



CIRS INSIGHT

**China-Origin Medicines Entering EU
Joint Clinical Assessment (JCA):
What Do Their Internationalisation
Pathways Mean for HTA Readiness?**

Introduction

The first wave of China-origin medicines entering the EU Joint Clinical Assessment (JCA) provides a unique opportunity to examine how different internationalisation pathways may influence preparedness for HTA assessment.* Among the first 20 products entering JCA, seven are China-origin medicines representing diverse globalisation pathways, ranging from China-first development and licensing partnerships to integrated international development programmes. By analysing these trajectories, this CIRS Insight explores how emerging approaches to global expansion may shape the evidence base available for European HTA decision making.

For the purposes of this article, a China-origin medicine is defined as a product for which a Chinese company held primary responsibility for clinical development and initial registration in China, irrespective of where the molecule was originally discovered or whether it was subsequently licensed, partnered or co-developed internationally.

Between the implementation of the EU Joint Clinical Assessment (JCA) in January 2025 and the end of June 2026, 20 medicinal products entered the JCA procedure (1). Among those, six (30%) were developed by top-tier multinational pharmaceutical companies (MNCs), seven (35%) by Chinese companies, and seven (35%) by medium-sized companies or research institutions, highlighting a diverse developer landscape. The presence of seven China-origin medicines— namely, catequentinib, ensartinib, rezvilutamide, senaparib, sintilimab, sonrotoclax, and taletrectinib— is particularly interesting and reflects the growing internationalisation of Chinese pharmaceutical innovation.

All seven of these products were approved in China by the National Medical Products Administration (NMPA) before being submitted to the European Medicines Agency (EMA). They were also listed in the China National Reimbursement Drug List (NRDL) for reimbursement, apart from sonrotoclax, which is currently undergoing the reimbursement application process in 2026. However, the products differ substantially in terms of the pace of international expansion, the pathways used to support internationalisation, and the way evidence has been generated for China market authorisation and international markets. These differences may have important implications for JCA, which places considerable emphasis on comparative clinical evidence, patient relevance and alignment with JCA PICO requirements.

*HTA readiness in this context relates to the extent to which the available evidence can support JCA requirements, including alignment with the requested PICO framework, appropriate comparative evidence, methodological transparency, and relevance to European decision making.

From China to Europe - Internationalisation timelines

One notable observation is the heterogeneity in timelines for internationalisation (Figure 1). The seven products appear to fall into four categories based on the time from NMPA approval to EMA submission (date of EMA validation of the marketing authorisation application [MAA]).

Over 5 years (>60 months)

The first category consists of products that followed a relatively long 'China-first' pathway before entering Europe. Catequentinib (2) and sintilimab (3) were approved in China more than seven years before entering the EMA review process (Figure 1). Notably, the indications under JCA differ from those therapeutic areas initially approved in China, where companies pursued line-extension strategies rather than direct internationalisation of the original indication (Table 1). This pattern reflects a sequential path to internationalisation, in which domestic approval serves as a foundation for subsequent expansion into new indications and geographies. However, it is worth noting that the JCAs for catequentinib and sintilimab were discontinued in June and September 2026, respectively, as the updated JCA dossiers failed to meet the requirements laid down in Article 9(2), (3) and (4) of Regulation (EU) 2021/2282 (1,4, 5).

Between 2 and 5 years (25-60 months)

The second category comprises rezvilutamide and ensartinib. Although rezvilutamide's EMA validation of submission was 1451 days after its initial NMPA approval (6) (Figure 1), the indication remained broadly unchanged (Table 1). Both EMA and NMPA submissions were supported by a Phase III multi-regional clinical trial (MRCT), with the EMA dossier incorporating updated long-term follow-up and overall survival data from the same MRCT.

Ensartinib also had a substantial gap of 1835 days between its initial NMPA approval and EMA submission (7). Although the indications were broadly similar, the EMA submission aligned more closely with the NMPA's 2022 label expansion, which broadened the indication from second-line to first-line treatment (8).

Less than 2 years (1-24 months)

The third category includes senaparib (9) and taletrectinib (10), which had considerably shorter intervals between NMPA approval and EMA submission (210 and 464 days, respectively) (Figure 1). Rather than representing a purely China-first strategy, these products appear to reflect a transitional pathway in which companies pursue global ambitions earlier in the product lifecycle while still leveraging the advantages of China-based development.

Less than one month (<1 month)

The fourth category is represented by sonrotoclax (11). The product was submitted to the EMA 23 days after China approval, suggesting a near-parallel global development and submission strategy (Figure 1). This pattern resembles that typically associated with multinational companies (MNCs), where development programmes are designed from an early stage to support regulatory submissions across multiple regions.

Taken together, these cases suggest that China-origin medicines are not following a single trajectory from domestic approval to overseas expansion. Instead, multiple pathways of internationalisation are emerging.

Figure 1 - Internationalisation Timelines of China-Origin Products Entering JCA

Date of NMPA Initial Submission → Date of NMPA Initial Approval → Date of EMA Validation of MAA

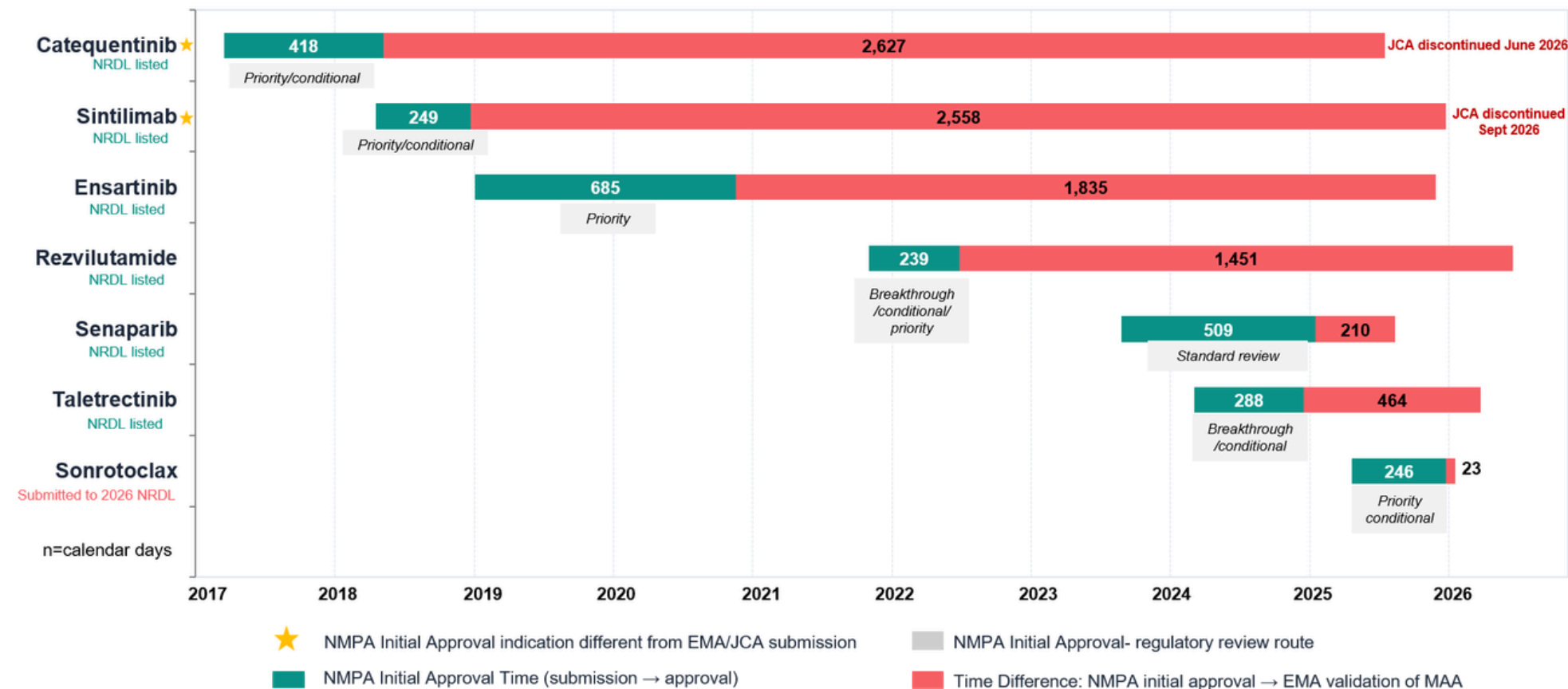


Table 1 - Internationalisation Pathways of China-Origin Products Entering JCA

Product	Initial NMPA approval indication	EMA/JCA submitted indication	Developers involved	Internationalisation pathway	Key features of development and evidence trajectory
Catequentinib	Treatment of locally advanced or metastatic NSCLC following progression or recurrence after at least two prior systemic chemotherapy regimens	Treatment of synovial sarcoma or leiomyosarcoma	Advenchen / CTTQ	- China-first - Co-development - Bridge-out	- US-discovered asset (Advenchen) - China development and first approval led by CTTQ - Pivotal trial (Phase III ALTER0303 trial) conducted across Chinese centres - Subsequent global development with Advenchen/CTTQ - Including multinational APROMISS Phase III trial in different indications and regions (12)
Sintilimab	Treatment of relapsed or refractory classical Hodgkin lymphoma after at least two prior lines of systemic therapy	Treatment of non-squamous NSCLC in adults	Innovent / Eli Lilly	- China-first - MNC co-development - Out-licensing	- China-discovered asset (Innovent) - China development and first approval led by Innovent, in partnership with Eli Lilly - Pivotal trial (Phase II ORIENT-1 trial in relapsed/refractory classical Hodgkin lymphoma) conducted across Chinese centres - Subsequent international expansion through Eli Lilly partnership and ex-China licensing - Including the Phase III ORIENT-11 trial in first-line non-squamous NSCLC, conducted in China and subsequently used to support US regulatory submission, with follow-up development programmes including multinational studies in other indications (13)
Ensartinib	Treatment of patients with ALK-positive locally advanced or metastatic NSCLC who have experienced disease progression following prior treatment with crizotinib or who are intolerant to crizotinib	Treatment of adult patients with ALK-positive advanced non-small cell lung cancer	Betta/ Xcovery Holdings	- China-first - Controlled-subsidary internationalisation	- China-discovered asset (Betta) - China development and first approval led by Betta - Pivotal trial (Phase II BTP-42322 trial in crizotinib-pretreated ALK-positive NSCLC) conducted across Chinese centres - Subsequent global development through controlled subsidiary Xcovery - Including the multinational eXALT3 Phase III trial across 120 centres in 21 countries, supporting first-line expansion in China and subsequent international approval (14)
Rezvilutamide	Treatment of patients with high-volume metastatic hormone-sensitive prostate cancer	Treatment of metastatic prostate cancer	Jiangsu Hengrui Pharma	- China-first - Go-alone internationalisation	- China-discovered asset (Hengrui) - China development and first approval led by Hengrui - Pivotal development included the multinational Phase III CHART (SHR-3680-III-HSPC) trial across China, Poland, Czech Republic and Bulgaria - Subsequent international regulatory expansion led by Hengrui (15)
Senaparib	Maintenance treatment of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer following response to first-line platinum-based chemotherapy	Maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer	IMPACT Therapeutics/ Junshi Huadong Medicine	- China-first - Biotech partnership - Go-alone internationalisation	- China-discovered asset (IMPACT Therapeutics) - China development led by IMPACT Therapeutics with Junshi Biosciences partnership - Pivotal trial (Phase III FLAMES trial) conducted across Chinese centres - Huadong Medicine partnered for commercialisation in Mainland China - Subsequent international development led directly by IMPACT Therapeutics (16)
Taletrectinib	Treatment of ROS1-positive locally advanced or metastatic non-small cell lung cancer following progression on prior ROS1 tyrosine kinase inhibitor therapy	Treatment of adults with ROS1-positive advanced non-small cell lung cancer	Nuvation / AnHeart / Innovent / Daiichi Sankyo	- China-first - Multi-partner internationalisation - Territory-based licensing	- Japan-discovered asset (Daiichi Sankyo) - Global development rights licensed to AnHeart (Chinese company), subsequently acquired by Nuvation Bio (Chinese company) - China development with Innovent (Chinese company) partnership - Pivotal trial (Phase II TRUST-I trial) conducted across Chinese centres - Subsequent global development led by AnHeart/Nuvation Bio - Including the multinational Phase II TRUST-II trial across North America, Europe and Asia, supporting subsequent US and international regulatory expansion - Regional commercialisation through Innovent (China), Nuvation Bio (US), Nippon Kayaku (Japan), and Eisai partnership for Europe and other territories (17)
Sonrotoclax	Treatment of relapsed or refractory mantle cell lymphoma after at least two prior systemic therapies, including a Bruton tyrosine kinase inhibitor	Treatment of adult patients with relapsed or refractory mantle cell lymphoma	BeOne Medicines	Fully integrated internationalisation	Discovery, international clinical development, international regulatory strategy and commercialisation all in-house (18)

NSCLC: Non-small cell lung cancer; CTTQ: Jiangsu Chia Tai Tianqing Pharmaceutical; ALK: Anaplastic lymphoma kinase

Comparison of internationalisation pathways

The observed differences in timelines are closely linked to the different pathways used for product internationalisation. Collectively, these seven products demonstrate that the traditional perception of Chinese pharmaceutical innovation as primarily dependent on licensing out assets to MNCs is changing. Multiple internationalisation pathways now coexist, ranging from partnership-driven expansion to fully integrated global development (Table 1).

Business strategies may influence not only internationalisation pathways but also the timing and design of evidence generation. Products developed primarily in China may rely heavily on evidence generated in Chinese clinical settings, whereas globally integrated development programmes may be better positioned to consider European comparators, treatment pathways and patient populations earlier in development. China-first or bridge-out pathways may need to generate additional evidence, new indication-specific datasets or supplementary analyses to support EMA and JCA submission.

Importantly, previous EMA approvals suggest that China-generated evidence is not necessarily a barrier to European regulatory approval. An example can be seen with sugemalimab, a China-origin PD-L1 inhibitor developed by CStone Pharmaceuticals (19). The EMA approval was largely supported by the GEMSTONE-302 study, a pivotal Phase III trial conducted in China. This demonstrates that evidence generated predominantly in China can be considered acceptable by European regulators when the study design, data quality and clinical effect are considered robust and relevant for regulatory decision making.

However, JCA may present a different challenge. Unlike regulatory reviews, which focus on the benefit-risk balance of a product, JCA places greater emphasis on comparative clinical effectiveness within specific healthcare settings. The discontinuation of catequentinib and sintilimab in the JCA process provides early examples of the importance of HTA readiness. According to the European Commission's published information, the missing elements in the updated JCA dossier for catequentinib related mainly to incomplete evidence identification, insufficient justification of study inclusion and exclusion, missing or inadequate comparative effectiveness analyses, lack of methodological transparency, and incomplete supporting documentation (4). For sintilimab, the updated JCA dossier was deemed incomplete due to insufficient study-level details and results to assess the exchangeability of studies included in the indirect comparisons, additional deficiencies including incomplete evidence searches and supporting documentation, and unclear and inconsistent presentation of data (5).

These cases therefore suggest that successful participation in JCA requires not only clinical evidence suitable for regulatory review, but also robust evidence synthesis, comparative assessment and transparent reporting aligned with EU HTA methodological expectations. Consequently, questions regarding comparator appropriateness, PICO alignment, external validity and transferability may become more prominent factors when considering internationalisation.

Looking ahead

The first wave of China-origin medicines entering EU JCA illustrates the emergence of diverse pathways of pharmaceutical internationalisation from China, ranging from China-first development followed by international expansion to globally integrated development from an earlier stage. These pathways differ not only in commercial structure, but also in the timing and maturity of the clinical evidence available for European regulatory and HTA review. JCA therefore provides a new lens through which to assess whether China-origin drug development is becoming globally integrated not only commercially, but also scientifically and methodologically.

The cases also suggest that internationalisation is not only a commercial process but also an evidence-generation strategy. However, given the small number of products and the early stage of JCA implementation, it would be premature to conclude that any particular internationalisation pathway is more likely to support better preparation for JCA.

In addition, six of the seven products examined have also been included in China's National Reimbursement Drug List, suggesting that post-launch experience in China may become a relevant area for future investigation. At present, it remains unclear whether, and how, real-world evidence generated in China could contribute to JCA submissions.

More broadly, these examples emerged against the backdrop of increasing pharmaceutical innovation from Chinese companies and their growing ambition to expand beyond the domestic market. Chinese innovation is moving from domestic development, approval and licensing-out toward multiple internationalisation pathways, and JCA is becoming a new test of whether those pathways generate evidence that is fit for European HTA and global patient needs.

As internationalisation becomes a strategic priority for more Chinese pharmaceutical companies, understanding the requirements for successful market access in Europe will become increasingly important. These considerations should not begin at the point of JCA submission but should be embedded earlier in development and internationalisation strategy planning.

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