# How RX-to-OTC Switch Disrupts Access to Care in Women's Health

*CEMAG CARE's journey to the first OTC tranexamic-acid treatment for Heavy Menstrual Bleeding*

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CEMAG CARE Empowered for care

*“Why, in 2026, are women still underserved in healthcare?”*

UNDERSTANDING THE GAP

# The Gender Health Gap, in three numbers

## 9 years

women spend in poor health — 25% more than men

*McKinsey Health Institute, 2024*

## <2%

of healthcare funding goes to women-specific conditions

*World Economic Forum, 2024*

## 6%

of global health investment goes to women's health

*World Economic Forum, 2024*

***This gap is not biology — it's decades of structural underinvestment.***

UNDERSTANDING THE GAP

# A gap built on access, awareness & barriers

### Access

Uneven across geographies & income

### Awareness

Conditions dismissed or underdiagnosed

### Availability

Too few solutions built for women

### System bottlenecks

Overloaded care pathways

### Rx dependency

One visit stands between patient & relief

### Patient drop-off

Many simply stop seeking care

OTC AS A DISRUPTIVE LEVER

# What OTC unlocks

### Faster access

Relief the same day, at the pharmacy counter

### Patient empowerment

Informed self-care for well-understood conditions

### Reduced burden

Frees physicians for complex cases

**RX** Appointment + wait → **OTC** At the counter, same day

***Regulatory evolution is opening the door for well-established, single-indication molecules.***

***A Rx-to-OTC switch is not simply a regulatory reclassification.***

It is a coordinated strategy across four dimensions built to remove the practical barriers that stop women from buying, starting and continuing treatment.

**Access**

**Safety**

**Pharmacy**

**Consumer brand**

THE RATIONALE

# Why switch in women’s health?

## A successful switch creates value on four levels:

### Patient access

Less time, cost, stigma and geographic barriers

### Health-system capacity

Moves low-complexity care to self-care & pharmacy

### Brand growth

Reaches women who self-recognise symptoms but don’t seek care

### Lifecycle management

A differentiated consumer-health asset beyond Rx

GLOBAL PROOF POINTS

# The switch already works — 4 precedents

### Norlevo® & EllaOne® — 1999/2015

**Rx → OTC / (P)**

First **emergency contraception** OTC sold in EU pharmacies + extensions WW

### Lovima® & Hana® — UK, 2021

**POM → Pharmacy (P)**

First OTC **oral contraceptives** sold in UK pharmacies

### Gina® — UK, 2022

**POM → Pharmacy (P)**

First UK pharmacy **HRT** — women 50+, amenorrhoeic 1yr+

### Opill® — US, 2023/24

**Rx → Unrestricted OTC**

First **daily oral contraceptive** OTC in the US, no age limit

***Four markets, one lesson: One indication + pharmacist safety net = a switch that sticks.***

# About CEMAG CARE

*Young, family-owned pharma — dedicated to women's health*

**2016**

Founded by Dr André Ulmann

**17 countries**

Worldwide footprint

**360°**

Fully integrated organization spanning R&D to pharma shelf

**+38%**

Revenue growth '25 vs '24

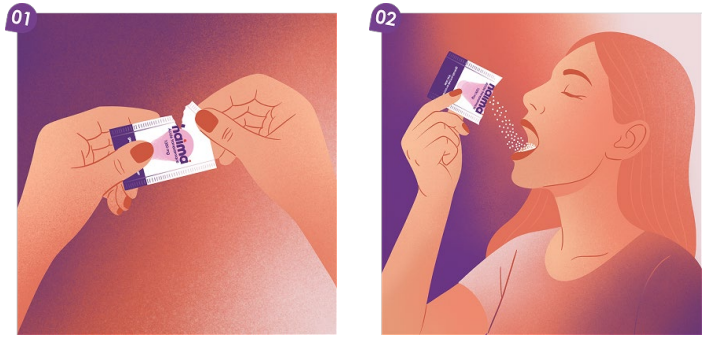
## Built to bring women's health innovation to market.

**FEMINISM** | **PASSION** | **PERSEVERANCE** | **BOLDNESS**

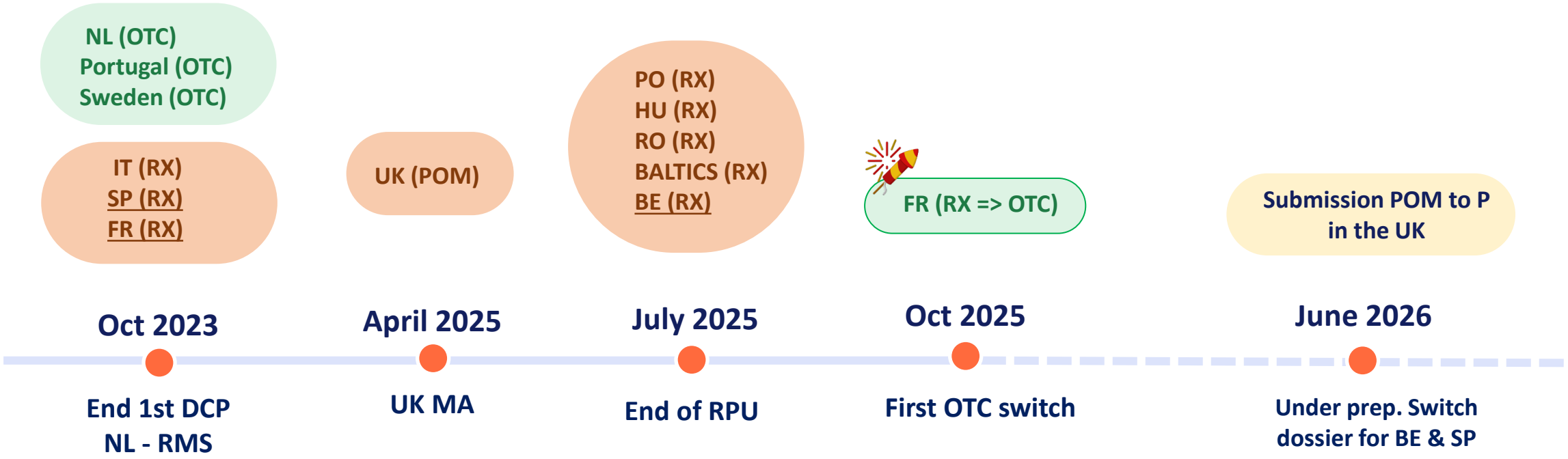
# The product: HAIMA® / NEXAG®

**Non-hormonal OTC treatment for Heavy Menstrual Bleeding**

- Tranexamic acid 1000 mg in microgranules in sachet — specific dosage for HMB
- Single indication — a clean, focused OTC positioning
- On-the-go innovative formulation, 1 sachet 3 times per day — consumer friendly
- Pack of 12 and 6 sachets



# A growing OTC footprint, built step by step




***HAIMA® became France's first OTC heavy-menstrual-bleeding treatment — a replicable playbook for switches across markets.***

# How we built the case for OTC

Early discussions with authorities

Single indication
Strong safety record

Bioequivalent reference (Cyklo-f®)

Aligned with WHO/EU guidelines

Robust KOLs network

Flexible pack sizes (6 & 12)

Pharmacist training & patient education

EU-wide real-world evidence survey

# Create an evidence package for actual use

**The pivotal question is *“Can the consumer use it safely without a prescriber?”***

- Mature Rx safety database & post-marketing evidence
- Consumer label-comprehension studies (contraindications, dose, red flags)
- Medication-error, misuse & delayed-diagnosis risk assessments
- Human-factors testing: pack, leaflet, digital screening, dosing device
- Pharmacy risk-minimisation plan: checklist, training, referral, resupply
- Real-world evidence plan: repeat purchase, discontinuation, safety signals

# Treat Europe as a portfolio of markets

There is no uniform “European OTC” market: legal classification, pharmacist roles, reimbursement and retail structures are all national.

Use a pragmatic sequence:

1

**Choose an anchor market**

Workable reclassification pathway & mature pharmacy network

2

**Generate local evidence**

Pharmacy uptake, safety, conversion, repeat rate

3

**Support EU applications**

Use anchor-market data; don’t assume automatic transfer to Member States

4

**Adapt market by market**

Label, claims, pharmacist protocol, price and channel strategy

5

**Preserve the Rx route?**

Where reimbursement or medical follow-up still adds value

BEYOND THE SWITCH

# Enabling real access — not just approval

### Patient education

Raise awareness of the indication

### Frontline pharmacists

Dedicated training to enable patient counselling

### De-stigmatization

Open conversation to encourage faster care-seeking

### Digital distribution

Reaching patients where they are

***"Improving care access relies on a holistic approach and teamwork between industry, authorities, HCPs and patients."***

THE ROAD AHEAD

# What needs to change

### Industry mindset

OTC as a strategic pathway, not a downgrade

### Regulatory frameworks

Predictable, science-based switch pathways

### Collaboration

Authorities, pharmacists, KOLs, patients, industry

***OTC is not the destination — it's one lever within a broader access ecosystem.***

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