

## Industry Report

# China Pharmaceutical & Healthcare

## 2022 NRDL negotiation preview

- Negotiation & tendering are likely to happen in 3Q22E and result will be announced in YE22E, consistent w/ the timeline of prev. yr
- We think the price cuts are likely to be more predictable w/ ~60% for initial inclusions and moderate cut for renewals
- We expect a potential “cooling down” in price competition among major domestic companies with established PD-1 labels

## 2022 NRDL update process kicks off

In Jun 29 2020, the NHSA has released the Work Plan for adjusting the 2022 NRDL. The Work Plan specifies that drugs or major indication expansions approved by NMPA before Jun 30, 2022 can apply for entering NRDL. We estimates there will be ~400 drugs eligible for 2022 NRDL updates. The Work Plan also releases a detailed timeline showing negotiation stage between Sep and Oct and the result release in Nov.

## More clarity on negotiation rules

We did not see significant rule changes in the Work Plan. Meanwhile, NMPA provides more clarity in the negotiation rules. Thus, we predict the avg. price concessions for new drugs will fall in the similar range of ~50-60%, consistent with the prior outcomes in 2017-2021. In addition, the Work Plan first detailed the renewal rules on price reduction range for existing indications (0-25%, see figure 8) or newly expanded indications (0-25%). We believe these rules are largely derived from the prior practice of NRDL negotiations, which should yield similar results in the 2022 NRDL updates. We believe NHSA’s measures will increase the predictability of price concessions and should ease market concerns on policy risks.

## Fierce PD-1 price competition might cool down

We expect a potential “cooling down” in price competition among major domestics companies (see figure 5, MNCs are likely to opt-out again). This is because major PD-1 players, such as Innovent (1801 HK), BeiGene (BGNE US) and Hengrui, are well positioned in the NRDL as they have had major indication included in the NRDL while rival PD-1 latecomers only have small indications available for 2022 NRDL negotiation. We think this should provide these PD-1 major players more wiggle room to choose optimal strategy for the upcoming negotiation. For this reason, we do not expect major PD-1 players to enter a price war again this year.

## Investment risk

Higher-than-expected degree of price reduction in NRDL initial inclusions/renewals.

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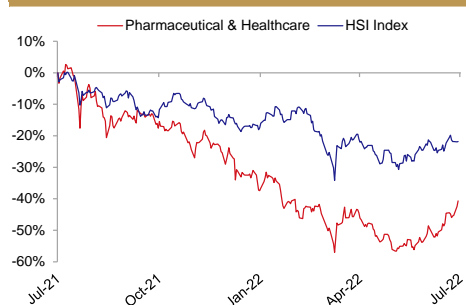
## WHAT'S NEW

2022 NRDL preview

# OVERWEIGHT

Previous	OVERWEIGHT
HSI (July 6, 2022)	21,587
HSCEI (July 6, 2022)	7,546

## Sector Performance



Source: Bloomberg

%	1m	6m	12m
Absolute return	23.4	(9.0)	(40.7)
Relative return	22.5	(2.8)	(18.8)

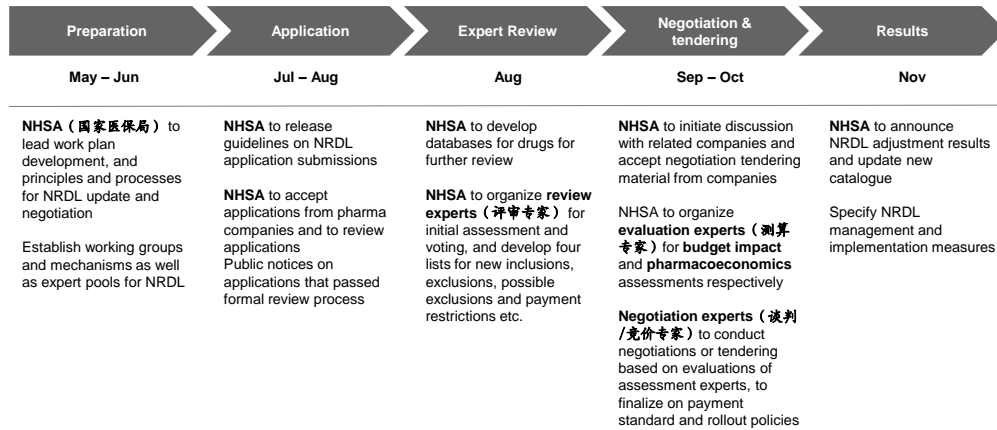
Source: Bloomberg

## Related Research

1. China Pharmaceutical & Healthcare – 2H22 Outlook: Never waste a good “crisis” (OVERWEIGHT) (Jul 4, 2022)
2. China Pharmaceutical & Healthcare – The 7th national VBP at the gate (NEUTRAL) (Jun 27, 2022)
3. China Pharmaceutical & Healthcare – Global 3CLs hit by recent regulatory and clinical results (NEUTRAL) (Jun 24, 2022)
4. China Pharmaceutical & Healthcare – Global funding cool-down continued in May (NEUTRAL) (Jun 22, 2022)
5. China Pharmaceutical & Healthcare – ASCO 2022 data review – ADC in focus (NEUTRAL) (Jun 18, 2022)

Focus charts

Figure 1: NRDL listing timeline and tasks have become more predictable



Sources: NHSA, CMS (HK), Simon-Kucher

Figure 2: NRDL renewal price adjustment has become more predictable

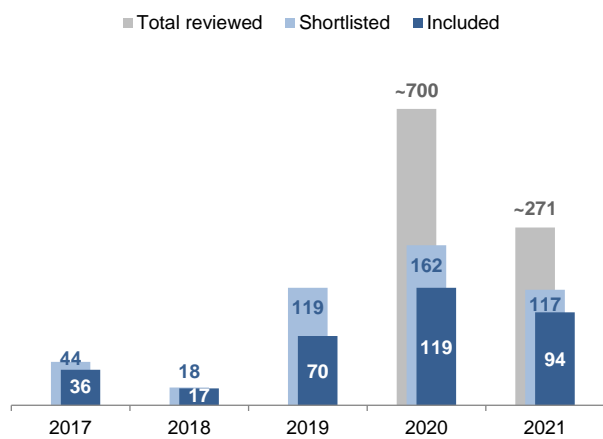
ASP1: adjustment based on below rules, if indication coverage remains unchanged					
Ratio A: actual exp. vs. Co.'s prev. budget	Actual annual expenditure of SHI				
	<RMB0.2bn	RMB0.2-1.0bn	RMB1.0-2.0bn	RMB2.0-4.0bn	>RMB4.0bn
A ≤ 110%	No change	-2%	-4%	-6%	-10%
110% ≤ A ≤ 140%	-5%	-7%	-9%	-11%	-15%
140% < A ≤ 170%	-10%	-12%	-14%	-16%	-20%
170% < A ≤ 200%	-15%	-17%	-19%	-21%	-25%
A > 200%	Unsuitable for simple renewal, full scale renegotiation is required				

ASP2: adjustment made based on above ASP 1 and below rules, if indication coverage is expanded					
Ratio B: budget increase vs. max (prev. budget or actual exp.)	Actual annual expenditure of SHI				
	<RMB0.2bn	RMB0.2-1.0bn	RMB1.0-2.0bn	RMB2.0-4.0bn	>RMB4.0bn
B ≤ 10%	No change	-2%	-4%	-6%	-10%
10% < B ≤ 40%	-5%	-7%	-9%	-11%	-15%
40% < B ≤ 70%	-10%	-12%	-14%	-16%	-20%
70% < B ≤ 100%	-15%	-17%	-19%	-21%	-25%
B > 100%	Unsuitable for simple renewal, full scale renegotiation is required				

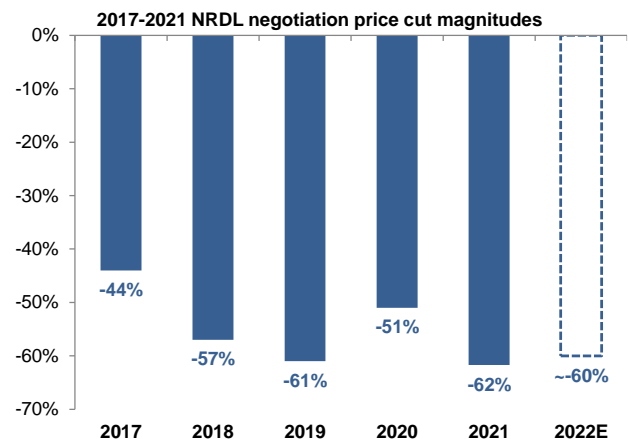
Sources: NHSA, CMS (HK), Simon-Kucher

Figure 3: 2017-2021 NRDL negotiation inclusion outcomes



Sources: NHSA, CMS (HK)

Figure 4: 2017-2022E NRDL negotiation price cut magnitudes



Sources: NHSA, CMS (HK) estimates

Based on the detailed renewal rules and competitive landscape of PD-1/L1 labels, we expect a potential “cease fire” among major domestic companies (see figure 6 below, MNCs are likely to opt-out again). These domestic companies may choose to simply renew without expanding their indication coverage to avoid ASP erosion given limited volume uptake from small labels. However companies that botched previous NRDL games will continue to face pricing dilemma.

Figure 5: Selected PD-1 products for 2022 NRDL negotiation

Molecule	Target	Company	NRDL covered indications	Not covered
Sintilimab	PD-1	Innovent	≥3L cHL; ≥1L sq/nsq-NSCLC; 1L HCC	1L G/GEJ; 1L ESCC
Camrelizumab	PD-1	Hengrui	≥3L cHL; HCC; 1L nsq-NSCLC; ≥2L ESCC;	1L NPC; 1L sq-NSCLC; 1L ESCC
Tislelizumab	PD-1	BeiGene	≥3L cHL; ≥2L UC; 1L sq/nsq-NSCLC; ≥2L HCC;	2/3L NSCLC; 2L ESCC; MSI-H/dMMR ST; 1L NPC
Toripalimab	PD-1	Junshi	Melanoma; ≥2L NPC; UC	1L NPC; 1L ESCC
Serplulimab	PD-1	Henlius	n.a.	MSI-H/dMMR ST
Penpulimab	PD-1	SBP/Akeso	n.a.	r/r nHL
Zimberelimab	PD-1	Gloria	n.a.	≥2L nHL;
Envafohimab	PD-L1	Alphamab	n.a.	MSI-H/dMMR ST (GC/CRC/other STs)
Sugemalimab	PD-L1	Pfizer/CStone	n.a.	1L sq/nsq-NSCLC (Stage IV) / 1L NSCLC (Stage III)
Cadonilimab	PD-1xCTLA-4	Akeso	n.a.	r/m CC
Pembrolizumab	PD-1	Merck	n.a.	2L melanoma; 1L sq/nsq-NSCLC; 1L NSCLC (PD-L1+); 2L ESCC; 1L HNSCC; 1L MSI-H/dMMR CRC; 1L G/GEJ
Nivolumab	PD-1	BMS	n.a.	1L sq/nsq-NSCLC; HNSCC (PD-L1+); 1L MPM; ≥2L G/GEJ; 1L G/GEJ; G/GEJ (adju.); 1L ESCC
Atezolizumab	PD-L1	Roche	n.a.	1L ES-SCLC; 1L HCC; 1L sq/nsq-NSCLC; 1L Stage II-III NSCLC (adju.)
Durvalumab	PD-L1	AZ	n.a.	2L Stage III NSCLC; 1L ES-SCLC

Sources: NHSA, CMS (HK)

Figure 6: Selected other major products for 2022 NRDL negotiation

Molecule	Target	Company	NRDL covered indications	Not covered
Osimertinib	EGFR (3rd Gen)	AZ	≥1L EGFRm NSCLC	n.a.
Almonertinib	EGFR (3rd Gen)	Hansoh	NSCLC (EGFRm)	1L NSCLC (EGFRm)
Furmonertinib	EGFR (3rd Gen)	Allist	n.a.	NSCLC (EGFRm); 1L NSCLC (EGFRm)
Savolitinib	c-MET	HutchMed	n.a.	NSCLC (MET+ exon 14)
Ensartinib	ROS1/ALK/c-MET	Betta	≥2L ALK+ NSCLC	1L ALK+ NSCLC
Pyrotinib	HER-2/EGFR	Hengrui	2L HER-2+ mBC	HER-2+ BC (neo adju.)
Dalpiciclib	CDK4/6	Hengrui	n.a.	HR+/HER-2- mBC
Rezvilutamide	AR antagonist	Hengrui	n.a.	mHSPC
Selinexor	XPO1	Antengene/Karyopharm	n.a.	≥2L MM
Carfilzomib	proteasome	BeiGene/Onyx	n.a.	r/r MM
Pemigatinib	FGFR1/2/3	Innovent/Incyte	n.a.	≥2L Cholangiocarcinoma
Olverembatinib	Bcr-ABL/KIT	Innovent/Ascentage	n.a.	T315Im CML
Pralsetinib	RET	CStone/Blueprint	n.a.	MTC; NSCLC
Ivosidenib	IDH1	CStone/Servier	n.a.	IDH-1 AML
Avapritinib	KIT/PDGFRα	CStone/Blueprint	n.a.	GIST (PDGFRα exon 18)
Duvelisib	PI3K	CSPC/Secura	n.a.	3L FL

Sources: NHSA, CMS (HK)

Figure 7: Selected renewal products for 2022 NRDL negotiation

Molecule	Target	Company	NRDL covered indications	Not covered
Ibrutinib	BTK	JNJ	2L MCL; CLL/SLL; WM	n.a.
Olaparib	PARP	AZ	OC; tubal cancer; PPC	n.a.
Flumatinib	Bcr-Abl	Hansoh	Ph+ CML	n.a.
TPO	Hematology	3sBio	CIT/ITP	n.a.
Xianbixin	Neurology	Sincere	Acute ischemic stroke (AIS)	n.a.
NBP (injection)	Neurology	CSPC	Acute ischemic stroke (AIS)	n.a.
NBP (capsule)	Neurology	CSPC	Acute ischemic stroke (AIS)	n.a.

Sources: NHSA, CMS (HK)

## Investment Ratings

Industry Rating	Definition
OVERWEIGHT	Expect sector to outperform the market over the next 12 months
NEUTRAL	Expect sector to perform in-line with the market over the next 12 months
UNDERWEIGHT	Expect sector to underperform the market over the next 12 months

Company Rating	Definition
BUY	Expect stock to generate 10%+ return over the next 12 months
NEUTRAL	Expect stock to generate +10% to -10% over the next 12 months
SELL	Expect stock to generate loss of 10%+ over the next 12 months

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