

Chapter 15 Template: Reimbursement & International Expansion Planner

Subtract to Ship: MDR Certification*, Chapter 15: Health Insurance, Reimbursement & International Expansion

Instructions

CE marking does not equal reimbursement. CE marking does not equal global market access. This template helps you separate the three tracks (regulatory, reimbursement, international) and build a realistic expansion sequence. Complete this before telling investors about your international plans.

Part 1: The Three-Track Separation

Track 1: Regulatory (CE Marking)

Field	Your Answer
CE marking scope	EEA (30 countries)
CE marking status	In progress Achieved
Expected / actual CE date	

Track 2: Reimbursement

Field	Your Answer
Primary market for reimbursement	
Reimbursement process researched?	Yes No
Health economic evidence available?	Yes No
Estimated time to reimbursement listing	____ years
Have you spoken to someone who achieved reimbursement for a similar device?	Yes No

Track 3: International Expansion

Field	Your Answer
Non-EU markets in your business plan	
Regulatory submission started for any?	Yes No
Budget allocated for non-EU submissions?	Yes No

Part 2: Reimbursement Reality Check

Does your business plan assume reimbursement? Yes No

If Yes:

Question	Answer
Which country?	
Which insurance body?	
What evidence do they require beyond clinical?	
Typical timeline for new device reimbursement in that country	____ years
Have you started the application process?	Yes No

Revenue Bridge Assessment

What is your revenue source between CE marking and reimbursement?

Revenue Source	Estimated Annual Revenue	Validated?
Hospital procurement budgets (direct purchase)	EUR _	Yes No
Private clinics	EUR _	Yes No
Innovation funds / research collaborations	EUR _	Yes No
Out-of-pocket (if applicable market)	EUR _	Yes No
Other: _____	EUR _	Yes No
Total bridge revenue	EUR _	

If total bridge revenue = EUR 0: your business model has a fatal gap. Fix this before CE marking.

Part 3: International Expansion Sequence

The One-Market-First Strategy

Phase	Markets	Timeline	Activities
Year 1-2	Home market only: _	Post-CE	Commercial launch, revenue, PMS data
Year 2-3	+1-2 adjacent EU markets: _		Distribution partners, local language, reimbursement
Year 3-4	First non-EU market: _		Regulatory submission, new budget
Year 4+	Additional markets: _		Sequential expansion

Per-Market Cost Estimate

For each non-EU market, estimate:

Cost Item	Market 1: _	Market 2: _
Regulatory submission	EUR _	EUR _
Additional testing	EUR _	EUR _
Local representation	EUR _	EUR _
Translation	EUR _	EUR _
Legal costs	EUR _	EUR _
Subtotal	EUR _	EUR _
Subtotal x2 (Double-It Rule)	EUR _	EUR _

Part 4: Non-EU Market Assessment

Market	Regulatory Body	CE Recognised?	Estimated Cost	Estimated Timeline
USA	FDA	No	USD 50,000-500,000+	6-18 months (510(k))
UK	MHRA (UKCA)	Transitional only		
Brazil	ANVISA	No		
Japan	PMDA	No		
China	NMPA	No		
Australia	TGA	No		
Canada	Health Canada	No		

Your priority non-EU market:

Reason for priority:

Is this market justified by current revenue, or is it a hope? - Justified by existing revenue/partnerships - Justified by market research - Based on assumption, **needs validation**

Part 5: MDSAP Assessment

MDSAP (Medical Device Single Audit Program), one QMS audit for US, Canada, Australia, Japan, Brazil.

Question	Answer
Are you planning to enter 3+ MDSAP member markets?	Yes No
If no: MDSAP likely not worth the investment for you.	
If yes: MDSAP covers QMS only, product submissions still required per country.	

Part 6: Business Plan Honesty Check

Question	Honest Answer
How many markets in your business plan in first 24 months?	–
If >2: is the timeline realistic?	Yes Probably not
Does the plan assume reimbursement? When?	
What is the revenue source between CE and reimbursement?	
Have you budgeted for non-EU market entry (per market)?	Yes No
Have you applied the Double-It Rule to international budgets?	Yes No
Do you know the difference between market access and market entry?	Yes No

Market access = legal permission to sell (CE marking gives you this in 30 EEA countries). **Market entry** = actually selling (requires distribution, local support, reimbursement, marketing).

These are NOT the same. If your plan treats them as the same, every country will take longer and cost more.

Date completed:

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Completed by:

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