MADE SCIENTIFIC · COMMERCIAL STRATEGY & REGULATORY AFFAIRS

# South Korea — Regulatory & Commercial Brief

Distributing Made regenerative products (MSC · EV/Exosome · Secretome) into Korea via GC Corporation

## The bottom line

**Pursue Korea through GC — but as a phased, two-speed build, not a single white-label deal, and drop the "FL SB 1768" framing.** Korea is a receptive, premium, largely private-pay regenerative market, and the barrier that stops most foreign entrants — a Korean entity must hold the biologic license and liability — is already solved because **GC Corporation is Made's long-term strategic shareholder** and Made is "a proud member of GC Corporation." The decisive commercial fact is not any right-to-try analogy but that **Korea regulates by route of administration, not biology:** topical + cosmetic claims = a light path (weeks); anything injected or therapeutically claimed = a multi-year licensed biologic.

## What the research established

- **Route/claim is the line.** Topical secretome/culture-fluid and non-human "exosome-like" skincare can go the Cosmetics Act path (self-notification + KPTA, weeks–months). Injected MSC/EV, or any medical claim, becomes an unapproved biologic under the Advanced Regenerative Bio Act + MFDS — full marketing authorization, K-GMP, multi-year.
- **The GC relationship removes the hard barrier.** GC can be license holder, overseas-GMP sponsor, in-country manufacturer (GC Cell CELL Center), lot-testing lab (GC Labs), and distributor (GC Wellbeing) — the whole import chain inside one group that co-owns Made. The question is *which GC entity*, not *whether*.
- **Korea's "non-approved use" pathway is real but gated.** The ARBA amendment (effective 21 Feb 2025) opened a *paid* "advanced regenerative medicine treatment" track to general patients — but it is designated-institution + committee/IRB-approved + risk-tiered, the **opposite architecture** to Florida SB 1768's self-executing physician permission. A US cultured product is *admitted* to it protocol-by-protocol, not shipped into it.
- **Exosomes are tightening.** MFDS banned the word "exosome" in cosmetic ads from 21 Jan 2025; no exosome drug is approved (first trial, S&E bio, May 2025); a 2026 crackdown targets human-tissue injectables. Human-derived injectables are getting harder.

## The recommendation — two speeds

| | Lane A — Fast (0–12 mo) | Lane B — Strategic (12–48 mo) |
|---|---|---|
| **What** | Topical secretome / EV cosmetics | Injectable MSC / EV therapy |
| **How** | Import/ODM under GC Wellbeing as Responsible Cosmetic Seller | Tech-transfer to GC Cell CELL Center (preferred) or import under GC MAH; place into ARMT / seek MFDS marketing authorization |
| **Speed / risk** | Weeks–months; low capital | Multi-year; full biologic program |
| **Constraint** | No "exosome" term, no medical claims (MFDS Jan-2025 rules) | K-GMP, clinical data, ARMT risk-tier + committee approval |
| **Value** | Near-term revenue + brand + proof point | The high-value franchise |

## Product → GC entity map

| Made product | GC entity | Structure |
|---|---|---|
| Topical secretome / EV skincare | **GC Wellbeing** | Cosmetic self-notification (Lane A) |
| Injectable MSC / EV therapy | **GC Cell** (mfg) / **GC Biopharma** (import MAH) | Tech-transfer or import; ARMT/marketing authorization (Lane B) |
| QC / lot testing / trial lab | **GC Labs / GCCL** | Service support |

## Top risks

1. **Claim fragility** — one medical/anti-aging claim or an injection reclassifies a Made topical as an unlicensed biologic.
2. **"White-label" ≠ pass-through for biologics** — the MAH must genuinely own the file and liability; name-only branding is lawful for cosmetics, not biologics.
3. **Human-derived injectables tightening** — lead with topical; build injectables only through the formal biologic/ARMT route, never clinic off-label.

## Next four decisions with GC

1. Confirm the entity map (GC Wellbeing / GC Cell / GC Biopharma / GC Labs).
2. Choose Lane B structure — bias to **tech-transfer to CELL Center** for the flagship injectable.
3. Lock the Lane A claim set with Korean cosmetic counsel before any launch.

4. Commission MFDS pre-submission consultation for the lead injectable (risk tier, ARMT vs marketing authorization, overseas-GMP plan).

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*Companion to the full 32-page assessment (14 chapters, 50 cited sources). Regulatory/commercial feasibility — not legal advice. Made Scientific — Confidential (internal & GC partnership).*