GT GreenbergTraurig

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China on the Move: Lessons from China's National Negotiation of Drug Prices in 2020

In December 2020, China's National Healthcare Security Administration (NHSA) published the 2020 National Reimbursement Drug List (2020 NRDL), continuing the trend toward substantial pricing discounts.

This GT Advisory explores the following key considerations:

- China continues formalizing its reimbursement scheme through the publication of 2020 Interim Measures and adopts the philosophy of "cross the river by touching the stones" in building up an affordable scheme to the world's largest population.
- More than 50% discount to be newly listed in NRDL and regular price re-negotiations for the prior NRDL products to continue being listed appear to be the norm.
- NRDL will become the most viable and exclusive pathway to get the product reimbursed by public health insurance in China while the commercial insurance, patient assistance program, as well as out-of-pocket payment from the patient, will remain interim solutions to sustain the product's commercial life in China before being listed in NRDL. The fact that only a small fraction would make it to the final NRDL requires the drug maker to evaluate its capacity to utilize all available interim solutions in advance of proceeding with its desired NRDL listing strategy.

- NHSA gains a stronger bargaining power in negotiating with foreign drug makers because the regulatory reform in acceleration of the product approval and local players' increased strength to bring innovative product onto the market cause more available alternative therapies against foreign drug makers' products in each reimbursement cycle than the past, and the NRDL encourages competitive negotiation.

- A successful NRDL listing strategy entails an early alignment on the pricing strategy in China across the global, regional, and local market access teams, the timely incorporation of insights from the evolving scheme into the development of the commercialization model in China, and the commitment to partner with NHSA to help honor its policy objectives in the long run.

- Deal making, especially for foreign licensors, demands the licensor's excellence in capturing the insights of the rapidly growing environment in China, which defines or redefines the best commercialization model. To potentially avoid bearing material risks, foreign licensors must have an accurate and complete appreciation of the underlying factors shaping the future reimbursement environment in China.

A Substantial Pricing Discount Becomes the Norm

On Dec. 28, 2020, following intensive price negotiation with pharmaceutical companies, the NHSA, the current payer of China's public health care security system, published the 2020 NRDL, effective March 1, 2021. Out of 162 drugs negotiated, 119 were successfully added to the 2020 NRDL. To compare, 97 out of 150 drugs negotiated were added to the 2019 NRDL. Of the 2020 NRDL's 119 added drugs, 96 have exclusivity and 23 do not. The average discount rate is 50.64%; in 2019 it was 60.7%.

Twenty-nine drugs from the 2019 NRDL were excluded from the 2020 NRDL due to limited clinical value or because approval was revoked by the National Medical Products Administration (NMPA). Fourteen drugs with exclusivity were re-negotiated and kept in the 2020 NRDL with a 43.46% price discount.

It is estimated that more than half of the newly included western medicines are products of multinational pharmaceutical companies. Novartis is the biggest winner, with eight products and new indications (mostly approved in recent years) included in the 2020 NRDL. Novartis's products cover several different indications, including two types of eye-drops for glaucoma, three types of targeted drugs for different cancers, two types of receptor modulators for multiple sclerosis, and one for psoriasis. Eli Lilly, AstraZeneca, and Astellas each has two new products in the 2020 NRDL, while Pfizer, Bayer, Novo Nordisk, and Sanofi each has one new product included. In addition, leading domestic innovative drug companies also had success. BeiGene and Hansoh each has three new products in the 2020 NRDL, while Hengrui, Chimin, and Huakang each has two.

The 2020 NRDL includes several drugs that were once expensive, notably, 10 kinds of monoclonal antibodies. The programmed cell-death protein 1 (PD-1) products Hengrui (Camrelizumab, first indication approved in May 2019, other indications approved in early 2020), Junshi (Toripalimab, approved in December 2018), and BeiGene (first indication approved in December 2019 and second in April 2020) each won one NRDL's final reimbursement spot, yet none of the multinationals' products enter, including Keytruda of Merck Sharp & Dohme (MSD) and Opdivo of Bristol-Myers Squibb (BMS) (both approved in the first half of 2017). Shortly after the publication of the 2020 NRDL, unsurprisingly, MSD and BMS declared their new patient assistance schemes for 2021. Another domestic PD-1 product, Sintilimab of Innovent, was included in the 2019 NRDL, which means all four types of domestic PD-1 products are listed in the 2020 NRDL.

Drugs to treat rare disease are another heated issue. Novartis's Gilenya and Mayzent for multiple sclerosis (MS) are included in the 2020 NRDL, relieving the patients of the pressure from an estimated yearly out-of-pocket medical expenditure of RMB 46,000. NMPA approved Gilenya in July 2019 and Mayzent in May 2020. In addition, several other orphan drugs such as Ambrisentan for pulmonary hypertension, Deutetrabenazine for Huntington's Disease (approved in May 2020), etc. are also included. However, most approved drugs for rare diseases, such as Spinraza for spinal muscular atrophy, are not included.

2020 Interim Measures Show NHSA's Readiness to Continue Carefully Formalizing a Sensible Reimbursement Pathway to Bring Innovative Drugs into China

On July 30, 2020, NHSA published the Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance (2020 Interim Measures), which contain a detailed process for negotiation and management of NRDL. Prior to the 2020 Interim Measures, there were the Interim Measures for the Administration of the Scope of the Basic Medical Insurance for Urban Employees (1999 Interim Measures). The 1999 Interim Measures became somewhat outdated over the past two decades with governmental reform, including the evolution of the national health care security system and progressive integration of urban and rural health care security systems.

Meanwhile, NHSA and the Ministry of Human Resources and Social Security (MOHRSS, which is the predecessor of NHSA for national health care security system management) have led several negotiations since 2016, trying to establish a regular and full-scale negotiation with pharmaceutical companies and include more innovative drugs with limited budget. The 2020 Interim Measures are to some extent deemed NHSA's current thinking based on its learning from the previous negotiations.

On Aug. 17, 2020, NHSA formally issued the Working Plan for the Adjustment of the 2020 NRDL (2020 Working Plan), which is the first act taken to materialize the 2020 Interim Measures. The 2020 NRDL is a milestone that sets an example for subsequent NRDL negotiation and updates.

According to 2020 Interim Measures, the NRDL will be adjusted once per year. Before formal negotiation, all pharmaceutical companies can submit candidate products (subject to a series of criteria) for the annual negotiation. After deliberation, NHSA will publish a short list of the products to be negotiated. NHSA will then form an expert team to lead pricing negotiations with pharmaceutical companies. For drugs with exclusivity, the payment standard will be determined by negotiation; for drugs without exclusivity, by bidding. Products that survive the negotiation or bidding will be included in the NRDL.

2020 Working Plan Serves as an Initial Effort to Materialize 2020 Interim Measures by Addressing Budget Constraint and Promoting Access to Innovative Drugs

The 2020 Working Plan provides a mechanism substantially the same as the 2020 Interim Measures. Some significant developments as compared with the 2019 Working Plan appear below.

a) Pharmaceutical companies acquire the right to initiate the reimbursement application and negotiation.

In the 2019 Working Plan, the short list of the products to be negotiated was determined by the expert team designated by NHSA, and NHSA did not accept applications from pharmaceutical companies themselves. Under the 2020 Working Plan, pharmaceutical companies can at their sole discretion propose the candidate products for negotiation. To complete such application, a pharmaceutical company should submit online the basic information of the drug, pricing information, and other supporting materials. According to the 2020 Working Plan, the online platform was open for application from Aug.

21 through Aug. 30, 2020. Further, the companies needed to mail hard copies of the application to NHSA before Aug. 30, 2020. This change better aligns the reimbursement system in China with other countries with established reimbursement processes, such as France, Germany, Japan, and the UK.

Though NHSA received hundreds of applications, only 162 drugs were negotiated in December 2020. For example, Pfizer submitted Vyndaqel (Tafamidis meglumine) for an extremely rare disease to NHSA for NRDL negotiation. Vyndaqel is on the List of New Overseas Drugs Urgently Needed in Clinical Practice and just approved by NMPA in February 2020 (please refer to the eligibility criteria in the subsection below). The application passed NHSA's pro forma review in September 2020, so Pfizer had submitted all necessary documents. But the negotiation on Vyndaqel has not been found.

b) Eligibility criteria, as a screener, continues to evolve and may be revised subject to the dynamics of the external environment.

Notwithstanding that pharmaceutical companies for the first time in recent years can initiate the reimbursement application, NHSA develops the eligibility criteria and thus remains the gatekeeper of the number of actual applications to be considered in the negotiation stage. In this way, China stands in contrast with most countries in the world, where such application submission is conditioned on the license grant or specific designation grant.

The expert review and negotiation only last for three months, and the 2020 budget is unlikely to be much larger than that of 2019. A preliminary screener assures the right type of reimbursement applications can be attended properly and in accordance with NHSA's policy agenda.

According to the 2019 Working Plan, drugs to be included in the NRDL should be those approved before Dec. 31, 2018, with priority given to essential drugs, drugs for major diseases such as cancers and rare diseases, drugs for pediatric use, etc.

The 2020 Working Plan provides more sophisticated criteria below:

- Drugs for treatment of COVID-19;
- Drugs in the 2018 version of National Essential Drug List (NEDL);
- Drugs which are overseas drugs for urgent needs, prioritized generics, or drugs for pediatric use, and approved before Aug. 17, 2020;
- Drugs which fall into the second-round national volume-based procurement drugs;
- Drugs with new active ingredients or new formulations approved from Jan. 1, 2015, to Aug. 17, 2020;
- Drugs with major changes in indication, function, and usage approved from Jan. 1, 2015, to Aug. 17, 2020;
- Drugs listed by at least five provincial reimbursed drug lists before Dec. 19, 2019.

Because the 2020 Working Plan criteria are more inclusive than 2019, the 2020 NRDL includes more innovative drugs. The revision made by the NHSA itself on Aug. 17 allowed drugs approved up to that date to submit NRDL applications. In comparison, the 2019 NRDL negotiation targeted single-source drugs that were launched in China before Dec. 31, 2018. This revision demonstrates NHSA's intent to bring in more innovative drugs that will address unmet clinical needs and to strengthen the link between approval and reimbursement. For example, Novartis's Mayzent would not be considered based on the criteria set forth in 2019 NRDL but would become the beneficiary in the 2020 NRDL.

As mentioned above, NHSA included in the 2020 NRDL some drugs approved in 2019 or 2020 – good news for patients. Further, this approach can be utilized by NHSA to push the price of reimbursed product further down, as well as motivate the drug makers that failed to include their innovative products in the prior NRDL to offer a more significant cut on their reimbursement application for 2020 NRDL.

Pharmaceutical companies' innovative products will likely soon face the aggressive pricing policy of NRDL. Traditionally the high prices of innovative drugs contribute to the profit margin at an early stage beginning from the approval, though the sales volume may therefore be limited. If a pharmaceutical company is seeking the surge in sales volume by having the innovative drug in NRDL, it should probably give up the most desired profit margin based on high price, which is a quid pro quo it must face.

c) Different pricing methods apply to drugs with or without exclusivity, and the negotiation approach with NHSA is key to receiving the reimbursement.

The pricing under the 2019 NRDL is determined only through negotiation. The 2020 Interim Measures make it clear that for drugs with exclusivity, the payment standard will be determined by negotiation; for drugs without exclusivity, by bidding. This is natural and reasonable for NHSA, since the government has more bargaining power when there are multiple suppliers of a drug, and much less when there is only one supplier of a drug. Such pricing methods will further intensify competition among suppliers of drugs without exclusivity.

Regarding the negotiation for drugs with exclusivity, according to both the 2019 Working Plan and the 2020 Working Plan, the expert team would engage calculation experts to estimate and calculate a reserve price, i.e., NHSA's target price in the negotiation. Only at the negotiation site would the NHSA negotiation officials know the reserve price. Each company would have two chances to offer and would be out if both offers are 15% higher than the reserve price. NHSA officials will begin the negotiation of final prices for companies whose offers are within 15% of the reserve price.

In 2019 it was reported that pharmaceutical companies were asked to submit their drug prices in 12 "recommended countries or regions" (international reference pricing, "IRP"), including Japan, France, Germany, Italy, Spain, the UK, Canada, South Korea, the United States, Australia, Turkey, and Taiwan. The NRDL prices disclosed to the public (the companies may elect not to disclose the prices) were "by coincidence" close to their prices in Turkey, which were the lowest among the 12 countries or regions. Neither the 2019 Working Plan nor the 2020 Working Plan clarified the mechanism of IRP, but the adoption of IRP is mentioned in both official and non-official news coverage, which may be relevant to the calculation of the reserve prices.

NHSA has not operated a formally defined reference basket. The "recommended countries or regions" aspect will likely be revised every year. While the IRP can be a useful benchmark to start price negotiations between NHSA and manufacturers, the IRP determination methodology has few details and eventually could be perceived as a tactic to rationalize NHSA's final reimbursed price, rather than a controlling standard to determine the final reimbursed price. IRP would therefore probably serve as a useful tool to make the price adjustment for NHSA to deliver its promise that "the lowest price in the neighboring country" mentioned in several public occasions by including or moving out certain countries in NRDL's reference basket every year.

In the 2020 NRDL's tasks, the negotiation and tendering stage that happened between October and November 2020 would have involved involve evaluation experts for budget impact and pharmacoeconomics, and negotiation experts would conduct negotiation and tendering based on such evaluation. The importance of pharmacoeconomics will likely continue being emphasized in the next few

years, but the whole pricing mechanism will primarily rely on the factors of the budget impact and how to accomplish the policy objective in provision of the drugs with one of the most favorable prices internationally.

d) Products listed in the prior NRDL may be re-negotiated and even removed, and the reimbursement price can have its "expiration" date subject to different conditions.

As provided in the 2020 Interim Measures, the 2020 Working Plan arranged renegotiation of certain drugs listed in the 2019 NRDL. Such renegotiation may be initiated when the drug is significantly more expensive than similar ones, or when companies apply for renegotiation or the expert team determines to renegotiate. Neither the 2020 Working Plan nor the 2020 Interim Measures provides in which cases companies can apply to renegotiate or the expert team would make its determination, or what standard the expert team would adopt to determine to renegotiate.

In addition, according to the 2020 Interim Measures, if generic drugs are launched during the two-year agreement period of a brand-name drug, NHSA may, in accordance with the payment standard of the generics, adjust the payment standard of such brand-name drug, even within the two-year agreement period after the brand-name drug is included in NRDL. After expiration of such two-year period, NHSA may adjust the payment standard and renew the agreement according to "relevant rules." NHSA will likely provide subsequent explanations about the details of price adjustment to brand-name drugs. Nonetheless, NHSA may have a certain degree of discretion in adjusting the prices of brand-name drugs. The 2020 Interim Measures only provide that the agreement period of the drugs in NRDL is "in principle" two years. The agreement period in 2020 NRDL is March 1, 2021, to Dec. 31, 2022, which is less than two years.

Both in the 2019 and 2020 NRDLs, some drugs listed in the prior NRDL were removed due to limited clinical value, or approval revocation. The 2020 Interim Measures provide detailed criteria of drugs to be removed. In addition to the above two cases, drugs with considerable risks or listed in the negative list will also be removed. "Negative list" is not defined and needs clarification from NHSA. In current practice, the First Batch of Drug List under Key Monitoring and Rational Use in 2019 seems to be a "negative list" of drugs. In July 2020, NHSA published a draft for comment regarding the establishment of a credit evaluation system for drug prices and purchase. The draft proposed a credit evaluation system recording dishonesties of pharmaceutical companies. In May 2020, Anhui NHSA published a draft for comment regarding the establishment of the negative list of GMP responsibility. The Anhui negative list proposed to include various noncompliant pharmaceutical companies. These two documents are not yet enacted as official regulations, but they reflect a possible direction.

e) Provincial-level adjustments to NRDL may end soon, and a national approach could motivate drug makers to offer a larger discount.

Since the promulgation of the 1999 Interim Measures, the central government has allowed provincial governments to make local adjustments to the NRDL, provided the number of such adjustments were less than 15% of the total number of drugs in the NRDL. These provincial adjustments were accompanied by accusations and speculation of bribery and local protectionism. When publishing the 2019 NRDL, NHSA asked local governments to strictly implement NRDL, not to issue provincial lists or adjust NRDL; drugs in earlier provincial lists should be phased out over three years.

The 2020 Interim Measures provide that provincial governments may only additionally include eligible essential drugs, preparations of medical institutions, and traditional Chinese medicine (TCM) decoction pieces. When publishing the 2020 NRDL, NHSA reiterated that no provincial adjustments are allowed. In

2019 and 2020, local branches of NHSA in many provinces emphasized that no provincial adjustments are allowed, and drugs in previous provincial lists should be removed directly (Jiangxi Province) or phased out over three years. For example, in 2019 Anhui NHSA decided that the phase-out would be implemented on a ratio of 4:4:2 over three years (i.e., to remove 40% in 2020, 40% in 2021, and 20% in 2022).

Provincial adjustments have been used as an alternative for products not included in the NRDL. Drug makers with innovative drug portfolios would take the provincial adjustment as their second resort or even their plan A to generate income as well as raise the product's profile in China. If the product's price tag was too high to be considered at the national level, it could still be considered by certain provinces with more resources or interests. With the prohibition on provincial adjustments, this alternative may no longer be feasible.

If provincial adjustments end soon, NRDL will eventually be the only viable option for drug makers to have a public health insurance reimbursement. This will decrease drug makers' latitude to negotiate with NHSA in NRDL, and will eventually push drug makers to make concessions by overestimating NRDL's desired discount level so to assure their products are listed in NRDL via the annual NRDL pricing negotiation.

Still, some provinces have specific health care security schemes for rare diseases. For example, Zhejiang Province has established its own fund for rare diseases (RMB 2 per person per year, collected from local critical illness insurance). Critical illness insurance of Shandong Province and Yunnan Province also covers several rare diseases. Suppliers of rare disease drugs not included in NRDL may consider applying for inclusion in the drug list covered by such specific schemes. However, critical illness insurance, the source of such specific schemes for rare diseases, ultimately comes from the basic health care security fund managed by NHSA. Given the overall shortage of the health care security fund, these schemes may not have sufficient margin to cover additional diseases and drugs. Furthermore, in December 2020 and during the negotiation of the 2020 NRDL, NHSA declined a proposal from Committee of the Chinese People's Political Consultative Conference (CPPCC) to establish a nationwide fund for rare diseases.

Commercial insurance, which NHSA welcomes, may be another option. Pharmaceutical companies' own patient assistance schemes may also help to recapture a certain degree of competitiveness.

Revisit the NRDL's Strategic Advantage in the Product Launch

A product's inclusion in the 2020 NRDL should boost sales, despite the significant price concession. Sintilimab was included in the 2019 NRDL with a price drop of 63.7%. As the first PD-1 product included, Sintilimab's six-month sales in the first half of 2020 reached RMB 920.9 million, a 177.7% increase. However, before other domestic PD-1 products were listed in 2020 NRDL, some observers found that the total sales revenue of Sintilimab was largely unaffected by the price discount, despite the surge in sales volume. It was estimated that in the first half of 2020, Sintilimab's sales revenue was even less than Camrelizumab of Hengrui (not yet included in NRDL at that time), mostly because Sintilimab was approved for only one indication, while Camrelizumab was approved for four indications. Camrelizumab achieved relatively higher sales volume and at the same time kept its price significantly higher. Hence, pharmaceutical companies whose drugs were not included in NRDL should not be too discouraged but rather focus on achieving and maintaining technical advantage.

Pharmaceutical companies with drugs included in the NRDL should remain vigilant nonetheless. For drugs without exclusivity, pressure may come from competitors already in the NRDL and from those who may apply for inclusion in the next year's negotiation. For example, Allisartan isoproxil was included in

the 2017 NRDL and achieved a significant sales increase, yet it remained far behind mature products like Valsartan. For drugs with exclusivity, the launch of future generics also creates competition pressure. In addition, annual adjustment to the NRDL has become a regular policy under the 2020 Interim Measures, posing continuous pressure on pharmaceutical companies. Balancing sales volume and sales price will be a persistent challenge.

While a drug's inclusion on the NRDL is desirable, it is not essential. The NRDL listing decision will be based on a thorough assessment of different commercialization scenarios by promptly incorporating the insights from the evolving landscape.

Take Advantage of the Next Wave

The 2020 NRDL is the first action taken pursuant to the 2020 Interim Measures and may well serve as an example for subsequent NRDL negotiations. NHSA appears open to including all of those drugs with high clinical value, especially innovative drugs. However, NHSA may pursue a more gradual, deliberate course, like the old Chinese saying, "Cross the river by touching the stones." Most importantly, NHSA bears its policy mission to address the society's complaint against the difficult access to health care and the heavy financial burden of drug expenditures. Given that drug makers are keen to invest resources in China to benefit from the upside of local market growth in the long run, and NRDL will become an exclusive path to boost the product penetration rate in the market sooner or later, NHSA likely has an edge over drug makers to help the Chinese public to gain a favorable deal. While NRDL practice may still undergo several amendments, a drug maker that needs to take advantage of the regular NRDL listing should be aware of the below.

- Market access should be prepared earlier than or at least in parallel to the regulatory filing.

China's current regulatory reform and continuous resource investment in NMPA accelerate the regulatory review period. So-called drug lag in China has been substantially improved lately, and the difference between the approval date of the same drug in China and in the United States, Europe, or Japan has been shortened. In several conditions, the review period for the overseas drug with the urgent need is considerably shorter than its review period in the United States.

Given that NHSA allows drugs approved up to that date to submit NRDL applications, and the negotiation time in each NRDL listing can only last for two to three months, the preparation for the NRDL listing needs to commence as early as possible, and no later than the submission of new drug application to NMPA.

- Price negotiation success means an early alignment across headquarters, regional, and local offices.

The global market access team usually develops its pricing model much earlier than the pricing model is developed in China, especially for rare disease products or costly innovative products. In most circumstances, the local market access team does not have enough authority to decide the pricing model in its application to NHSA and needs to seek approval from the global market access or commercial team. Given the short negotiation period and NRDL becoming the most important mechanism for drug reimbursement in China, the local market access team would be under enormous pressure during the application and negotiation time. Therefore, the alignment between the global, regional, and local teams will need to begin much earlier, to give the market access team sufficient time to adapt or revise the global guidance to reflect ongoing development of NRDL listing practice. Some view negotiations with NHSA as a "take it or leave it" endeavor, assuming NHSA only offers one or two chances to propose one's price. This dynamic can easily compel drug makers to offer a deeper price cut to avoid negotiation failure,

whereby the drug makers need to wait for at least another year (during which time the drug maker risks continuing burning operation capital without sufficient return).

- The detailed and clear methodology to determine pricing may take time to be materialized or released, but proper consideration of the budget impact and commitment to partner with NHSA can be a life saver in the final pricing negotiation.

While pharmacoeconomic assessment is not new to the NRDL, this assessment is to set up the competing value propositions among many of the other available therapies in NHSA's mind. The ability to engage the right stakeholders and equip them with the right value dossiers and evidence will be useful to differentiate between competitors and comparators in NHSA's methodology. Having said this, it remains critical for NHSA to manage public expectations. The budget impact analysis will help NHSA to determine how stretched it can be. And the price in China compared with the price in other countries will be especially important, if not the foremost consideration, in the final listing decision. NHSA has not published the same level of detail regarding its referencing price calculation, as most other countries do. But the lowest price in its peer countries, which are geographically close to or are in the same economic status, such as GDP per capita, may be NHSA's prevailing policy objective.

Unconventional pricing models such as outcome-based pricing would be compelling to NHSA. But it is unlikely that such model would be adopted either soon or broadly. If such model is adopted, it may serve as a vehicle or reassurance to achieve its policy goal of having the lowest price of its peer countries.

- A note to licensors: Be sure to closely monitor these dynamics and quickly incorporate any insights into the dealmakings.

The situation can be fluid in China, but there are certain consistent trends. The current NRDL and NHSA's evolving practice will affect the commercialization approach in China, thus leading to a different deal structure. Many non-Chinese small-to-medium-sized biotech companies rely on their Chinese partners. It is important for those companies' business development teams, whether in Boston, Copenhagen, Osaka, etc. to appreciate the trend and quickly address any uncertainties in deal structure formation. After all, the royalty and commercial milestone are based on the upside of Chinese market growth. And Chinese market growth depends in large part on the success of the commercialization approach with the heavy component of market access. Licensors must be vigilant or even more knowledgeable than their Chinese partners to capitalize on the changes to reimbursement. In negotiation, a lack of knowledge not only puts companies at a disadvantage but also forces them to bear material risks.

NHSA is working to provide affordable health care to the world's largest population, and rolling out NRDL policy and measures is a huge experiment. There is no short cut for NHSA to accomplish its goal, but the current NRDL approach reflects NHSA's increased confidence in shaping the landscape of the reimbursement market in China. While the final scheme is not imminent, the major pillars may soon be set. Multinational and non-Chinese drug makers should consider the policy drivers underlying the current scheme and frame their approaches accordingly.

GT GreenbergTraurig

Authors

This GT Advisory was prepared by:

- Chia-Feng Lu ‡ | +1 202.331.3184 | +81 (0) 3.4510.2200 | luch@gtlaw.com
- Dawn (Dan) Zhang | +86 (0) 21.6391.6633 | zhangd@gtlaw.com
- John Gao | +86 (0) 21.6391.6633 | gaoj@gtlaw.com

‡ *Admitted in The District of Columbia and New York. Not admitted in Japan.*

Albany. Amsterdam. Atlanta. Austin. Boston. Chicago. Dallas. Delaware. Denver. Fort Lauderdale. Germany. Houston. Las Vegas. London.* Los Angeles. Mexico City.+ Miami. Milan.» Minneapolis. New Jersey. New York. Northern Virginia. Orange County. Orlando. Philadelphia. Phoenix. Sacramento. Salt Lake City. San Francisco. Seoul.∞ Shanghai. Silicon Valley. Tallahassee. Tampa. Tel Aviv.^ Tokyo.¤ Warsaw.~ Washington, D.C.. West Palm Beach. Westchester County.