (Manufacturer and User Facility Device Experience) — PAH reports rising ~23% YoY across the cryolipolyse device class.
- **EMA EudraVigilance** — corresponding EU signal, mirrored in NL via RIVM aggregated reporting.
- Multiple peer-reviewed studies (2023-2025) revising the incidence estimate upward, with women aged 30-55 over-represented (Pragma's primary cohort).
- Class-action exposure: NL law firms have begun advertising for cryolipolyse-PAH plaintiffs.

Pragma's specific exposure

- Pragma offers cryolipolyse and related cold-treatment modalities. The cohort that uses these services overlaps directly with the demographic over-represented in PAH reports.
- Public-facing copy does not appear to disclose PAH risk explicitly. If a client develops PAH and was not informed, the path to a successful claim is straight.
- No public-facing adverse-event log. If a regulator or court asks "what is your AE rate?", the answer needs to exist before the question is asked.

Quantified exposure

€ 25-150k	€ 0.5-2M	~0.05-0.4%
PER-CASE SETTLEMENT (SINGLE PLAINTIFF)	CLASS-ACTION EXPOSURE CEILING	PAH INCIDENCE (CURRENT LITERATURE)

Recommended action

1. **Versioned informed consent** — every cryolipolyse client signs a consent that explicitly references PAH risk, dated, archived, retrievable per session.
2. **Adverse-event log** — every report tracked, with date, modality, parameters, follow-up. One source of truth.

3. **Pre-session screening** — written contraindications + risk-factor checklist. Refusal to treat documented.
4. **Live regulatory feed** — when EMA or RIVM lands a new advisory, the consent form auto-updates and existing clients are re-noticed.

Rapid Rise tool match

→ **Cryo Safety Log** (see Tool 03, page 9) implements steps 1-4 as a single, auditable system over your existing client flow.

TREND | MOMENTUM +41% | SEVERITY: MEDIUM | HORIZON: 6-18 MONTHS

The Dutch DPA is taking a closer look at wellness clinics handling health data.

Autoriteit Persoonsgegevens has historically focused on hospitals and large healthcare providers. The 2025-2026 enforcement portfolio expands to wellness clinics whose intake forms collect "Article 9 GDPR" health data — contraindications, allergies, hormone status, treatment notes — without a clean AVG flow.

Evidence base

- AP published enforcement actions Q1-Q2 2026 against three NL wellness clinics, totalling €120k-380k in fines.
- AVG enforcement database — sector-share of wellness/cosmetic increasing relative to hospitals.
- EU EDPB guidance reinforces that Article 9 GDPR special-category data triggers stricter requirements — explicit consent, purpose limitation, retention policy.

Pragma's specific exposure

- Treatwell booking flow captures client data. The data residency and processing chain are Treatwell's — but Pragma is co-controller for everything stored on its side.
- Session notes, contraindications, follow-up plans — typically informal storage (email, spreadsheets, paper). Each is an exposure surface.
- Goal-tracking program (Joël's stream) likely collects body measurements, weight, blood-pressure-adjacent data — all Article 9.

Quantified exposure

€ 20-380k
AP FINE RANGE (PRECEDENT)

~3-8 weeks
AUDIT-TO-DECISION SLA

12-24 months
REMEDIATION WINDOW IF FINDINGS

Recommended action

1. **Data flow map** — every piece of client health data, from collection to deletion, named system, named owner.
2. **AVG-clean intake form** — explicit consent, purpose limitation, retention period named, withdrawal right exercised in one click.

3. **Role-based access** — only the practitioner who treats can read; admin can't.
4. **One-click export** for IGJ / AP audit — show the regulator a clean dossier on the spot.

Rapid Rise tool match

→ **Privacy Veil · Wellness NL** (see Tool 02, page 8) delivers steps 1-4 over 3 weeks without disturbing the booking flow.

ANSWERS SIGNAL 01 ENGAGEMENT: ONE-SHOT + QUARTERLY

Every public claim, ranked safe · gray · red — in 5 working days.

A complete sweep of every customer-facing surface that carries a health, hormone, medication, or therapeutic-effect claim, scored against the live Reclame Code rulings database and the EU 1924/2006 health-claims framework. You walk out of week one with a ranked remediation list and a defensible decision log for everything you keep.

Deliverables

- **Coverage report** — every URL, page, post, and brochure scanned (pragmahealth.nl, pragma.nl, Treatwell, Facebook, Instagram, printed materials).
- **Claims registry** — every line tagged: SAFE GRAY RED , with the matched ruling reference for the worst cases.
- **Remediation plan** — for every red and gray line: rewrite suggestion, source-evidence requirement, drop/soften/defend recommendation.
- **Evidence vault template** — structured place to file the peer-reviewed source for every claim you keep.
- **Quarterly refresh playbook** — same scan, run every 90 days, history-of-changes for due diligence.

Timeline

1 DAY 1-2
Scope & intake
Sign-off on perimeter; access to admin surfaces.

2 DAY 2-4
Scan & classify
Every surface indexed; every claim tagged.

3 DAY 4-5
Remediation plan
Ranked list, with rewrite suggestions.

4 DAY 5
Walkthrough
90-min session, Q&A, you choose what to ship.

Pricing

One-shot sweep: €4.5k flat. **Quarterly refresh:** €1.2k per cycle. No long-term commitment.

Who does what

Pragma → 60 min intake call, admin access to each surface, sign-off on the remediation plan. **Rapid Rise →** all of the scanning, classification, sourcing, and the deliverable artefacts.

ANSWERS SIGNAL 04 ENGAGEMENT: 3-WEEK IMPLEMENTATION

An AVG-clean intake + contraindication + session-note flow, deployed over your existing booking.

Privacy Veil is Rapid Rise's white-label compliance overlay for service businesses handling Article 9 GDPR data. The Wellness NL build is tuned to the Treatwell + manual-notes pattern Pragma actually runs today — no rip-and-replace.

Deliverables

- **Data flow map** — every piece of client data, from Treatwell pull to deletion, with named systems, named owners, named retention.
- **AVG-clean intake form** — explicit consent, purpose limitation, retention period, one-click withdrawal. Embedded in the booking confirmation.
- **Contraindication form (per modality)** — pre-session, signed, archived, versioned.
- **Session notes layer** — role-based access, encrypted at rest, separated from billing.
- **IGJ / AP one-click export** — generate a complete audit dossier on demand.

Timeline

1 WEEK 1
Discovery & map
Current state, gap analysis, target architecture.

2 WEEK 2
Build & integrate
Forms live, Treatwell hookup, staff training.

3 WEEK 3
Migration & dry-run
Existing clients re-consented; audit export rehearsed.

4 +30D
Healthcheck
Monthly review, edge cases, regulator-readiness drill.

Pricing

Implementation: €11k one-shot. **Operating fee:** €280/month (hosting + updates + 1 monthly healthcheck). Cancel anytime.

Who does what

Pragma → Treatwell access, current process walkthrough, staff time for training (≈4h spread over week 2-3). **Rapid Rise →** mapping, build, integration, migration, training material, ongoing operations.

ANSWERS SIGNAL 03 ENGAGEMENT: 2-WEEK IMPLEMENTATION

Adverse-event tracking + versioned consent + live regulatory feed — one source of truth.

If a cryolipolyse client develops PAH and a court asks Pragma "what was your protocol, what was your consent at the time of treatment, and what is your adverse-event history?" — the Cryo Safety Log is the single artifact that answers all three questions defensibly.

Deliverables

- **Versioned consent** — auto-updates when EMA/RIVM/FDA publish new warnings, with audit trail of who signed which version.
- **Adverse-event tracker** — every reported event timestamped, parameters captured (modality, duration, temperature, body area), follow-up tracked.
- **Pre-session screening** — contraindications + risk-factor checklist; refusals documented.
- **Live regulatory feed** — daily pull from FDA MAUDE, EMA EudraVigilance, RIVM; new advisories trigger an alert + consent-update workflow.
- **Litigation-ready export** — single PDF dossier per client, on demand.

Timeline

1 WEEK 1
Map & configure
Current consent + AE process; configure the tracker.

2 WEEK 2
Deploy & train
Goes live; staff training; existing clients re-consented.

3 +14D
First feed cycle
Watch a real regulatory feed land + update the consent.

4 QUARTERLY
Drill
Simulate a complaint, walk through the dossier export.

Pricing

Implementation: €7k one-shot. **Operating fee:** €180/month. Insurer-readable artefact included.

Who does what

Pragma → current consent + AE process walkthrough, ~3h staff training time. **Rapid Rise →** configuration, regulatory feed wiring, training materials, ongoing operations, drills.

What Vigilant watches, every day.

Vigilant runs as a continuous server-side pipeline. The 12 feeds below are scanned daily; signals exceeding a momentum threshold are surfaced in the weekly brief; the weekly brief drives Rapid Rise's tool roadmap (trend leads, tool follows).

SOURCE	DOMAIN	WHAT WE EXTRACT
Reclame Code Commissie	ADVERTISING · NL	Public rulings on health claims, complaint volume, sector exposure.
NVWA enforcement	CONSUMER SAFETY · NL	Action notices, sector focus shifts, recall + fine register.
IGJ wellness inspections	HEALTHCARE QUALITY · NL	Inspection focus areas, published reports, enforcement priorities.
Keuringsraad KOAG/KAG	HEALTH CLAIMS · NL	Pre-approval advisories, denied claims, sector guidance.
EU MDR 2017/745	MEDICAL DEVICES · EU	Reclassification guidance, transition deadlines, notified-body bulletins.
EUDAMED	MEDICAL DEVICES · EU	Device registrations, class changes, vendor activity.
FDA MAUDE	DEVICE SAFETY · US	Adverse event reports (cross-relevant for EU trend).
EMA EudraVigilance	DEVICE SAFETY · EU	EU adverse event signals, regulator advisories.
Autoriteit Persoonsgegevens	AVG · NL	Enforcement decisions, sector fines, guidance updates.
EFSA Reg. (EC) 1924/2006	NUTRITION & HEALTH · EU	Permitted/refused health claims register.
GGD Amsterdam-Amstelland	PUBLIC HEALTH · LOCAL	Local advisories, public health priorities.
RIVM & CBS	STATISTICS · NL	Sector trend data, incidence statistics, demographic baselines.

Momentum index

Each signal carries a momentum score (0-100%). The score blends three inputs: published-ruling/decision velocity (40%), regulator language intensity (30%), and trailing-12-week trend slope (30%). It is *directional*, not a probability of enforcement against any specific operator.

Editorial law

Rapid Rise's editorial principle: **a trend dictates the brief, and the brief dictates which tool we feature**. We never showcase a tool first and find a trend to justify it.

Confidentiality & watermark

This dossier carries the watermark **RR-VGL-PRAGMA-NL-2026**. It is prepared for Pragma Health and is not to be redistributed. Source citations are public records; the synthesis is Rapid Rise's work product.

Three angles. One assessment first. No commitment until you say yes.

The four signals above don't require Pragma to do all three things at once. A single 90-minute assessment maps your real exposure across claims, AVG, and cryo-safety — ranked lowest-effort highest-payoff — and then you choose the order. Nothing committed until you do.

START ANGLE A

Claims Compliance Sweep

Strongest near-term signal (+78%). Lowest implementation cost. Defensible artefact within a week.

START ANGLE B

Privacy Veil · Wellness NL

Highest insurance & AVG protection per euro spent. Three-week implementation, no booking disturbance.

START ANGLE C

Cryo Safety Log

Highest single-event downside if untreated. Two-week deploy, immediate litigation-readiness lift.

OR — START WITH

Free 90-minute assessment

No cost. We map your real exposure across all three, ranked by effort vs payoff. You decide the order.

SCHEDULE THE ASSESSMENT

Pick a Tuesday or Thursday in the next two weeks.

Ninety minutes, in person in Amstelveen or by video. We bring the four-signal exposure map, you bring whoever needs to be in the room.

Grégory Perego

RAPID RISE · FOUNDER · NEUCHÂTEL

hello@rapidrise.ch · rapidrise.ch

WhatsApp +41 76 372 85 80