





## China

# Overweight (no change)

#### **Highlighted companies**

#### BeiGene Ltd ADD, TP HK\$169.7, HK\$88.9 close

BeiGene is one of the leading domestic biotech companies by annual revenue, with a deep innovative R&D pipeline as well as global marketing capabilities. Its key product, zanbrutinib, has been approved for multiple lymphoma indications globally.

#### **Summary valuation metrics**

P/E (x)	Dec-23F	Dec-24F	Dec-25F
BeiGene Ltd	NA	NA	NA
P/BV (x)	Dec-23F	Dec-24F	Dec-25F
BeiGene Ltd	4.09	4.78	4.66
<b>Dividend Yield</b>	Dec-23F	Dec-24F	Dec-25F
BeiGene Ltd	0.00%	0.00%	0.00%

# **Healthcare - Overall**

# New pricing mechanism to support innovation in drug development

- The National Healthcare Security Administration (NHSA) yesterday (5 Feb) issued a draft pricing mechanism to support innovation in drug development.
- We think this new mechanism, coupled with last year's modification of NRDL rules, demonstrate the government's support for the development of innovative drugs.
- Key beneficiaries of these changes are leading-edge pharmaceutical firms, in our view. Maintain sector Overweight. Our top pharma pick is BeiGene.

# NHSA issues new drug pricing mechanism draft

On 5 Feb 2024, the National Healthcare Security Administration (NHSA) issued a draft paper entitled "Notice on Establishing a New Pricing Mechanism for New Chemical Drugs to Encourage Innovation", with the main objective being to establish a system that allows the determination of drug prices via market forces and to support innovation. The draft paper proposes that when new chemical drugs are first included in the drug procurement platform of the provincial government, pharma companies would have the option to self-assess their new drugs based on NHSA's evaluation criteria, which include pharmaceutical science, clinical value, and evidence-based medicine. The new drugs would then be categorised into high, medium, or low, depending on their scores. The higher the self-assessment scores, the greater the innovative value of the drug and, consequently, the higher degree of flexibility accorded to the company in determining the price of the drug. Policy support could also be offered to high-scoring new drugs, including a price protection period, during which the price of the drug would be stable, the paper said.

#### Benefits leading-edge pharmaceutical companies

In our previous sector note (link), we highlighted that the National Reimbursement Drug List (NRDL) renewal rules were modified last year to support innovation. In 2023, a total of 57 (of 121) drugs were both approved and added to the NRDL. In addition, the new NRDL renewal rules (released in 2023) also suggested a milder price cut for NRDL renewals. In 2023, a total of 100 drugs were successful renewed, of which 70% were renewed at their previous price. The average price cut for the rest was 6.7%. We think this latest NHSA draft paper is also aimed at supporting innovation-driven drugs and pushing pharmaceutical companies towards shifting their focus to innovative medicine R&D based on clinical demand, which is consistent with the NRDL renewal rule modifications last year.

#### Our top pharmaceutical company pick: BeiGene

We think leading-edge pharmaceutical companies are the key beneficiaries of the government's policy support for innovation in drug development. Our top pharma pick is BeiGene (6160.HK, Add, CP: HK\$86.8). BeiGene is one of the leading domestic biotech companies by annual revenue, with a deep innovative R&D pipeline and global marketing capabilities. Our initiation report on BeiGene provides more details of this pipeline (link). Downside risks for pharmaceutical companies: 1) possibility of failure in new drug R&D, hurting revenue growth outlook, 2) unsuccessful application for a new drug, impacting net profit margins, and 3) increased competition on expiry of patent of a new drug, leading to lower drug prices and revenue. We think the new policy support from the government would be a re-rating catalyst for innovative pharmaceutical companies as the government has clearly stated that it would consider manufacturing and R&D costs when determining drug pricing.



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# New pricing mechanism to support drug innovation

# **Drug registration in China**

The China drug registration system classification, based on the National Medical Products Administration (NMPA), is as follows: a) traditional Chinese medicine (TCM), b) chemical drugs, and c) biological products.

Registration of TCM is categorised by: a) innovative traditional Chinese medicines, b) modified new TCMs, c) TCM compound preparations of ancient classical prescriptions, and d) medicines with the same names and the same prescriptions, according to the NMPA.

Registration of biological products is categorised by: a) innovative biological products, b) modified new biological products, and c) marketed biological products (including biosimilars), according to the NMPA.

#### Classification of chemical drugs

The registration classification of chemical drugs covers: a) innovative drugs, 2) modified new drugs, 3) generic drugs, and 4) chemical drugs marketed overseas but not in China, according to the NMPA.

Class 1: Innovative drugs that have not been marketed in China or overseas. These refer to drugs that contain new compounds with clear structures and pharmacological effects, and have clinical values.

Class 2: Modified new drugs that have not been marketed in China or overseas. These refer to drugs that have their structure, dosage form, formulation and process, route of administration and indications optimised on the basis of known active ingredients and have significant clinical advantages.

- Class 2.1: Drugs that contain an optical isomer of known active ingredients obtained by splitting or synthesising methods, or esterification of known active ingredients, or saltification of known active ingredients (including salt containing hydrogen bonds or coordination bonds), or modifications in acid group, basic group, or metal elements of known active ingredients of salt, or formation of other non-covalent bond derivatives (complex or chelate), and have significant clinical advantages.
- Class 2.2: Drugs that contain known active ingredients with new dosage form (including new drug administration system), new formulation process or new route of administration, and have significant clinical advantages.
- Class 2.3: New compound preparations that contain known active ingredients and have significant clinical advantages.
- Class 2.4: Drugs with new indications that contain known active ingredients.

Class 3: Drugs manufactured by domestic applicants by imitating the original drugs that have been marketed overseas but not yet in China. Such drugs shall have the quality and efficacy consistent with the reference listed drugs.

Class 4: Drugs manufactured by domestic applicants by imitating the original drugs that have been marketed in China. Such drugs shall have the quality and efficacy consistent with the reference formulations.

Class 5: Drugs that have been marketed overseas and are under application for being marketed in China.

• Class 5.1: Original drugs and modified drugs that have been marketed overseas and are under application for being marketed in China.





Modified drugs shall have obvious clinical advantages compared to the original drugs.

• Class 5.2: Generic drugs that have been marketed overseas and are under application for being marketed in China. Generic drugs should have the same quality and efficacy as the reference product.

Original drugs refer to drugs that have been firstly approved to be marketed in China and overseas and have complete and sufficient safety and effectiveness data as the basis for being marketed. Reference listed drugs refer to the reference drugs used in the R&D of generic drugs that have been evaluated and confirmed by NMPA.

Figure 2: Registration classification of chemical drugs					
Cla	Class Definition		Local clinical trial requirement		
	1 The new drug not marketed anywhere globally		Phase I, II and III		
	2.1		Optical isomer		
	2.2	2.2 Modified/improved new drug not marketed anywhere globally 2.4	New dosage form		
2	2.3		New compound preparations	Phase I, II and III	
	2.4		New indications		
	A China-manufactured generic drug that is only approved outside China		Pharmacokinetics (PK) and Phase III		
	A China-manufactured generic drug that is already approved in China		Bioequivalence (BE) study		
5	5.1	Imported original drug, approved outside of China		PK and Phase III	
	5.2	Imported generic drug, approved outside of China		BE study	
				SOURCES: CGIS RESEARCH, NMPA	





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Description:	Excellent	Very Good	Good	N/A	N/A

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636 companies under coverage for quarter ended on 31 Dec 2023			
	Rating Distribution (%)	Investment Banking clients (%)	
Add	67.5%	1.3%	
Hold	22.5%	0.0%	
Reduce	10.1%	0.2%	





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