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Medical Affairs priorities: Italy

An anonymised extract from a longer sAImone session. This dated example shows how evidence, practical constraints and conditional planning estimates can inform a programme of work. Original page numbering and source references are retained.

Strategy Stage -- Medical Affairs Priorities for Italy

Strategic call

Prioritise an integrated centre-readiness and scientific-exchange programme as the core Medical Affairs investment for the next 12 months. It should address patient selection, amyloid confirmation, APOE-informed risk discussion, MRI-based ARIA monitoring, infusion logistics and referral governance, while capturing structured evidence that can later answer payer and guideline questions.

This is the most robust posture because Italy's constraint is currently access and implementability, rather than lack of EU authorisation or lack of competing product activity. Both lecanemab and donanemab are EU-authorised for restricted early-Alzheimer's populations, but AIFA's June 2026 decision found that neither met the minimum requirements for Italian NHS reimbursement, citing modest clinical effect, uncertainty in longer-term estimates, ARIA risk and substantial diagnostic and monitoring requirements. [1, 2]

A planning model comparing four strategic choices found scientific exchange and integrated readiness effectively tied for highest scenario-robust value, with mean scores of 80.5 and 80.4 out of 100 respectively across 10,000 modelled scenarios. Formal access-supporting synthesis is a trigger-gated priority; broad comparator communications is materially less robust while the national access question remains unresolved.

What this means for resource allocation

Priority	Strategic objective	Why it leads now	What is deprioritised
1. Centre readiness linked to evidence generation	Establish a credible Italian understanding of which conditions enable appropriate treatment delivery.	AIFA's stated objections include patient selection, biomarker confirmation, MRI monitoring and organisational burden. [1]	Standalone education that does not produce readiness insight or evidence relevant to access.
2. Scientific exchange on pathway-critical questions	Position Medical Affairs as the balanced scientific partner on appropriate use, safety governance and referral design.	Leqembi use requires specialist supervision, MRI access and scheduled ARIA monitoring; these are practical questions that centres, societies and guideline actors must resolve. [2]	Broad product-led differentiation messaging before a clinically meaningful, locally relevant question is established.
3. Evidence interpretation and access readiness	Maintain a payer- and guideline-ready evidence package that can be activated rapidly if the Italian process moves.	Donanemab remained visible in the September 2026 pricing-and-reimbursement agenda, while no final outcome was publicly identified by September 16, 2026. [3]	A full-scale access campaign without a defined reassessment route or evidence request.
4. Competitor intelligence translated into clinical insight	Track whether donanemab site activity changes centre expectations, operational models or scientific questions.	Competitor-linked treatment experience may shape peer discussion before it changes access; it does not, on current evidence, establish prescribing or reimbursement impact.	Reactive claim-versus-claim communications or cross-trial comparisons presented as direct comparative evidence.
5. Integrated insight governance	Convert field, society, patient and access insights into decisions at a consistent executive cadence.	The strategic value comes from detecting whether access, readiness or evidence assumptions have changed early enough to redirect work.	High-volume insight collection without defined escalation criteria or accountable action owners.

Strategic objectives and success measures

Priority	Twelve-month objective	Proposed success measures	Accountable owner	Critical dependency
Centre readiness and implementation evidence	By September 2027, complete a structured readiness baseline across all selected sentinel centres and document the main constraints in eligibility, diagnostics, monitoring, infusion and follow-up.	Percentage of selected centres with complete baseline; number of operational gaps validated; number of evidence questions converted into an evidence plan.	Medical Affairs Evidence Lead	Centre participation, compliant data collection, local clinical validation
Scientific exchange and pathway alignment	By September 2027, establish a consistent, balanced scientific dialogue with priority memory centres, external experts and relevant professional bodies.	Coverage of prioritised stakeholders; quality and actionability of insights; proportion of priority scientific questions with approved response materials.	Medical Affairs Scientific Exchange Lead	Appropriate access to stakeholders; compliant materials; aligned medical narrative
Access-ready evidence synthesis	Maintain a decision-ready package that translates Italian clinical, implementation and patient-pathway evidence into questions relevant to formal access reassessment.	Evidence-gap register refreshed quarterly; time from formal question to evidence-response plan; readiness of approved evidence modules.	Medical Affairs with HEOR and Market Access	A defined formal question, local value evidence, agreed cross-functional governance
Competitor and ecosystem interpretation	Detect competitor changes that alter the scientific or operational environment rather than merely increasing share of voice.	Material competitor signals assessed within the agreed governance cycle; number of signals resulting in a documented strategic decision; evidence-response time for priority issues.	Medical Strategy / Competitive Intelligence Lead	Reliable field insight, regulatory monitoring, consistent evidence review
Insight-to-decision governance	Ensure external insight changes priorities only when it crosses a pre-agreed clinical, access or operational threshold.	Quarterly executive review completed; proportion of priority insights with disposition; number of decisions revised because of validated new evidence.	Italy Medical Affairs Leadership	Cross-functional attendance and decision rights

Priority architecture

Priority 1 -- Make implementation readiness the evidence engine

Objective: Build an Italy-specific evidence base on how an appropriately selected early-Alzheimer's population can be assessed, monitored and treated through capable centres.

Medical Affairs focus

- Define a common readiness framework across selected centres: diagnostic confirmation, APOE testing and counselling, MRI scheduling, ARIA escalation pathways, infusion capacity, multidisciplinary decision-making and caregiver support.

- Convert recurring implementation questions into a prospective evidence plan rather than treating them as isolated field insights.
- Develop a balanced evidence interpretation package that separates regulatory-label requirements, operational practice variation and unresolved real-world questions.
- Engage scientific leaders around capability standards and evidence gaps, not around assumed product preference.

Strategic value: This priority remains useful if reimbursement remains blocked, if AIFA opens a reassessment, or if regional centres begin building capability ahead of a national decision.

Trade-off: It requires disciplined focus on a limited sentinel-centre network first. Attempting national breadth before the readiness model is validated would dilute insight quality and produce little evidence usable for access or guideline discussion.

Priority 2 -- Own the scientific questions that determine appropriate use

Objective: Ensure Leqembi-related scientific exchange is anchored in the questions Italian clinicians and societies need answered to evaluate appropriate delivery.

Scientific question	Why it matters strategically	Medical Affairs response
Which patients are sufficiently well characterised for treatment consideration?	Patient-selection uncertainty is central to AIFA's reimbursement rationale. [1]	Align scientific materials and insight capture around eligibility, diagnostic confirmation, contraindications and multidisciplinary review.
What constitutes a practical ARIA-monitoring pathway?	MRI access and ARIA management are intrinsic to the authorised use conditions. [2]	Support balanced scientific discussion on monitoring workflow, symptom recognition and escalation pathways.
How should specialist centres interface with community neurology and primary care?	Referral delays and unclear responsibility can prevent readiness even in capable centres.	Develop a referral-pathway evidence agenda with clinical stakeholders; defer broad primary-care education until specialist pathway requirements are clearer.
What implementation outcomes are credible in Italian practice?	Formal reassessment is more likely to require evidence on feasibility, safety governance, resource burden and patient experience than additional promotional differentiation.	Prioritise protocol-ready real-world evidence concepts and transparent publication planning.
Which differences between anti-amyloid agents matter in practice?	Cross-trial comparisons cannot establish a direct clinical advantage.	Use balanced evidence interpretation and identify the specific question that would justify future comparative work.

Priority 3 -- Keep formal access support ready, but do not lead with it

AIFA's June 2026 rationale means a future access discussion is likely to revisit clinical relevance, uncertainty beyond controlled trial periods, safety management and health-system burden. [1] The Medical Affairs role is to maintain the evidence, scientific communication and implementation insight that Market Access can use through appropriate formal channels.

Activate this priority at higher intensity only if:

- AIFA issues a new assessment, reconsideration or specific evidence request for either medicine.
- A definitive outcome is published for donanemab procedure 20157.
- A regional authority establishes an early-access, centre-designation or implementation pathway.
- Italian real-world evidence provides material data on selection, ARIA management, resource use or patient experience.

Trade-off: Moving substantial Medical Affairs effort into payer-facing synthesis before a defined procedural opening risks building a dossier that is too generic. Maintain readiness now; scale only when the evidence question becomes specific.

Priority 4 -- Treat donanemab as an operational benchmark, not the primary narrative

Donanemab is the relevant direct competitor for specialist attention, particularly where centres gain practical treatment experience or contribute to the professional discussion. Its September 2026 procedural visibility warrants continued monitoring, but agenda presence does not establish a change in Italian reimbursement status. [3]

Medical Affairs implications

- Track competitor activity for changes in centre expectations: treatment duration, patient-selection practices, MRI burden, infusion workflow and discontinuation decision-making.
- Use external insights to test whether the Leqembi scientific narrative needs clarification, not automatic revision.
- Avoid presenting indirect trial comparisons as definitive evidence of product superiority.
- Escalate comparative work only when new head-to-head, sufficiently comparable real-world or guideline-relevant evidence creates a concrete decision question.

Scenario-based priority shifts

Twelve-month trajectory	Observable condition	Priority increase	Priority decrease
Access remains blocked	No formal AIFA reconsideration or regional funded pathway emerges.	Centre readiness, Italian implementation evidence, scientific-exchange quality and pathway insights.	Broad payer-facing activity and high-volume comparator communications.
Formal reassessment emerges	AIFA publishes a reconsideration, a new procedure outcome or an explicit evidence request.	Access-ready evidence synthesis, rapid evidence-gap closure, formal cross-functional response.	Lower-value exploratory activity not connected to the specified assessment question.
Regional readiness accelerates	Multiple regions or networks begin defining centres, referral criteria or monitoring pathways.	Regional pathway evidence, centre-to-centre learning and scalable education on appropriate use.	Nationally uniform assumptions about readiness or referral flow.
Competitor operational visibility grows	Donanemab-related centre activity produces new Italian implementation data, society discussion or referral interest.	Comparative evidence interpretation, field insight synthesis and selected expert engagement.	Generic competitor monitoring without a defined clinical or access implication.
New safety or label development occurs	EU label, risk-minimisation or pharmacovigilance information changes.	Safety-science communication, centre education and medical-information readiness.	Non-safety-related differentiation work until the new implications are understood.

Priority-change triggers

Trigger	Decision implication	Required Medical Affairs response
Published AIFA action affecting either therapy	Access posture may move from readiness to active evidence support.	Convene cross-functional evidence review; map the stated decision questions to available Italian and global evidence.
New Italian centre-level data on ARIA, treatment discontinuation, MRI burden or patient selection	Operational feasibility assumptions may change.	Assess whether findings alter readiness standards, evidence plans or scientific materials.
National society or guideline statement on eligibility, centre standards or referral pathways	Clinical expectations may become more standardised.	Refresh scientific narrative, educational priorities and insight questions.
Regional decision on centre designation, diagnostic funding or treatment delivery	Geographic implementation may become a near-term determinant of access.	Shift from national-only readiness to region-specific pathway support.
Competitor-led scientific activity that changes clinician questions	Clinical attention may shift before access changes.	Validate the signal, identify the evidence question beneath it and respond through balanced scientific exchange.
Material EU safety or indication update	Appropriate-use requirements may change.	Update medical-information, training and safety-science content before expanding external scientific activity.

Executive implications

1. **Fund the integrated readiness-and-scientific-exchange platform as one strategic programme.** The evidence model indicates that separating these priorities would create a false choice: exchange generates the questions, while readiness work converts them into locally relevant evidence.
2. **Set access support at a maintained-readiness level rather than as the dominant workstream.** It becomes the immediate priority only when AIFA or a regional authority creates a defined reassessment or implementation opening.
3. **Use Italy-specific evidence generation to address the access objection, not to duplicate registration evidence.** The highest-value gaps concern practical eligibility, monitoring, resource burden, referral flow and patient experience.
4. **Keep donanemab intelligence clinically specific.** The relevant question is whether competitor activity changes care-pathway expectations, not whether it creates short-term promotional pressure.
5. **Deprioritise national-scale awareness activity until referral and specialist-centre pathways are sufficiently defined.** Early breadth would be difficult to convert into appropriate treatment access while funding and delivery criteria remain unresolved.

References

[1] Anti-beta-amyloid medicines: rationale for the Scientific and Economic Committee decision -- Italian Medicines Agency -- 2026 -- https://www.aifa.gov.it/documents/20142/3462301/Anti-amiloidi_motivazioni_CSE_26.06.2026.pdf
[2] Leqembi -- European Medicines Agency -- 2026 -- https://www.ema.europa.eu/en/medicines/human/EPAR/leqembi
[3] Scientific and Economic Committee agenda, September 2026 -- Italian Medicines Agency -- 2026 -- https://www.aifa.gov.it/documents/20142/4039302/ODG_UPR_CSE_SETTEMBRE_2026.pdf
Internal: internal references and frameworks