MADE SCIENTIFIC · COMMERCIAL STRATEGY & REGULATORY AFFAIRS

South Korea Regulatory Assessment

Distributing Made Regenerative Products into Korea via GC Corporation

Mesenchymal Stem Cells · Extracellular Vesicles / Exosomes · Secretome — Market-Entry, White-Label Feasibility & Commercial Opinion

Prepared for	Made Scientific — Office of the VP, Commercial · GC Corporation partnership discussion
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Date	July 15, 2026
Classification	Made Scientific — Confidential (internal & GC partnership)
Contents	Executive Summary · 8 Chapters · 5 Appendices · 50 cited sources

Regulatory and commercial feasibility assessment. External legal, regulatory and industry claims are cited to primary and secondary sources; commercial recommendations and figures are strategic parameters, not commitments, and this document is not legal advice. Prepared for internal Made Scientific strategy and partnership discussion with GC Corporation.

Executive Summary

The question. Can Made Scientific profitably distribute its US-manufactured regenerative products — culture-expanded mesenchymal stem cells (MSCs), extracellular vesicles/exosomes (EVs), and secretome/conditioned media — into South Korea on a white-label basis through GC Corporation and GC Wellbeing, taking advantage of a Korean legal environment for stem-cell use analogous to Florida's SB 1768? This report answers that question from a regulatory and commercial standpoint, built on a full web crawl of Korean primary law, MFDS notices, peer-reviewed regulatory literature, law-firm analyses, and corporate sources, all cited.

The short answer. Korea is one of the most attractive and receptive regenerative-medicine markets in the world, and — uniquely for Made — the single hardest barrier to selling there is already solved, because **GC Corporation is Made's own strategic shareholder** [37]. But the FL SB 1768 framing does not transfer cleanly. Korea does have a genuine, recently-liberalized legal channel to administer regenerative therapies that are *not* fully approved drugs, but it is a **government-gated, committee-approved, institution-anchored** system — the opposite architecture to Florida's self-executing physician permission. The commercially decisive fact is a different one: **in Korea, the boundary that governs Made's products is route of administration, not biology.** Anything *injected* is a licensed biologic (multi-year MFDS pathway); anything *topical with cosmetic-only claims* can travel a light cosmetic-import pathway in weeks-to-months. That single line, more than any "right-to-try" analogy, defines where Made can move fast and where it cannot.

What we recommend. Pursue Korea, through GC, as a **two-speed program**:

1. **Fast lane (0–12 months): topical cosmetic secretome & (non-human-labeled) EV skincare through GC Wellbeing.** Korea permits human-cell *culture fluid* / conditioned media as a cosmetic ingredient under a defined safety standard, and GC Wellbeing is already an aggressive aesthetics player (botulinum toxin via its Innibio acquisition; the "Giselle Rebonne" ECM skin booster) [33]. This is a low-capital, near-term revenue beachhead — provided marketing avoids the word "exosome" and any medical claim, both of which MFDS began actively policing on 21 January 2025 [17].
2. **Strategic lane (12–48 months): injectable MSC / EV therapy via the GC biologic route** — either import under a GC-held marketing authorization or, better, **tech-transfer to GC Cell's CELL Center** GMP site to manufacture in-country and place product into the newly-opened "advanced regenerative medicine treatment" (ARMT) paid-treatment track [1][31]. This lane carries the full regulatory weight of a cell/gene-therapy biologic and should be scoped as a multi-year, capital-and-clinical program, not a distribution deal.

Why the white-label/import question is really a "which GC entity" question. Korea absolutely prohibits a foreign firm from holding a drug/biologic marketing authorization or acting as importer-of-record; a Korea-based Marketing Authorization Holder (MAH) must own the regulatory file and its liability [25][26][27]. For most companies this is the deal-killer. For Made it is a solved problem: GC already operates MFDS-licensed biologics (plasma, vaccines), an MFDS-approved cell therapy (Immuncell-LC), a GMP cell-therapy CDMO, an FDA-approved biologic (ALYGLO IVIG), the country's largest reference-lab network, and a live aesthetics commercial arm [31][34][36]. The task is therefore to **map each Made product to the right GC subsidiary** — GC Wellbeing for topicals/aesthetics, GC Cell for injectable cell/EV therapy and manufacturing, GC Biopharma/GC Labs for import MAH and lot testing — not to find a partner.

The honest caveats. (1) True "white-label" — Made's product under a GC brand with GC carrying no regulatory ownership — is available for cosmetics but **not** for biologics, where the MAH must genuinely own the file. (2) Korea's regulatory trend for human-derived *injectables* is tightening, not loosening (the 2025 exosome ad ban; the 2026 ECM/"cadaver-tissue" skin-booster crackdown) [17][19]. (3) The FL SB 1768 the client referenced is the **2025** Florida law (effective 1 July 2025), not a 2024 statute; its true 2024 predecessor is Utah SB 199 [40][45]. (4) Neither the Florida law nor Korea's ARMT track converts an unapproved cultured-cell biologic into an approved drug — in both countries these carve-outs sit *below* the national drug regulator [42][47].

Bottom line. Made's interest in Korea is real and, unusually, de-risked on the partner axis by the GC relationship. The right move is not a single white-label distribution agreement but a **phased entry**: bank near-term revenue and brand presence through GC Wellbeing's cosmetic/aesthetic channel now, while building the GC Cell biologic/ARMT pathway for the higher-value injectable franchise over a multi-year horizon.

1. Scope, Method & How to Read This Report

1.1 Purpose and audience

This is a regulatory-and-commercial feasibility assessment prepared for Made Scientific's commercial leadership, intended to inform partnership discussions with **GC Corporation** and **GC Wellbeing** on distributing Made's US-manufactured regenerative products into South Korea. It answers three linked questions:

1. **What does Korean law actually permit** for mesenchymal stem cells, extracellular vesicles/exosomes, and secretome/conditioned media — as products and as clinical treatments?
2. **How would a US-manufactured product legally reach a Korean patient or consumer**, and what would a "white-label through GC" structure really require, product class by product class?
3. **Is there a Korean analog to Florida's SB 1768** legal-use-of-stem-cells framework, and what is Made's commercial interest given the answer?

1.2 Products in scope

Product class	Made's form	Typical positioning
Culture-expanded MSCs	2D and 3D bioreactor-expanded mesenchymal stem cells (allogeneic and autologous)	Cell-therapy drug; regenerative/longevity
Extracellular vesicles / exosomes	MSC-derived EVs, incl. lyophilized exosome API	Therapeutic (injectable) and cosmetic (topical)
Secretome / conditioned media	MSC-secreted growth-factor-rich conditioned media	Cosmetic ingredient and biologic

Related Made assets (e.g., NK senotherapy, partner exosome programs) are referenced only where the regulatory logic is shared.

1.3 Method — full web crawl + bibliographer discipline

The evidence base was assembled with Made's standard research pipeline: a **Firecrawl** web crawl of primary and secondary sources into the Made RAG corpus (topic `korea-regen-regulatory`), combined with targeted multi-source research across MFDS notices, Korean statute translations, PubMed regulatory literature, law-firm alerts, trade press, and corporate filings. Every external factual claim in this report carries a bracketed citation `[n]` keyed to the consolidated bibliography in Appendix E. We applied a bibliographer standard: **primary law and government sources first, at least two independent sources for load-bearing claims, and explicit flagging where a claim rests on a single or lower-tier source.**

1.4 Three framing corrections carried through the report

Our research surfaced three facts that reframe the brief and should be read before the analysis:

- **Made is already inside GC.** GC Corporation is Made Scientific's long-term strategic shareholder with board representation, positioning Made as GC's specialized cell-therapy manufacturing arm [37]. The Korea "market-entry" question is therefore largely an **intra-group execution** question. This is the report's most important single input.
- **The Florida statute is the 2025 SB 1768**, signed and effective **1 July 2025** — not a 2024 law. The genuine 2024 precedent the brief likely had in mind is **Utah SB 199** (effective May 2024), the first US law to greenlight non-FDA-approved placental stem-cell therapy [40][45][46]. We analyze the correct instrument.

- **In Korea the operative dividing line is route of administration and claim, not biology.** The same MSC-derived material can be a lightly-regulated cosmetic (topical, beauty claims) or a heavily-regulated unapproved biologic (injected, or making a therapeutic claim). This boundary governs every commercial option below [11][14][22].

1.5 Status and limitations

This report states the law and regulatory posture as of July 2026. It is a strategic and regulatory assessment, **not legal advice**; product-specific market authorization strategy should be confirmed with Korean regulatory counsel and MFDS pre-submission consultation. Commercial figures drawn from third-party market research are directional and labeled as such. Items resting on a single lower-tier source, or requiring confirmation with counsel, are consolidated in Chapter 8.

2. Korea's Regulatory Architecture for Regenerative Medicine

2.1 A deliberately dual system

South Korea regulates cell, gene, and tissue-engineered therapies under a dedicated statute that stands apart from both the EU (ATMP) and US (FDA/RMAT) models. The foundational law is the **Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biological Products** — commonly the *Advanced Regenerative Bio Act* (ARBA) — enacted August 2019 and effective **28 August 2020** [2]. Its defining move was to split the field into **two parallel tracks** [2]:

- **The clinical/institution track — "advanced regenerative medicine"** — supervised by the **Ministry of Health and Welfare (MOHW)**. Medical institutions specifically *designated* under the Act conduct regenerative medicine on processed human cells (stem cells, somatic cells, immune cells, and — post-amendment — as clinical treatment).
- **The product-approval track — "advanced biological products"** — supervised by the **Ministry of Food and Drug Safety (MFDS)**, which licenses manufacturing/import, approves cell-processing facilities, and grants marketing authorization for four product categories: **Cell Therapy Products, Gene Therapy Products, Tissue-Engineered Products, and Advanced Bio-Convergence (combination) products** [2].

The practical consequence for Made: a regenerative product can reach Korean patients either as a **licensed biologic** (the MFDS product track) or as an **institution-delivered treatment** (the MOHW clinical track) — two different doors, with different keys.

2.2 The pivotal 2024 amendment (effective 21 February 2025)

The single most consequential recent development is the amendment **passed by the National Assembly in February 2024 and effective 21 February 2025**, which created a new legal category: **"advanced regenerative medicine treatment" (ARMT)** [1][6]. This converted Korea from a research-centric regime to an access-plus-safety one. Its core provisions, per the definitive peer-reviewed analysis [1] and industry reporting [5][6]:

- **Access expanded from rare/serious-only to all treatments.** The prior law limited regenerative therapy to patients with "a rare and life-threatening or severely debilitating condition with no current treatment option." The amendment extends eligibility to the general patient population — cell, gene, and tissue-engineered therapy delivered "during medical procedures" [1].
- **Providers may now charge patients.** Under the old clinical-research regime, patients could not be billed. ARMT permits designated institutions to **charge for treatment**, on a **non-reimbursable, full out-of-pocket** basis; authorization to charge runs **5 years** before institutional re-approval [1].
- **Delivered outside clinical trials**, at MOHW-designated institutions, under ethics-committee and national-committee review [1][8].
- **Risk-tiering retained.** ARMT is classified high / moderate / low risk — high = embryonic- and iPSC-derived cells; moderate = manipulated autologous and allogeneic cells; low = minimally-manipulated autologous cells — with evidence and review burden scaling by tier [1].

Korean cell-therapy companies (GC Cell, CHA Biotech, GI Cell and others) publicly welcomed the amendment as a demand catalyst for manufacturing and treatment, while flagging **CMC/quality-control readiness** as its principal risk [5][6]. The peer-reviewed critique notes two gaps: the amended rules do not explicitly require telling patients the therapy is unapproved/investigational, and impose no ARMT-specific mandatory long-term follow-up [1].

Why this matters for Made: ARMT is the closest thing Korea has to a "legal use of non-approved stem cells" pathway, and it is now a *paid* channel. But — as Chapter 6 details — it is institution-gated and committee-approved, not a blanket physician right, and a culture-expanded MSC/EV product would enter it only through a designated Korean institution's approved, risk-classified treatment plan.

2.3 The MFDS product-approval track and its accelerators

For a marketed cell/EV product, MFDS licensing runs IND → clinical trials → biologics marketing authorization, under ARBA read with the Pharmaceutical Affairs Act, with **K-GMP** aligned to **PIC/S** standards [2][3]. Korea is notably fast and receptive here: it has achieved among the **highest numbers of world-first regenerative-medicine approvals** [2], supported by several expedited routes [2][3]:

- **Conditional (provisional) approval** on Phase 2 surrogate-endpoint data, conditioned on post-marketing Phase 3 — for serious, rare, or life-threatening disease.
- **Priority review**, compressing the standard ~115-day review to ~90 days.
- **Customized / rolling ("step-by-step") review**, with incremental data submission.
- The **GIFT** fast-track program (from August 2022), cutting end-to-end timelines by roughly a quarter.

Post-market obligations are stringent, reflecting Korea's safety culture: long-term follow-up on the product track is reported at **30 years for cell therapies, 15 for gene therapies, 5 for stem-cell therapies**, via an MFDS/KIDS reporting platform launched November 2021 [3]. Reimbursement is a separate, harder gate — Korea shows a persistent authorization-vs-reimbursement gap, with high-cost cell/gene therapies handled through risk-sharing agreements, and many approved products never listed for national insurance [3]. Regenerative-aesthetic and most advanced therapies are consequently **private-pay**, which favors premium imported product.

2.4 The history that shaped the guardrails

Korea's "liberalize access, but hard-wire safety" posture is a direct product of three episodes:

- **The Hwang Woo-suk scandal (2004–2006).** Fabricated claims of patient-specific cloned human-embryonic stem cells collapsed in 2005, entrenching a cautious government stance and driving Korean patients toward "stem-cell tourism" abroad — the very outflow the 2020 Act and 2024 amendment aim to reverse by bringing treatment onshore [1].
- **The Kolon "Invossa" scandal (2017–2019).** Invossa-K, approved in 2017 as a cell-mediated gene therapy for knee osteoarthritis, was found in 2019 to contain mislabeled kidney-derived (293) cells rather than the labeled cartilage cells. **MFDS revoked the license in July 2019** and Korean courts upheld the revocation [7]. Invossa hardened MFDS's insistence on cell-identity and CMC rigor — the same rigor GC and Made would face.
- **The humidifier-disinfectant tragedy.** Mass lung injury from a product approved on paperwork alone durably elevated Korea's public-safety expectations and underpins the Act's heavy long-term-follow-up and safety-information machinery [9].

The net posture is exactly the environment Made should expect: **a receptive, fast, world-leading approver of legitimate regenerative products — paired with low tolerance for identity/quality shortcuts and a tightening grip on unapproved human-derived injectables** (Chapter 3).

2.5 Governing bodies at a glance

- **MFDS** — owns the product track (IND, clinical trials, marketing authorization, K-GMP, import, lot handling, product long-term follow-up).
- **MOHW** — owns the ARM/ARMT treatment track (institution designation, the Policy Committee and 5-year roadmap, treatment-track safety reporting).

- **Committee for Deliberation on Advanced Regenerative Medicine and Advanced Biopharmaceuticals** (~25 members plus an expert subcommittee) — reviews and approves ARM research/treatment plans [1].
- **NIFDS / KIDS / HIRA / NHIS** — scientific evaluation, post-market follow-up platform, and reimbursement listing, respectively [2][3].

3. Product-by-Product Classification: MSC, EV/Exosome, Secretome

The most important commercial insight in this report is that **Korea classifies Made's products by route of administration and marketing claim — not by the underlying biology** [11][14][22]. The same MSC-derived material can travel a light cosmetic pathway or a heavy biologic pathway depending on whether it is applied topically with beauty claims or injected/claimed as therapy. This chapter fixes each product on that map.

3.1 The controlling rule

> ***Topical + cosmetic claims → Cosmetics Act (light: self-notification / import notice, no premarket approval). Injectable, OR any therapeutic/structural claim, OR culture-expanded cells for administration → biologic drug under the Pharmaceutical Affairs Act + ARBA (heavy: full MFDS marketing authorization, IND/clinical data, K-GMP).***

A narrow middle band — **quasi-drugs (의약외품)** — exists for topical items with mild care/prevention claims, but it is defined by *exclusion from drugs* and does **not** rescue an injectable or a genuine cell/biologic [15]. There is **no research-use-only (RUO) or 361/HCT-P-style carve-out** in Korea for a cultured cell product intended for patients [22].

3.2 Culture-expanded MSCs — a licensed biologic (and Korea is the world leader at licensing them)

Culture-expanded MSCs are **"cell therapy products," a subclass of biological products** under the PAA and ARBA, regulated by MFDS [2][22]. Korea applies the classic **minimal- vs. more-than-minimal-manipulation** line: *ex vivo* culture expansion is by definition more-than-minimal manipulation, which pulls the product into the biologic regime and requires marketing authorization supported by an IND and clinical data [22]. **Any culture-expanded MSC product — precisely the category Made makes — is an unapproved biologic in Korea unless individually MFDS-licensed.**

The encouraging half of this story is that **Korea has licensed more first-in-class MSC drugs than any other country** — proof the pathway is real, if demanding [21]:

Product	Company	Cell type	Indication	Approval
Hearticellgram-AMI (Cellgram-AMI)	Pharmicell	Autologous BM-MSC	Acute myocardial infarction	2011 — world-first autologous MSC drug
Cartistem	Medipost	Allogeneic cord-blood MSC	Knee cartilage defect / osteoarthritis	2012 — world-first allogeneic cord-blood MSC drug
Cupistem	Anterogen	Autologous adipose MSC	Crohn's complex perianal fistula	2012
Queencell	Anterogen	Autologous adipose MSC	Subcutaneous tissue defect	~2010
Neuronata-R (Lenzumestrocel)	Corestem	Autologous BM-MSC (intrathecal)	ALS (orphan/conditional)	2014

Sources: [21], cross-checked against product/registry records.

For Made this means the injectable-MSC opportunity in Korea is **credible but is a drug program**, not a distribution play — and it is exactly where GC Cell's MFDS-licensed cell-therapy infrastructure becomes decisive (Chapters 4–5).

3.3 Extracellular vesicles / exosomes — the key gray zone (and the tightening one)

This is the most nuanced and most strategically important classification. The finding splits cleanly:

As a drug/biologic — injectable exosomes are unapproved. MFDS classifies human-cell-derived exosomes/EVs as **biological products** and was an early global mover, issuing the NIFDS *Guideline on Quality, Non-clinical and Clinical Assessment of Extracellular Vesicles Therapy Products* (first issued December 2018; revised 2023; English version 2024) [24]. Critically, **no exosome drug has ever been approved for marketing in Korea**; the first-ever MFDS clinical-trial (IND) approval for an exosome therapeutic came only in ~May 2025 (S&E bio's SNE-101, an IV umbilical-cord-MSC-derived exosome for stroke) [18]. Everything injected outside a trial is pre-approval and, in aesthetic clinics, **off-label** — the products used are typically *cosmetic* exosome preparations injected outside their legal indication, and documented harms (granuloma, adverse reactions, a necrosis case) have followed [20].

As a topical cosmetic — conditionally permitted, but claims are policed. Human-cell-derived material can enter cosmetics only through the **"human cell/tissue culture fluid"** route — not as free-standing "exosomes" — under the Cosmetics Act (Article 8, Appendix 3, "Safety Standards for Human Cell and Tissue Culture Liquids"), as amended by **MFDS Notification 2023-73 (November 2023)** [12][13]. The controls are **donor/source screening, GMP-grade production, and mandatory absence-testing** for the source cells and prohibited substances — i.e., the legal test is **provenance and purity, not a numeric concentration cap** [13].

The enforcement trend is toward tighter control of human-derived material:

- **21 January 2025 — the "exosome" advertising ban.** MFDS's updated *Guidelines for Cosmetic Labeling & Advertising Management* **prohibit the word "exosome" in cosmetic advertising** unless the ingredient is clearly plant/animal-derived, and ban medical-setting/"hospital-only" framing, device/procedure terms, and quantitative anti-aging claims [17]. By late May 2025, MFDS inspections had flagged 237 online ad violations, ~48% of which could be mistaken for drug/medical claims — many tied to exosome/stem-cell wording [17].
- **2026 — the ECM "skin booster" / human-tissue crackdown.** MFDS moved to tighten unapproved human-tissue-derived injectables (the "cadaver-tissue" skin-booster controversy), signaling legal amendments over injectables lacking clinical data and residue standards [19].

Human vs. non-human is decisive for claims. Plant/rose/milk/synthetic "exosome-like vesicles" are treated far more permissively than human-derived exosomes and escape the human-tissue ethical/biologic controls [12] [16]. Regionally, Korea's culture-fluid allowance is actually *permissive* compared with China (bans all human-derived cosmetic ingredients), Japan (restricts human placenta), and the EU/Australia (prohibit human tissues/cells in cosmetics) [16].

3.4 Secretome / conditioned media — same fork, cosmetic-viable topically

MSC conditioned media/secretome follows the **identical topical-vs-injectable fork** as exosomes. Topically, it is handled as the cosmetic ingredient **"human stem cell conditioned media"** — the growth-factor-rich culture supernatant — legal in cosmetics only through the same Article 8 / Appendix 3 "human cell and tissue culture fluid" safety-standard gateway strengthened by Notification 2023-73, with the same source-screening, GMP, and absence-testing obligations [13][23]. It is **not** ordinarily a quasi-drug [15]. **Any secretome/CM that is injected, or carries a therapeutic/structural claim, exits cosmetics and becomes an unapproved biologic** [11] [22]. As with exosomes, there is **no published percentage cap** — the constraint is provenance/GMP/absence-testing [13].

Of Made's three classes, **secretome/conditioned media is the cleanest fit for the fast cosmetic lane**: it has an established, named cosmetic-ingredient pathway in Korea and does not carry the specific "exosome" advertising restriction (though it must still avoid medical claims).

3.5 Product classification matrix

Product class	Korean legal classification	Governing statute/agency	Topical cosmetic viable?	Injectable status	Approval needed
Culture-expanded MSC	Cell therapy product (biologic)	PAA + ARBA / MFDS	No (it is a cell product)	Unapproved biologic unless licensed	Full marketing authorization + IND/clinical + K-GMP
Exosome / EV (human-derived)	Biologic if therapeutic; cosmetic ingredient only as "human cell culture fluid"	PAA + ARBA / MFDS; Cosmetics Act	Yes, as culture fluid — but "exosome" ad term banned (Jan 2025)	Unapproved biologic; off-label in clinics	Biologic: full MA. Cosmetic: self-notification + safety standard
Secretome / conditioned media	Cosmetic ingredient ("human stem cell conditioned media"); biologic if injected/claimed	Cosmetics Act (Art. 8 App. 3); PAA if injected	**Yes — cleanest cosmetic fit**	Becomes unapproved biologic if injected	Cosmetic: self-notification + safety standard. Biologic: full MA
Non-human "exosome-like" vesicles	Ordinary cosmetic ingredient	Cosmetics Act	Yes (most permissive)	n/a for cosmetic use	Self-notification

Strategic read: the cosmetic pathway is genuinely open and light for **secretome/culture-fluid** (and non-human vesicles) topicals, but it is **claim-fragile** — the moment marketing implies medical benefit, or the product is injected, it reclassifies as an unlicensed biologic. Human-derived exosomes and culture-expanded MSCs cannot be sold or administered as anything but licensed biologics when injected, and the enforcement trend is tightening. Made's fast money is in topical secretome/EV cosmetics; its big money is in the injectable biologic franchise, which is a multi-year GC-anchored program.

4. Import, Marketing Authorization & the White-Label Reality

4.1 The linchpin: a Korean entity must hold the license

For biologics and cell products, Korean law is unambiguous and unavoidable: **a foreign manufacturer cannot hold the Korean product license or act as importer-of-record.** A **Korea-based entity** must serve as the license/registration holder — variously the In-Country Caretaker (ICC), local Marketing Authorization Holder (MAH), or Korea License Holder (KLH) — and imported products may be brought in only by MFDS-certified licensed importers [25][26][27][28]. That local holder must be a legally established Korean company with the relevant import/manufacturing business license and a qualified quality/regulatory manager as MFDS's counterparty, and it **carries the regulatory liability** for safety, GMP, labeling, pharmacovigilance, and recall [26][28].

This is the single fact that ends most foreign companies' Korea ambitions before they start. For Made it is already solved (Chapter 5) — which is why the report treats the import question as "which GC entity holds the file," not "can we enter."

4.2 What importing a US-made biologic actually requires

Beyond the license holder, a US-manufactured cell/EV therapy would face the full biologic import chain [26][29][30]:

- **Overseas GMP (K-GMP) assessment of Made's US site.** The Korean importer (not Made) files for GMP evaluation, and **MFDS conducts document review and an on-site inspection of the US manufacturing facility** — recent overseas certifications have followed multi-day on-site inspections with pass criteria of no critical/major findings [29]. K-GMP standing is tied to the specific Korean importer that filed it.
- **Import testing / lot handling.** Korea operates a national lot-release system for designated biologics under PAA Article 53 (routine for vaccines/plasma; patient-specific autologous products are handled differently), and imported biologics clear through MFDS-registered testing/import procedures managed by the local importer [30].
- **Korean-language labeling and pharmacovigilance**, owned by the MAH [26].

The realistic result: a US-made injectable cell/EV product reaches a Korean patient only through a Korean MAH that (i) holds the license, (ii) sponsors the overseas GMP inspection of Made's site, (iii) manages MFDS import testing, and (iv) owns Korean labeling and safety reporting. This is a **multi-year program**, not a shipping arrangement.

4.3 The far lighter cosmetic import channel

For a **topical cosmetic** (e.g., a secretome serum or non-human EV skincare making only cosmetic claims), the burden collapses [14]:

- Register a **Responsible Cosmetic Distributor/Seller** (a Korea-based entity) with a Responsible Distribution Manager.
- **General cosmetics need no premarket MFDS registration**; imported general cosmetics require a standard customs-clearance notice from the Korea Pharmaceutical Traders Association (KPTA) before release.
- **Functional cosmetics** (whitening, anti-wrinkle, UV) require a premarket report/review — largely automatic if the ingredient/efficacy matches an existing MFDS notification.

Timeline is **weeks to a few months** and cost is a small fraction of a biologic filing — versus the multi-year, inspection-heavy biologic route. The Responsible Seller must still be Korea-based, so GC (e.g., GC Wellbeing) remains the natural holder — but the friction is trivial by comparison.

4.4 What "white-label" can and cannot mean, by product class

"White-label" means different things in the two regimes, and conflating them is the most common strategic error:

- **Cosmetics — genuine white-label is normal.** Korea is the global capital of cosmetic ODM/OEM (Kolmar Korea, Cosmax), and "one formula, one company" exclusive private-label is routine. A Made topical sold under a GC Wellbeing brand — imported from Made's US line under a Responsible Seller, or filled by a Korean ODM — is entirely standard and fast.
- **Biologics — "white-label" does not neutralize MAH liability.** Whoever's name is on the Korean biologic license bears full regulatory responsibility regardless of whose brand is on the box [26]. A pure "Made product, GC label, GC carries no regulatory ownership" arrangement is **not available** for a biologic. The workable biologic structures are:
  - **(a) In-license / contract-import** — GC (as Korean MAH) licenses and imports Made's US-manufactured product, registers it, sponsors the overseas GMP inspection, and distributes (possibly co-branded); or
  - **(b) Tech-transfer / contract manufacture** — Made's process is transferred to a Korean GMP site (GC Cell's CELL Center) and made in Korea under a Korean license, avoiding import/lot-release friction entirely.

Structure (b) is often the superior long-run model for a cell/EV franchise: it removes the overseas-inspection and import-testing burden, localizes supply, and plays directly to GC Cell's existing capability — at the cost of transferring process know-how into the group (which, given GC's shareholding in Made, is a smaller concern than for an arm's-length partner).

4.5 Import pathway comparison

Product class	Pathway	License holder	GMP requirement	Approx. timeline	Difficulty/cost
Injectable MSC / EV therapy (import)	MFDS marketing authorization (PAA+ARBA); licensed importer; import testing; Korean labeling	Korea-based MAH (GC Biopharma/GC Cell)	K-GMP + **on-site inspection of Made's US site**	Multi-year (clinical + review; conditional/priority can shorten review to ~90 days)	Highest
Injectable made in Korea (tech-transfer to GC Cell)	Korean GMP manufacture + MFDS product license	Korean manufacturer/MAH (GC Cell)	K-GMP at CELL Center (already authorized)	Tech-transfer + review; no overseas inspection/import testing	High but de-risked
Functional cosmetic (topical, efficacy claim)	MFDS premarket report (auto if ingredient matches notification) + KPTA import notice	Responsible Cosmetic Seller (GC Wellbeing)	Cosmetic GMP/QC standards	Weeks–few months	Low–moderate
General cosmetic (topical, no functional claim)	No premarket registration; KPTA customs-clearance notice	Responsible Cosmetic Seller (GC Wellbeing)	Cosmetic QC / distribution-manager standards	Weeks	Lowest

5. The GC Corporation Partner Fit

5.1 Why the hard problem is already solved

Chapter 4 established the barrier that stops most foreign firms: only a Korea-based entity can hold a biologic license and be importer-of-record, and it carries the regulatory liability. **Made does not have to find that entity — it is already inside GC.** Made Scientific describes itself as "a proud member of South Korea's GC Corporation," which is Made's **long-term strategic shareholder**, and Made's board includes two GC-affiliated directors — **Soyoung Park** (Managing Director of GC Corporation's Strategy Planning Division) and **Jin Pyun** (CEO of GC Ventures) [37]. The Korea opportunity is therefore not a market-entry negotiation with a third party; it is an **intra-group execution** decision about which GC subsidiary holds each product file. That materially lowers commercial, trust, and IP-transfer risk relative to any arm's-length distribution deal. (The precise equity stake is not publicly disclosed; the "member/strategic shareholder" characterization here is Made's own public description and should be paired with the internal cap-table detail when used externally.)

5.2 GC is a full-stack biologic operator, not just a shareholder

GC Corporation sits atop roughly 45 affiliates and possesses — in one group — every capability the Chapter 4 chain requires [31][33][34][36]:

- **GC Biopharma** (formerly Green Cross) — plasma-derived therapeutics and vaccines; a genuinely **stringent-regulator-experienced biologics company**, having won **US FDA approval for its IVIG ALYGLO in December 2023** [34]. This demonstrates GC can operate biologics under FDA-grade scrutiny — the discipline needed to sponsor Made's product before MFDS. Natural role: **import MAH** for an imported biologic.
- **GC Cell** (formed 2022 from GC LabCell + Novacel) — the cell-therapy core. It markets **Immuncell-LC**, Korea's MFDS-approved autologous immune-cell therapy for post-resection liver cancer, administered to 10,000+ patients; runs allogeneic **NK / CAR-NK** programs; and operates Korea's **CELL Center** GMP cell-therapy manufacturing and a full **CDMO/QC/RA/CMC** operation [31]. GC Cell also executed a **process-transfer agreement with BioCentriq** (its US cell-therapy CDMO affiliate) to bring Immuncell-LC toward the US — evidence GC routinely runs exactly the kind of transatlantic cell-therapy tech-transfer Made would need [32]. Natural role: **tech-transfer/contract-manufacture home** and **cell-therapy MAH**.
- **GC Wellbeing** — nutraceuticals, placenta/vitamin injections, and — decisively for Made's near-term play — **an aggressive aesthetics move**: it acquired botulinum-toxin company **Innibio (₩40bn)** and launched the **"Giselle Rebonne" ECM skin booster** into Korean derm/aesthetic clinics; GC Holdings bought GC Wellbeing's full stake in April 2026 to focus it on high-margin aesthetics [33]. Natural role: **commercial channel for Made's wellness/aesthetic topicals and, over time, aesthetic injectables.**
- **GC Labs / GCCL** — Korea's largest reference laboratory (serving 90%+ of university hospitals; ~25,000 samples/day) and a leading APAC clinical-trial central lab [36]. Natural role: **QC, import lot-testing, biobanking, and clinical-trial lab support.**

The strategic point: GC can be the **license holder, the overseas-GMP sponsor, the in-country manufacturer, the lot-testing lab, and the distributor** — the entire biologic import chain sits inside one group that already co-owns Made.

5.3 Product-to-entity mapping

Made product / positioning	Best GC entity	Structure	Speed
Topical secretome / conditioned-media skincare	**GC Wellbeing**	Responsible Cosmetic Seller; imported or ODM-filled; GC-branded	Fast (weeks–months)

Made product / positioning	Best GC entity	Structure	Speed
Non-human / "exosome-like" topical cosmetics	**GC Wellbeing**	Cosmetic self-notification	Fast
Aesthetic injectables (longer-term, e.g., regenerative boosters)	**GC Wellbeing + GC Cell**	Biologic MA; clinic channel	Slow (multi-year)
Injectable MSC / EV therapy	**GC Cell** (mfg) / **GC Biopharma** (import MAH)	Tech-transfer to CELL Center, or import under GC MAH; ARMT treatment track	Slow (multi-year)
QC / lot testing / trial lab	**GC Labs / GCCL**	Service support across all lanes	Enabling

5.4 The Korean market GC would sell into

Korea is a top-tier, largely private-pay destination for regenerative aesthetics and cell therapy [38][39]:

- **Medical aesthetics** is variously sized from ~US$0.5bn (device-centric) to ~US$3.8bn (broad, 2026), growing ~9–11% and shifting decisively **"from fillers to regeneration"** — collagen stimulators, polynucleotides, exosomes, skin boosters [38].
- **Medical tourism is a demand amplifier**: Korea drew ~2 million foreign medical patients in 2025, dermatology ~60% of foreign-patient visits, US visitors rising sharply [39].
- **Reimbursement**: regenerative-aesthetic and most advanced therapies are **out-of-pocket/private-pay**, reflecting Korea's authorization-vs-reimbursement gap — favorable for premium imported product [3][39].

For Made, this is a market where GC already has brand, clinics, and regulatory standing — and where the regenerative wave GC Wellbeing is riding (skin boosters, exosome trend) is precisely Made's product wheelhouse.

6. The "Florida SB 1768 Analog" Question

The brief asks whether Korea offers a legal environment "similar to FL SB 1768" — a route to use stem-cell therapies that are not fully FDA/MFDS-approved. The answer is a qualified yes: **Korea has a real, recently-liberalized, paid pathway for non-approved regenerative therapy, but its architecture is the opposite of Florida's.** This chapter fixes both instruments precisely.

6.1 What Florida SB 1768 actually is (and a date correction)

First, the record: the operative statute is **CS/CS/SB 1768 of Florida's 2025 Regular Session**, which passed unanimously, was signed, and took effect **1 July 2025** — not a 2024 law [40][41]. The genuine 2024 US precedent the brief likely had in mind is **Utah SB 199 (2024)**, the first state law to greenlight non-FDA-approved placental stem-cell therapy [45][46]. Florida is the *tightened successor* to Utah.

SB 1768 creates parallel sections of the Florida Statutes for MDs (§458.3245) and DOs (§459.0127) that authorize a licensed physician to **"perform stem cell therapy that is not approved by the FDA,"** provided it is within the physician's scope and relates to **orthopedics, wound care, or pain management** — a hard indication limit that excludes neurological, systemic, aesthetic, anti-aging, and general-wellness uses [40][42]. Cells must be **retrieved/manufactured/stored in an FDA-registered facility**, that facility must be **accredited** (AABB, AATB, NMDP, or WMDA), the product must **contain viable cells on post-thaw analysis**, and cGMP per **21 CFR Part 1271** applies [40]. Mandatory **informed consent** must disclose that the therapy "has not yet been approved by the FDA," and advertising must carry a verbatim disclaimer [40][42]. Crucially, the statute's own text **requires compliance with the federal FDCA and 21 CFR 1271** — it is drafted as a *state-practice permission that expressly does not displace federal law* [40].

6.2 The federal ceiling neither Florida nor Korea removes

Both regimes sit *below* their national drug regulator. Under **21 CFR Part 1271**, a human cell/tissue product is regulated solely under Section 361 of the PHS Act (no premarket approval) only if it meets every 1271.10(a) criterion — most importantly **minimal manipulation** and **homologous use** [47][48]. **Culture-expanding cells, or using MSC/EV products for non-homologous indications, pushes the product into the Section 351 "biologic/drug" column, requiring an approved BLA or active IND** [47]. This is Made's own internal frame — there is no RUO exemption for cultured cell/biologic products; culture-expanded MSC, secretome, and exosome fail 1271.10(a) and are unapproved 351 biologics. State laws like SB 1768 create **state-law permission** (removing state-board discipline, and in Florida licensing the marketing) but provide **no shelter** for a 351 product in interstate commerce; Holland & Knight's analysis is blunt that the Florida law "is in direct conflict with federal law" and enforcement risk remains [42]. The identical logic applies in Korea: neither track converts an unapproved cultured-cell product into an approved drug.

6.3 Korea's actual analog: the ARMT treatment track

Korea's closest structure is the **"advanced regenerative medicine treatment" (ARMT)** track under the Advanced Regenerative Bio Act, created by the 2024 amendment effective **21 February 2025** (Chapter 2) [1]. It is genuinely consequential: it created a legal route to give **non-fully-approved** cell/gene/tissue therapies to patients **outside a clinical trial**, expanded eligibility from rare/serious-only to the general population, and — for the first time — **permits charging patients** [1]. In spirit, this answers the brief's question affirmatively: Korea now has a paid, legal channel for regenerative therapies that have not cleared ordinary drug approval.

But the **mechanism is fundamentally different from Florida's**, in four structural ways [1]:

1. **Institution-gated, not a physician right.** Only MOHW-*designated* provider institutions may offer ARMT, each submitting a treatment plan for prior approval. Florida grants *every* licensed MD/DO a standing statutory permission.
2. **Centralized committee/IRB review, per protocol.** Every ARMT plan is reviewed by the national Deliberation Committee plus the institution's IRB. Florida has **no protocol-review body** — consent plus accredited sourcing is the whole gate.
3. **Statutory risk-tiering drives the evidence bar.** ARMT is high/moderate/low risk, and higher tiers require the same institution to have completed prior clinical research before offering paid treatment. Florida substitutes indication limits and tissue-source accreditation, with no graduated evidence requirement.
4. **Safety reporting to the state.** ARMT institutions must run safety monitoring and file reports through a national system; Florida's oversight is disclosure-plus-consent and after-the-fact board discipline.

In one line: *US/Florida = a deregulatory state permission, self-executing per physician, with federal law untouched above it. Korea/ARMT = a government-run, committee-approved, institution-designated controlled-access system administered by MOHW alongside the MFDS product track.* Same purpose, opposite architecture.

6.4 What this means for porting a Made product

For Made's real question — "could our non-approved regenerative products find a legal home in Korea?" — ARMT is the only non-drug route, but it is **not a drop-in**. A US-manufactured, culture-expanded MSC/secretome/exosome product entering ARMT would face: (a) import/quality qualification of Made's US site; (b) placement into the correct risk tier (culture-expanded/engineered → high or moderate risk, triggering the institution's prior-clinical-research prerequisite); and (c) Deliberation-Committee-plus-IRB approval of a specific institutional treatment plan [1]. It is a genuine paid pathway, but a **gated, protocol-by-protocol, institution-anchored one** — a market a product is *admitted into*, not one it simply ships to. Notably, this is *milder* than the same product's US problem, where absent an IND/BLA it is an unapproved 351 biologic and Florida's statute offers no interstate shelter [42][47].

6.5 Bottom line

Korea does offer a real, paid legal route to administer regenerative therapies that are not full MFDS-approved drugs — the ARMT track, materially broadened in 2025 to reach general patients and to permit charging — so in spirit it answers the "FL 1768-like pathway?" question yes. **But it is not a Florida-style analog in mechanism**: Florida hands every physician a self-executing permission; Korea runs a designated-institution, committee-approved, risk-tiered channel. For Made, a US-made cultured product cannot simply "ship into" Korea under ARMT — it enters only through a designated Korean institution's approved plan, which in practice means a **GC-anchored, protocol-by-protocol program**, not open-market distribution. And in both countries the carve-out sits below the national regulator: neither converts an unapproved cultured biologic into an approved drug.

7. Commercial Opinion & Recommendation

This chapter is Made Scientific's internal strategic opinion. It integrates the regulatory findings above with Made's commercial position and the GC relationship.

7.1 The opinion in one paragraph

Made should pursue Korea — but reframe the opportunity. This is not a single "white-label distribution deal" for stem-cell products; it is a **phased, two-speed market build executed intra-group with GC.** The near-term, low-risk value is in **topical cosmetic secretome / EV skincare through GC Wellbeing**, which can generate revenue and brand presence within a year. The larger, slower value is the **injectable MSC/EV therapy franchise via GC Cell** — a multi-year biologic/ARMT program, not a distribution arrangement. The "FL 1768 legal-use" thesis should be retired as the framing: Korea's liberalization is real and favorable, but it does not create an open-market shortcut for a US cultured product; it creates a *gated* paid pathway that GC must sponsor.

7.2 Why Made's interest is genuine and unusually de-risked

Three things make Korea materially more attractive for Made than for a typical US regenerative company:

1. **The license-holder barrier is pre-solved.** The one requirement that ends most foreign entries — a Korean MAH that owns the regulatory file and liability — is satisfied by GC, Made's own strategic shareholder, which already runs MFDS-licensed biologics, an approved cell therapy, GMP cell manufacturing, an FDA-approved biologic, and a live aesthetics channel [31][34][37]. Made is negotiating with the house, not a stranger.
2. **The market is receptive and premium.** Korea is a world-leading, fast approver of regenerative products [2], its aesthetics market is shifting "fillers → regeneration," exosomes/skin boosters are a headline trend, and demand is amplified by ~2M/yr medical tourists and a private-pay model that rewards premium imports [38][39].
3. **Product-market fit with GC Wellbeing is immediate.** GC Wellbeing is *already* selling into the exact channel (botulinum toxin, an ECM skin booster) where Made's regenerative topicals belong [33].

7.3 The recommended path: a two-speed program

Lane A — Fast (0–12 months): topical cosmetic secretome/EV via GC Wellbeing

- **What:** launch a GC Wellbeing–branded topical line built on Made's secretome/conditioned-media (and, positioned carefully, non-human or culture-fluid EV) skincare.
- **Why it works:** Korea permits human-cell culture fluid/conditioned media as a cosmetic ingredient under a defined safety standard; the pathway is self-notification plus KPTA clearance, measured in weeks-to-months; GC Wellbeing is the ready-made Responsible Seller and channel [13][14][33].
- **Hard constraints:** marketing must avoid the word **"exosome"** and any medical/clinic-exclusive or quantitative anti-aging claim — MFDS began actively policing exactly these on 21 January 2025 [17]. Source/GMP/absence-testing under the culture-fluid safety standard must be met [13].
- **Value:** near-term revenue, a live Korea presence, brand co-building with GC, and a real-world proof point — with minimal capital and regulatory exposure.

Lane B — Strategic (12–48 months): injectable MSC/EV therapy via GC Cell

- **What:** build the injectable cell/EV franchise through GC Cell, choosing between **(a) import under a GC-held MAH** or, preferably, **(b) tech-transfer to GC Cell's CELL Center** to manufacture in-country, then place product into the **ARMT paid-treatment track** and/or pursue MFDS marketing authorization [1][31].

- **Why (b) over (a):** in-country manufacture removes the overseas-GMP-inspection and import-testing burden, localizes supply, and leverages GC Cell's existing MFDS-licensed capability; the usual downside (transferring process know-how to a partner) is muted because GC is a Made shareholder, not an arm's-length counterparty.
- **Recognize it for what it is:** a multi-year, capital-and-clinical program carrying the full weight of a cell/gene-therapy biologic (IND/clinical data, K-GMP, long-term follow-up, ARMT risk-tiering and committee approval). Scope and staff it accordingly; do not let the cosmetic lane's speed set expectations for this one.

Sequencing logic

Lane A funds attention and credibility while Lane B is built. The two share a partner (GC), a market thesis (regeneration), and a brand — but they are on different regulatory clocks and must be resourced separately.

7.4 What to decide with GC next

1. **Confirm the entity map** (Chapter 5): GC Wellbeing for Lane A; GC Cell (manufacture) / GC Biopharma (import MAH) for Lane B; GC Labs/GCCL for QC/lot testing.
2. **Pick the Lane B structure** — import vs. tech-transfer — with a bias toward tech-transfer to CELL Center for the flagship injectable.
3. **Lock the Lane A claim set** with Korean cosmetic-regulatory counsel to stay inside the Jan-2025 advertising rules before any launch.
4. **Commission MFDS pre-submission consultation** for the lead injectable product to fix the risk tier, the ARMT-vs-marketing-authorization route, and the overseas-GMP plan for Made's US site.

7.5 The one-sentence recommendation

Yes to Korea, through GC, as a phased build — bank near-term revenue and brand through GC Wellbeing's cosmetic/aesthetic channel now, and construct the higher-value injectable MSC/EV franchise through GC Cell over a multi-year horizon — while dropping the "FL 1768 open-use" framing in favor of Korea's real, but gated, ARMT and biologic pathways.

8. Risks, Caveats & Open Items

8.1 Regulatory and commercial risks

#	Risk	Why it matters	Mitigation
R1	**Human-derived injectables tightening.** MFDS is moving *toward* stricter control of unapproved human-tissue injectables (2025 exosome ad ban; 2026 ECM/"cadaver-tissue" skin-booster crackdown) [17][19].	The injectable EV/skin-booster route may narrow before it widens.	Lead with topical cosmetic (Lane A); build injectables only through the formal biologic/ARMT route, not clinic off-label.
R2	**Claim fragility (cosmetic → biologic).** A single medical/anti-aging claim, or any injection, reclassifies a Made topical as an unlicensed biologic [11][14].	Turns a weeks-long cosmetic launch into a multi-year drug problem — or an enforcement action.	Lock the claim set with Korean cosmetic counsel; ban "exosome" and medical wording in Lane A marketing.
R3	**"White-label" mis-scoping for biologics.** The MAH must genuinely own the biologic file and liability; a name-only GC label is not lawful for a biologic [26].	A deal drafted as pass-through white-label would fail.	Structure Lane B as in-license or tech-transfer with GC as true MAH.
R4	**Overseas GMP inspection of Made's US site.** Import route requires MFDS on-site inspection of Made's facility [29].	Findings could delay or block import.	Prefer tech-transfer to CELL Center; if importing, pre-audit Made's site to K-GMP/PIC/S.
R5	**Authorization ≠ reimbursement.** Korea's advanced therapies are largely private-pay [3].	Volume depends on cash-pay demand, not insurance.	Price and position for the private aesthetic/wellness and medical-tourism market (a strength, not just a risk).
R6	**ARMT is gated, not open.** Entry requires designated institution + committee + risk-tier evidence [1].	No open-market shortcut for a US cultured product.	Treat ARMT as a sponsored, protocol-by-protocol program via GC-affiliated institutions.
R7	**Channel/brand conflict inside GC.** Multiple GC entities (Wellbeing, Cell, Biopharma) could contend for the same product.	Internal ambiguity slows execution.	Agree the entity map (Ch. 5) explicitly before launch.

8.2 Items to verify before external use

These are load-bearing points that rest on a single or lower-tier source, or that should be confirmed with counsel/primary text:

- **Exact ARMT implementing-rule detail** (which specific indications are practically reachable at each risk tier; consent-disclosure requirements) — confirm against the MFDS/MOHW enforcement decree, beyond the peer-reviewed summary [1].
- **Cosmetic culture-fluid safety standard specifics** (the precise absence-testing panel and source-screening under Cosmetics Act Art. 8, Appendix 3) — confirm current text of MFDS Notification 2023-73 with counsel [13].
- **Whether patient-specific autologous cell products are subject to national lot release** (distinct from vaccine/plasma practice) [30].
- **Made–GC relationship characterization** — *confirmed* against Made's public site: Made is "a proud member of South Korea's GC Corporation," GC is its "long-term strategic shareholder," and two Made directors are GC-affiliated (Soyoung Park, GC Strategy Planning MD; Jin Pyun, GC Ventures CEO) [37]. Only the **precise equity percentage** is not public — pair with internal cap-table detail before external use.
- **Market-size figures** (aesthetics, exosome segment, medical-tourism volumes) are third-party research and directional; commission a bespoke sizing before investment decisions [38][39].

- **The 2026 ECM/"cadaver-tissue" enforcement** is now corroborated across multiple sources (MFDS announced legal amendments within H1 2026 on 30 Mar 2026, citing absence of clinical trials, no SDS/residue standards, decellularization contradictions, and donor-purpose deviation) [19] — continue to monitor MFDS notices directly as the rulemaking finalizes.

8.3 What this report deliberately does not do

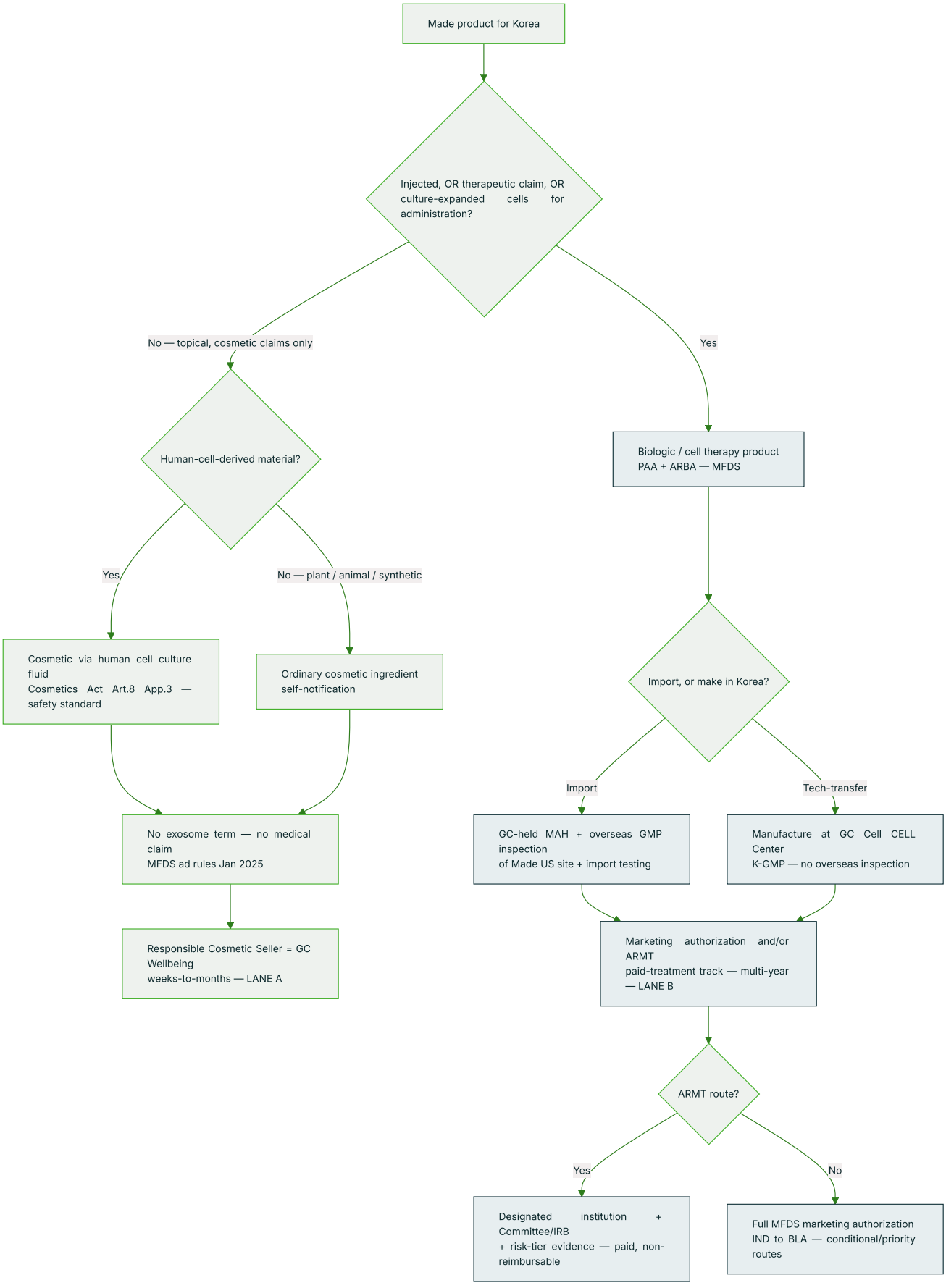
It does not provide legal advice, a market-authorization dossier strategy, or a financial model. It fixes the regulatory landscape and Made's strategic options; the recommended next steps in §7.4 — entity map, Lane-B structure, claim-set sign-off, and MFDS pre-submission consultation — convert this assessment into an executable plan.

Appendix A — Regulatory Timeline

Date	Jurisdiction	Event	Cite
2004–2006	Korea	Hwang Woo-suk hESC fraud → entrenched restrictive posture, drove stem-cell tourism	[1]
1994–2011	Korea	Humidifier-disinfectant tragedy → elevated public-safety culture underlying the Act	[9]
2011	Korea	Pharmicell Hearticellgram-AMI — world-first autologous MSC drug approved	[21]
2012	Korea	Medipost Cartistem — world-first allogeneic cord-blood MSC drug approved	[21]
Dec 2018	Korea	NIFDS issues EV-therapy-product guideline (Guidance-0917 series)	[24]
Aug 2019	Korea	Advanced Regenerative Bio Act (ARBA) enacted	[2]
Jul 2019	Korea	MFDS revokes Kolon Invossa license (mislabeled cells); later upheld by courts	[7]
28 Aug 2020	Korea	ARBA takes effect (dual track: MOHW treatment / MFDS product)	[2]
Nov 2021	Korea	MFDS/KIDS long-term-follow-up reporting platform launched	[3]
Aug 2022	Korea	MFDS GIFT fast-track program launched	[3]
Nov 2023	Korea	MFDS Notification 2023-73 — human cell/tissue culture fluid permitted in cosmetics under safety standard	[13]
Dec 2023	US/Korea	GC Biopharma ALYGLO IVIG wins US FDA approval	[34]
Feb 2024	Korea	National Assembly passes ARBA amendment creating ARMT	[1][6]
May 2024	US	Utah SB 199 effective — first US law greenlighting non-FDA-approved placental stem-cell therapy	[45] [46]
21 Jan 2025	Korea	MFDS cosmetic labeling/advertising rules ban "exosome" in cosmetic ads + medical/anti-aging claims	[17]
21 Feb 2025	Korea	ARBA amendment (ARMT) takes effect — general-patient access, paid treatment	[1]
~May 2025	Korea	S&E bio SNE-101 — Korea's first exosome-therapeutic IND approval	[18]
1 Jul 2025	US	Florida SB 1768 (2025) takes effect — physician-administered non-FDA-approved stem-cell therapy (ortho/wound/pain)	[40] [42]
2026	Korea	MFDS moves to tighten unapproved human-tissue injectables (ECM "skin booster"/"cadaver-tissue" controversy)	[19]

Appendix B — Korea Market-Entry Decision Flow

The controlling question for any Made product is set by route of administration and claim. The flow below routes each product to its pathway and GC entity.


Made product for Korea
Injected, OR therapeutic claim, OR culture-expanded cells for administration?
No — topical, cosmetic claims only
Yes
Human-cell-derived material?
Biologic / cell therapy product
PAA + ARBA — MFDS
Yes
No — plant / animal / synthetic
Import, or make in Korea?
Cosmetic via human cell culture fluid
Cosmetics Act Art.8 App.3 — safety standard
Ordinary cosmetic ingredient self-notification
Import
Tech-transfer
GC-held MAH + overseas GMP inspection
of Made US site + import testing
Manufacture at GC Cell CELL Center
K-GMP — no overseas inspection
No exosome term — no medical claim
MFDS ad rules Jan 2025
Marketing authorization and/or ARMT
paid-treatment track — multi-year — LANE B
Responsible Cosmetic Seller = GC Wellbeing
weeks-to-months — LANE A
ARMT route?
Yes
No
Designated institution + Committee/IRB
+ risk-tier evidence — paid, non-reimbursable
Full MFDS marketing authorization
IND to BLA — conditional/priority routes

Classification quick-reference

If the product is…	…it is treated as	Pathway	GC entity	Speed
Topical secretome/conditioned-media serum, cosmetic claims	Cosmetic (culture-fluid ingredient)	Self-notification + KPTA	GC Wellbeing	Weeks–months
Topical non-human "exosome-like" skincare	Ordinary cosmetic	Self-notification	GC Wellbeing	Weeks
Topical human "exosome" cosmetic	Cosmetic — but term banned in ads	Self-notification (rename/reframe)	GC Wellbeing	Weeks–months
Injectable exosome/EV	Unapproved biologic	Marketing authorization / ARMT	GC Cell / GC Biopharma	Multi-year
Culture-expanded MSC (any injected use)	Cell therapy product (biologic)	Marketing authorization / ARMT	GC Cell	Multi-year

Appendix C — Florida SB 1768 vs. Korea ARMT Track

Dimension	Florida SB 1768 (2025; §§458.3245 / 459.0127)	Korea ARMT track (2024 amendment, eff. 21 Feb 2025)
Legal basis	State statute; new Florida Statutes sections for MDs/DOs [40]	National statute (Advanced Regenerative Bio Act), enacted 2019 / eff. 2020, amended 2024 / eff. Feb 2025 [1]
Who authorizes	Self-executing: any licensed FL physician within scope; no protocol pre-approval; board discipline after the fact [40]	MOHW *designates* provider institutions; national Deliberation Committee + IRB approve each treatment plan in advance [1]
Who may perform / where	Individual MD/DO, in ordinary practice [40]	Only MOHW-designated institutions, per approved plan [1]
Product-source rules	Placental/perinatal or HCT/Ps; FDA-registered + accredited facility; cGMP per 21 CFR 1271; post-thaw viability; no fetal/abortion-derived cells [40]	Human-cell cell/gene/tissue therapy; risk-tiered (high/moderate/low); higher tiers need prior clinical research by same institution [1]
Permitted indications	Narrow: orthopedics, wound care, pain management only [40][42]	Broad after amendment: expanded from rare/serious to general patients (per committee approval) [1]
Paid / commercial	Yes — commercial physician practice; advertising disclaimer required [40]	Yes — amendment newly permits charging; non-reimbursable/out-of-pocket; 5-yr authorization then re-review [1]
Oversight / safety reporting	Informed consent + advertising disclaimer; board discipline; no central committee/registry [40]	Committee + IRB review; national safety-information uploads; interim/final MOHW reports [1]
Relationship to national drug regulator	Does **not** override FDA; text requires FDCA & 21 CFR 1271 compliance; 351 products still need BLA/IND [40][42][47]	Parallel track to MFDS product approval, same government; treatment track ≠ marketing authorization [1]
Portability of a US product	N/A domestically; a culture-expanded 351 product gets no interstate shelter from the state law [42] [47]	Possible only via a designated institution's approved plan + risk-tier evidence + foreign-manufacturer qualification — gated, not open-market [1]
One-line character	Deregulatory practice permission	Government-run controlled-access system

Reading: analogous in *purpose* (a legal channel to administer non-approved regenerative therapy, distinct from the drug-approval track), opposite in *architecture* (self-executing physician permission vs. designated-institution committee approval). In both, the carve-out sits *below* the national drug regulator — neither converts an unapproved cultured biologic into an approved drug.

Appendix D — GC Corporation Group Map (for the Made deal)

Entity	Role in group	Assets relevant to Made × Korea	Natural role in the deal	Cite
GC Corp (Holdings)	Group holding company; **Made's long-term strategic shareholder** (Made = "a proud member of GC Corporation"); 2 GC-linked Made directors — Soyoung Park (GC Strategy Planning MD) & Jin Pyun (GC Ventures CEO)	~45 affiliates; the corporate parent tying the group to Made	Sponsor/owner of the intra-group strategy	[37]
GC Biopharma (formerly Green Cross)	Plasma therapeutics + vaccines (flagship)	MFDS-licensed biologics infrastructure; **US FDA-approved ALYGLO IVIG** (stringent-regulator credibility)	Import **MAH** for an imported biologic	[34]
GC Cell (GC LabCell + Novacel, 2022)	Cell-therapy development + **CDMO** + bio-logistics	**Immuncell-LC** (MFDS-approved autologous immune-cell therapy, 10,000+ patients); NK/CAR-NK pipeline; **CELL Center** GMP; BioCentriq (US) process-transfer track record	**Tech-transfer / contract-manufacture home**; cell-therapy MAH	[31] [32]
GC Wellbeing	Nutraceuticals + injections + **aesthetic medicine**	**Innibio** botulinum toxin (₩40bn); **"Giselle Rebonne" ECM skin booster**; placenta/vitamin injections; clinic/aesthetics distribution	**Lane-A commercial channel** — Responsible Cosmetic Seller for topicals; aesthetic injectables later	[33]
GC Labs / GCCL	Reference lab + Global Clinical Central Lab (CRO)	Serves 90%+ of Korean university hospitals; ~25,000 samples/day; QC/release testing; trial-lab	**QC, import lot-testing, biobanking, trial support**	[36]
Made Scientific	US (NJ/Princeton) cell-therapy CDMO; GC member company	US cGMP MSC/EV/secretome manufacturing — the product/process to import or tech-transfer	Manufacturer / process owner	[37]

Key implication: GC can simultaneously be the license holder, the overseas-GMP sponsor, the in-country manufacturer, the QC/lot-testing lab, and the distributor. The entire Chapter-4 import chain sits inside one group that already co-owns Made — which is why the Korea question is execution, not entry.

Appendix E — Bibliography

Sources are grouped by theme and numbered for the inline `[n]` citations used throughout. Reliability tags: **[Primary]** = statute/regulator/official; **[Peer-reviewed]**; **[Law-firm/consultancy]**; **[Trade press]**; **[Corporate]**; **[Reference]**.

Korea — regulatory architecture, amendment & pricing

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Corpus note: 47 of these and adjacent sources were crawled via Firecrawl and embedded into the Made RAG corpus (topic `korea-regen-regulatory`, ~1,880 chunks) for retrieval and traceability. Load-bearing claims independently re-verified against primary/authoritative sources during a second pass: the Made–GC relationship (madescientific.com/about), FL SB 1768 (2025 session, eff. 1 Jul 2025; flsenate.gov), the ARBA amendment effective date (Yoon et al. 2026, primary text), the 21 Jan 2025 MFDS exosome cosmetic-ad ban (ChemLinked + GPC Gateway), the approved Korean MSC products and dates, and the S&E bio SNE-101 first exosome IND (May 2025).