生物制药创新：
促进研发和患者药品可及性

PhRMA企业报告-呈中国发展高层论坛
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执行摘要

生物制药研究与开发（研发）对于改善患者健康及挽救生命至关重要。在过去十年中，全球生物制药行业每年在寻找新的治疗方法和药物方面的投入已经翻了不止一倍，其中2023年的投入达到2620亿美元。[1]尽管这些投入是在之前的医学进步的基础上进行的，但它们才刚刚开始在最新突破方面取得成果，为当前一些最棘手疾病的全新治疗方案带来曙光。

过去十年里，中国的研发管线取得了巨大的进展，处于临床前期和临床开发阶段的药物数量增长超过了 10 倍，目前仅次于美国。我们预计在未来几年内，中国将以更快的速度批准更多的创新药物。

近年来，中国在新药可及性方面取得了相当大的进展，但过去 10 年在全球推出的新药中，在中国获批的仍只有24%，而美国的这一比例为85%，经合组织国家平均为38%。此外，在中国的国家医保药品目录下，只有15%的全球新药能够获得报销。[2]因此，在提高患者的创新药物可及性方面，中国仍有很大发展空间。

随着这些趋势的发展，人口老龄化以及对更健康的身体和长寿的期望加

[1] 评估（Evaluate），https://www.evaluate.com/thought-leadership/pharma-reports/world-preview-2023-pharmas-age-uncertainty。
[2] PhRMA，*全球新药可及性报告*，https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report。

速了中国对医疗保健服务的需求。例如，据估计中国有 2 亿肥胖成年人，未来 10 年预计还会增加 1 亿；[3]这些人可能会极大地受益于先进的肥胖治疗方法。生物制药行业的持续增长需要一个支持性的政策环境，以使患者能够获得创新药物，以及激励对下一代治疗方法和药物的持续研究。

在就药物的研发和上市作出决策时，创新生物制药公司会寻求稳定且可预测的支持创新的政策环境。这些政策包括：1) 保护创新的强有力的知识产权；2) 可预测的、基于科学的监管途径，确保及时市场准入；以及 3) 奖励创新并为激励下一代药物投入提供可能性的支付体系。这三个方面对于为患者提供更快速获得救命疗法的强劲创新生态体系的可持续发展缺一不可。

本文提供了来自全球生物制药市场的数据和经验，展示了支持创新的公共政策与对创新药物更大投入和可及性之间的关系。在市场开放、创新受到重视且知识产权得到保护和执法的地方，生物制药创新者拥有他们与合作伙伴合作、成功竞争及加速新药上市所需要的可预测性和确定性。

I、全球研发趋势及新药可及性情况

a、研发管线

我们正处于一个全新的医学时代，突破性的科学正在改变医疗保健和我们对患者的治疗方法。生物制药公司在研发方面的大力投入正在带来前所未有的进步和发现。基因组学在开发个性化药物方面的应用使医生能够根据患者的独特需求定制治疗方案，而免疫疗法则利用患者自身的免疫系统来对抗癌症和罕见疾病等各种疾病。如今，全球正在临床开发的药物超过 8,000 种，以解决迫切的、未满足的医疗需求，包括：

经过数十年的研究，**癌症**的本质和根源得以揭示，进而帮助靶向治疗方

[3] 华尔街日报，https://www.wsj.com/health/pharma/ozempic-is-taking-off-with-the-worlds-largest-obese-population-hint-it-isnt-the-u-s-a7c2498c。

法达到前所未有的数量，且许多癌症患者的预后得到改善。一系列颠覆性的新治疗方法，如个性化药物、CAR-T 细胞疗法、免疫检查点抑制剂等，已经面向癌症患者提供。从 2000 年到 2016 年，新的癌症治疗方法拯救了美国近 130 万患者。目前有 1600 种癌症疫苗和治疗方法正在临床开发中。[4]

老年群体尤其容易受到糖尿病、关节炎和心脏病等**慢性病**的影响。近 95%的老年人至少患有一种慢性病，近 80%的老年人患有两种或两种以上的慢性病。[5]慢性病往往会限制老年人的工作能力，影响他们进行日常活动的能力，使他们失去独立性，并导致需要长期护理。管理慢性病的综合成本占美国所有医疗费用的三分之二。[6]目前，有超过 400 种治疗老年患者慢性病的药物正在临床试验中，有望改善生活质量并节约医疗成本。[7]

中国的研发管线取得了巨大的进展，在过去十年中，处于临床前和临床开发阶段的药物数量增长超过了 10 倍，目前在全球仅次于美国。(见图 1 和图 2)。因此，我们预计未来几年内，中国将以更快的速度批准更多的创新药物。

[4] PhRMA，*在研抗癌药物：2023 年报告*，https://phrma.org/resource-center/Topics/Medicines-in-Development/Medicines-in-Development-for-Cancer-2023-Report。
[5] 全国老龄化委员会，www.ncoa.org/article/the-inequities-in-the-cost-of-chronic-disease-why-it-matters-for-older-adults。
[6] 凯撒家族基金会，www.kff.org/interactive/medicare-spending/。
[7] PhRMA，2023 年在研药物报告：影响美国老年人的主要慢性病，https://phrma.org/resource-center/Topics/Medicines-in-Development/Medicines-in-Development-for-Chronic-Illness-Older-Americans-2023-Report。

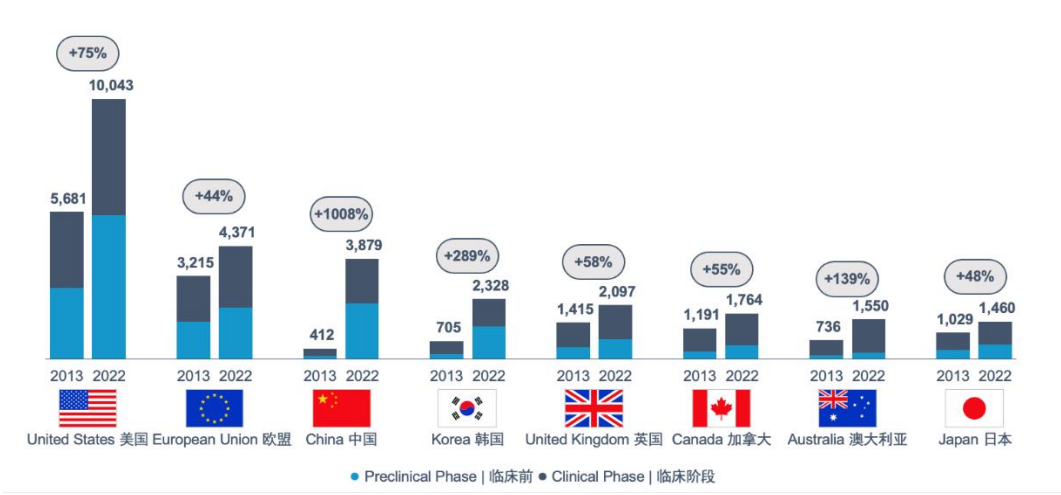

图 1：按地理区域划分的临床前和临床开发阶段的药物数量（2013 年与 2022 年对比）[8]

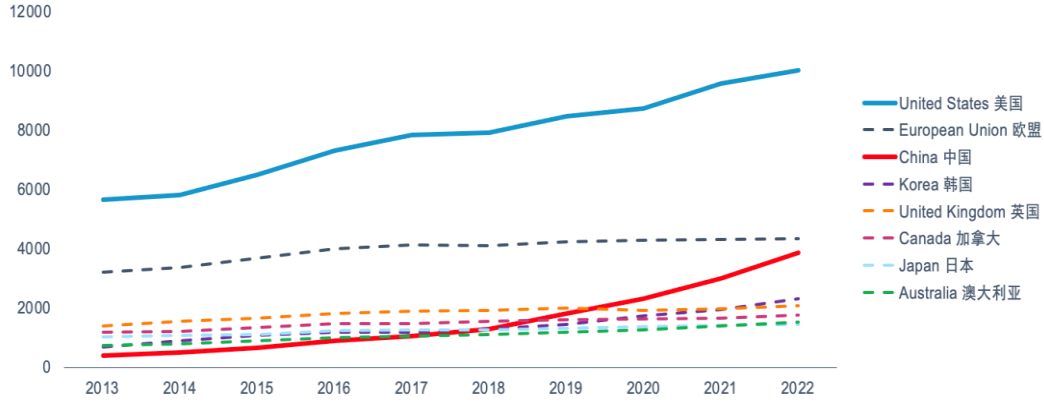

图 2：2013 年至 2022 年按地理区域和年份划分的在研药物数量[9]

b、新药可及性

最近的一项分析研究了 72 个不同市场的新药可及性和公共报销情况，结果显示全球正在推出创纪录数量的新药，但大多数国家的患者，包括许多发达国家的患者，只能获得其中很小一部分。虽然在大多数的二十国集团国

[8] 来源：PhRMA 对 Informa 关于管线和临床试验之数据的分析。2023 年 8 月。
[9] 同上。

家，新药的获批逐渐减少，但中国从 2017 年到 2021 年获批的新药数量翻了一番，成为二十国集团中改善最为显著的国家。即便如此，如下文图 3 所示，过去 10 年在全球推出的新药中，在中国可获得的只有 24%，而美国的这一比例为 85%，二十国集团的国家平均为 38%。此外，2012 年至 2021 年期间，中国的国家医保药品目录下可报销的全球推出之新药的比例仅为 15%，而美国的公共报销比例为 85%，二十国集团国家的公共报销比例平均为 28%。因此，在提高患者的创新药物可及性方面，中国仍有很大潜力。

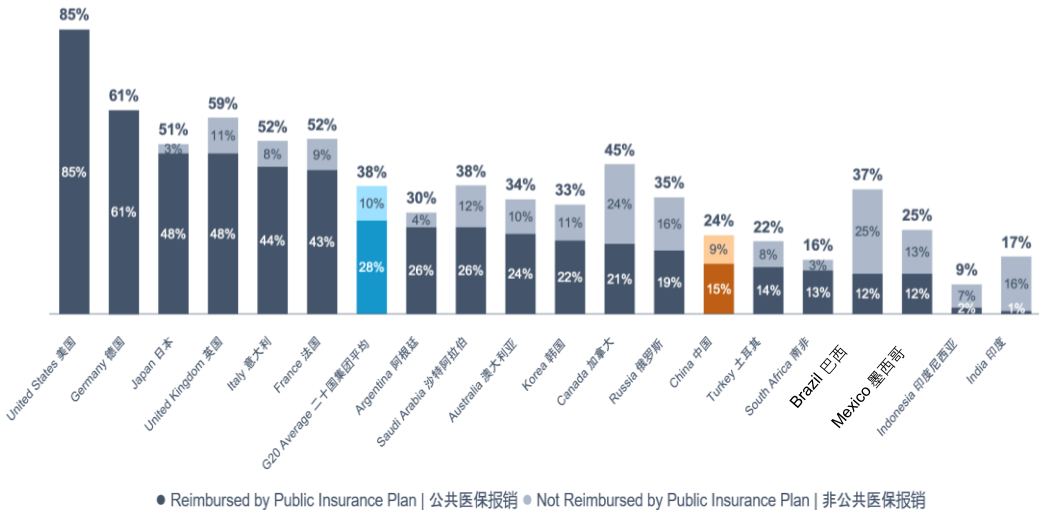

图 3：2012 年至 2021 年底推出的全部 460 种新药中，获批并获得公共报销的药物比例

II、市场需要支持创新的政策以促进研发和患者及时的药品可及性

将创新药物推入市场需要经历漫长、有风险且成本高昂的研发过程。平均而言，开发一种新药需要 10 到 15 年的时间，耗费 26 亿美元（约合 177 亿元人民币），其中包括多次研发失败的成本。[10]进一步推动对生物制药研发

[10] PhRMA，*研发政策框架*，https://phrma.org/policy-issues/Research-and-Development-Policy-Framework。

和患者药品可及性的投入，取决于一个促进创新的政策生态体系。

一个成功的生物制药创新政策生态体系由三个核心组成部分构成，这三者密切相关，对于生物制药创新的增长和可持续性具有**同等**的必要性：

知识产权体系：通过提供必要的激励措施以投入大量资本和其他资源来研究、开发和推出创新药物，强劲的知识产权体系推动了生物制药创新。为了给患者带来有价值的新药，生物制药创新者必须能够有效地获得和执行专利，就上市审评审批中证实药物安全性和有效性的临床信息获得监管数据保护，并保护商业秘密和保密商业信息。只有通过强有力的知识产权保护和执法，创新者才能够获得他们与合作伙伴合作、成功竞争及加速新药推出所需要的可预测性和确定性。

监管体系：一套有效的监管体系能够建立并始终将清晰的、基于科学的且公正的规则应用到产品的安全性、有效性和质量评估中，包括从临床前和临床开发到上市后监测和风险管理。这些特征将使监管体系能够在合理的时间范围内作出一致且可预测的批准决定，并为全球同步开发提供可能。成功的监管体系采用协调一致的指导方针，并在可能的情况下消除基于特定市场的要求。

定价和报销体系：定价和报销体系应当反映创新药物为患者和社会提供的整体价值，使公司能够继续对下一代治疗方法和药物进行投入。这包括及时、透明、可预测且以证据为基础的、使利益相关方有意义地参与其中的系统。商业健康保险是多层次医疗保障制度体系的一部分，其提高了患者的药品可及性并降低了他们的自付成本。

有了这些制度体系的支持，中国可以进一步加强其创新生态体系，持续推动其在研发领域的增长，并确保患者在这些药物获得批准后能够获取该等

药物。

III、公共政策对研发投入以及患者药品可及性的影响：案例分析

下文提供了来自生物制药市场的案例分析，展示了支持创新的公共政策与创新药物的强劲开发和可及性之间的关系。在市场开放、创新受到重视且知识产权得到保护和执法的地区，生物制药创新者拥有他们与合作伙伴合作、成功竞争及加速新药推出所需要的可预测性和确定性。相反，缺乏支持创新的政策，或者政策与创新相悖，则可能会对患者药品可及性以及研发投入产生阻碍作用。在这种情况下，研发水平和患者药品可及性可能会受到影响。

a、监管数据保护

全球拥有高度创新生物制药产业的主要市场通常拥有强大的知识产权保护和执法体系。与专利不同，监管数据保护对为了上市审评审批而生成的证明生物制药产品安全性和有效性的临床数据提供了一段独占期。在许多情况下，监管数据保护可能与创新药物的专利相辅相成，而在其他情况下，监管数据保护可能是唯一可用的保护手段。因此，对监管数据保护的强有力实施，对于促进新药的研发以及推动本地和全球生物制药创新的努力至关重要。

监管数据保护对于大分子药物（即生物制品）尤为重要。通过使用来自生物体的材料生产，生物制品的生产相当复杂且有挑战性，仅仅通过专利可能无法为生物制品提供充分的保护。与传统化合物的仿制药不同，生物类似药与原研创新药并非完全相同，这可能导致对创新者的专利权是否覆盖生物类似药存在更大的不确定性。如果无法确定地获得一段市场独占期，创新者将没有足够的动力投入大量的金钱和时间及承担巨大的风险，以发现并向市场推出新的生物制品。

监管数据保护为研发的投入和新药的推出提供了有力的激励。如图4和图5所示，提供监管数据保护的市场平均有31.5%的全球药物可供患者使用，而不提供监管数据保护的市场这一比例则为11.1%。在这一差异中，监管数据保护在药物可及性方面的贡献与其他因素相比高了9.2%，相当于该差异的45%。[11]在实际情况中，这意味着，对于提供监管数据保护的市场和不提供监管数据保护的市场之间在药品可及性方面的差异，其中一半可以归因于监管数据保护。[12]

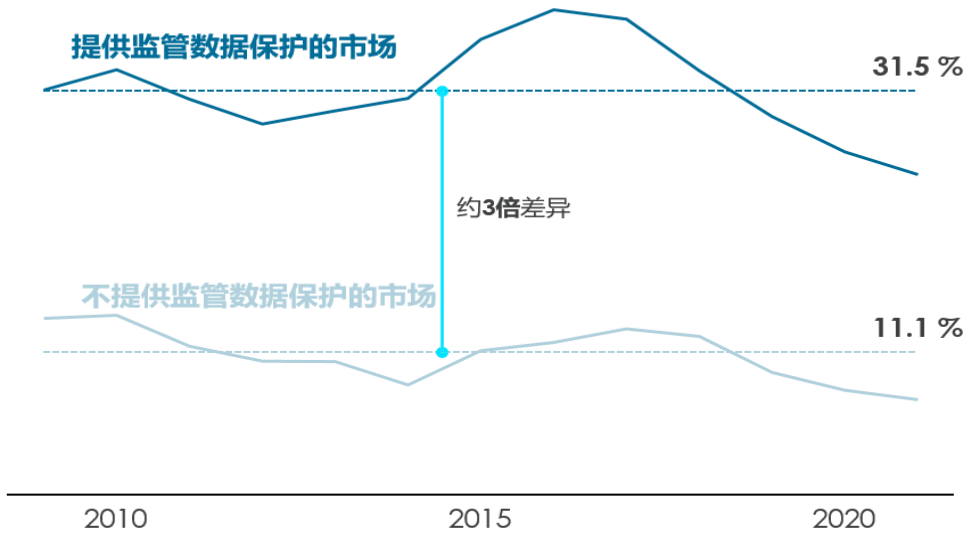

图4：创新药物在提供和不提供监管数据保护的市场上的可及性[13]

[11] 来源：哥本哈根经济（Copenhagen Economics），以来自 IQVIA、世卫组织和世界银行的数据为基础。

[12] 哥本哈根经济（Copenhagen Economics），监管数据保护：实施监管数据保护制度将如何提高药品的可及性、创新和投入（2023），https://copenhageneconomics.com/publication/regulatory-data-protection-how-adopting-regulatory-data-protection-can-increase-medicine-availability-innovation-and-investment/。

[13] 来源：哥本哈根经济（Copenhagen Economics），以来自 IQVIA 的数据为基础。

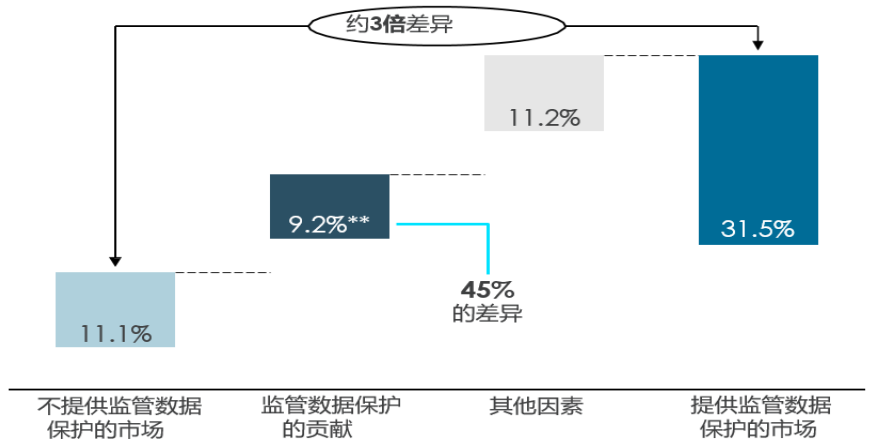

图5：与监管数据保护相关的创新药物的可及性比例和可及性百分点增加情况[14]

监管数据保护还与更多的临床试验活动相关。不提供监管数据保护的市场平均每百万人口有4个临床试验，而提供监管数据保护的市场平均每百万人口则有21个临床试验（图6）。对监管数据保护的孤立效应的评估显示，因为有监管数据保护，每百万人口临床试验增加2.8个（图7）。这相当于在不提供监管数据保护的市场的临床试验基线数量基础上，增加了70%。

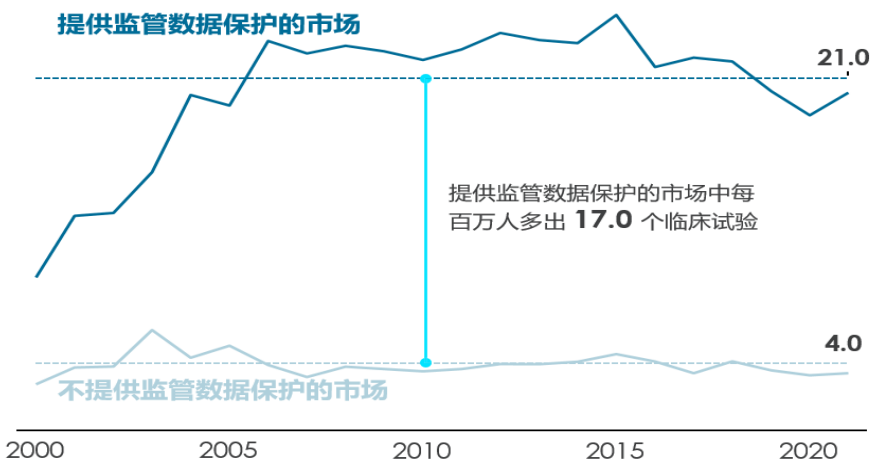

图6：提供监管数据保护和不提供监管数据保护的市场上临床试验的平均数量

[14] 来源：哥本哈根经济（Copenhagen Economics），以来自 IQVIA、世卫组织和世界银行的数据为基础。

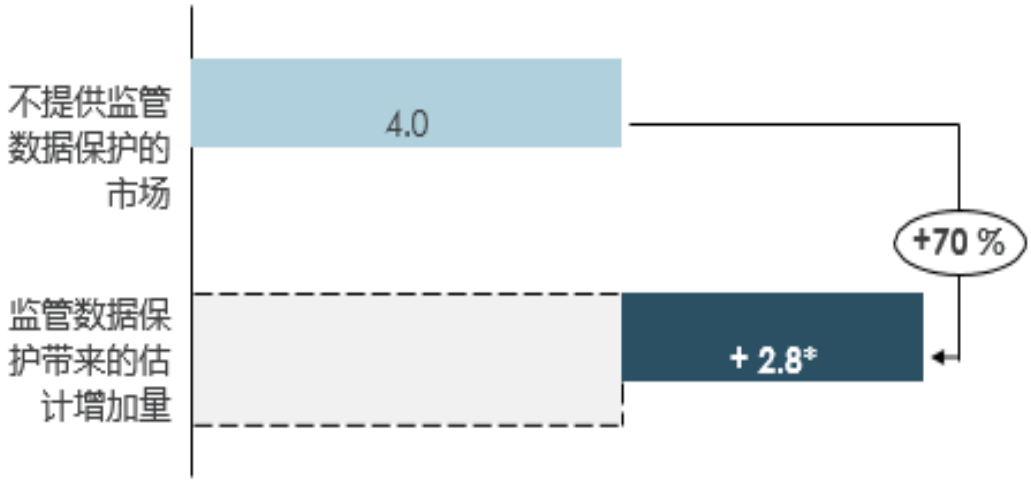

图7：每百万人口的临床试验数量及与监管数据保护相关的预估增加量[16]

案例分析：克罗地亚和日本

克罗地亚和日本的经验证据与监管数据保护可获得性对临床试验的预估影响一致（图8）。在克罗地亚，自引入监管数据保护后，从2007年至2012年，每百万人口的临床试验数量增加了 1.5。同样地，在日本，自引入监管数据保护后，从2007年至2017年，每百万人口的临床试验数量增加了3.5。临床试验数量的增加发生在数年后，这可能是由于计划临床试验需要一定的时间。值得注意的是，日本在引入监管数据保护后采取了限制性的定价政策，这对该国2016年后的临床试验数量产生了负面影响（见第 III.b 节）。

[15] 来源：哥本哈根经济（Copenhagen Economics），以来自 IQVIA 的数据为基础。
[16] 哥本哈根经济（Copenhagen Economics），监管数据保护：实施监管数据保护制度将如何提高药品的可及性、创新和投入（2023），https://www.wsj.com/health/pharma/ozempic-is-taking-off-with-the-worlds-largest-obese-population-hint-it-isnt-the-u-s-a7c2498c。

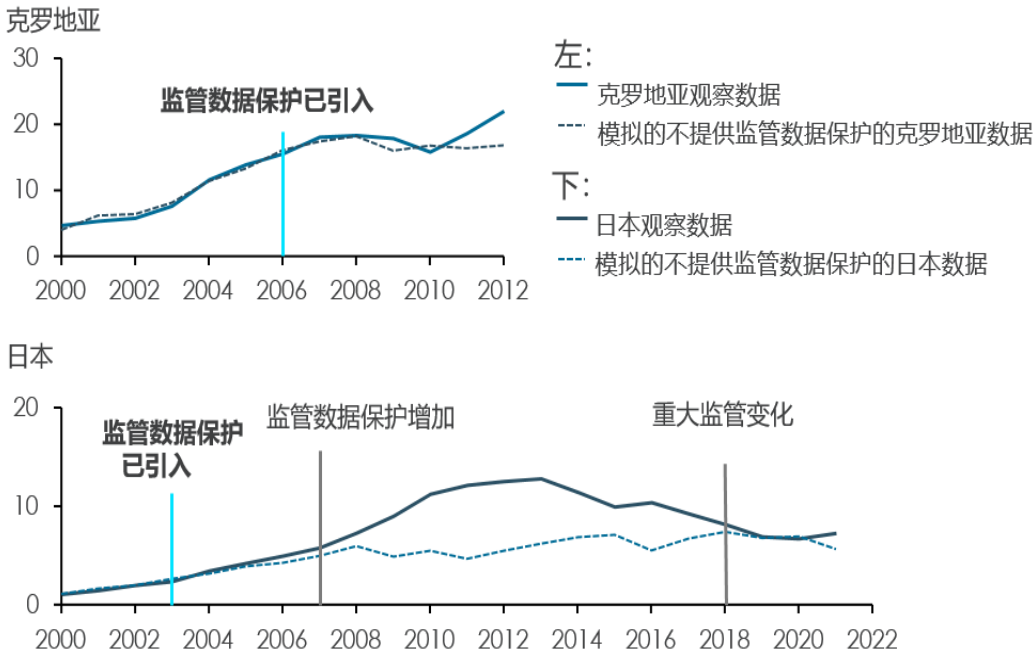

图8：克罗地亚和日本实施监管数据保护后，观察到的监管数据保护对临床试验数量的影响。[17]

建议

中国已承诺提供监管数据保护，包括在加入世贸组织、签署《TRIPS 协定》和《中瑞自由贸易协定》时均有此承诺。《TRIPS 协定》长期以来一直规定，签署国必须保护提交给监管机构以确保新药获得批准的检测和其他数据，防止对其不公平的商业使用和披露。尽管在 2018 年[18]和 2022 年[19]均有在中国实施监管数据保护的提议，但监管数据保护在中国仍然没有实施。

为了提高生物制药行业的信心和可预测性，我们建议中国迅速采取行动，

[17] 来源：哥本哈根经济（Copenhagen Economics），以来自 IQVIA、世界银行、世卫组织、WGI、和全国统计学（National Statistics）的数据为基础。
[18] 国家药监局 《药品试验数据保护实施办法（暂行）（征求意见稿）（2018 年）
[19] 《药品管理法实施条例》（修订草案征求意见稿）（2022 年）

提供与国际最佳实践同等级的监管数据保护，包括：

1. 对于在中国首次上市的小分子药和生物制剂提供监管数据保护，其保护期限符合国际最高标准；[20]

2. 在申请人有新的临床数据的前提下，对于旨在改变小分子药中先前批准的活性成分的药物改良和新用途提供与美国和瑞士等市场一致的监管数据保护；

3. 监管数据保护期限从国家药品监督管理局批准上市许可之日起计算。

我们注意到，对于已在中国境外批准上市的药物，先前关于监管数据保护的提议会限制其能否获得监管数据保护或保护期限，这种做法与全球主要市场的做法不一致。这种做法也与中国的创新目标背道而驰，使国内外创新厂商更难从监管数据保护为创新提供的激励措施中受益，这反过来可能会影响在中国开发和/或推出产品的决策。鉴于“全球首次上市”要求可能带来的相关问题， 监管数据保护必须平等地提供给在中国推出的所有创新产品，这一点至关重要。

b、定价和报销

及时、透明和有依据的定价和报销体系可确保创新者的投资得到回报，并为未来的研发提供资金。

- *透明度和正当程序*——关于药品选择、评估、定价和报销方式的拟议法律、法规和程序应予公布，并在实施前及时征求意见。具体的认定和决定应该是公平的、有依据的、合理和一致的，有利益攸关方的实际参与，并有书面理由的支持。对于决定，应提供对现有证据进行独立审查的申诉程序。

[20] 例如，美国为含有新活性部分的小分子药物提供 5 年的监管数据保护，为生物制剂提供 12 年的 监管数据保护，这两个期限都从在美国首次获得批准之日开始。21 U.S.C. § 355；42 U.S.C. § 262. 欧盟授予小分子药物和生物制剂自其在欧洲首次获得授权之日起十年的监管数据保护，并有可能根据额外适应症的批准再延长一年。

- *价值评估*——价值评估框架应具从整体考虑，并认可多个价值领域，包括治疗益处、未满足的需求、更广泛的社会经济效益和对医疗创新的贡献。价值评估还应关注那些对患者而言重要的结果，认可个体患者的需求，并关注患者对治疗的不同反应。

- *定价和报销*——报销金额应通过对适当的比较药物的溢价定价来确认产品的评估价值，并在知识产权保护期间通过可预测的价格调整规则予以维持，从而为早期获取和持续创新（例如，新适应症和新配方）创造激励。

- *灵活性*—应允许创新的定价和支付模式以及支持它们所需的基础设施，以加快患者获取药品，同时管理真实世界临床结果和预算影响的不确定性。

只有当创新得到充分的回报时，创新者才能投资于下一代治疗手段和方法的开发和推出。另一方面，限制性定价报销政策可能会对研发和患者获取药品产生负面影响。

案例分析：日本

十多年前，日本在药品定价、评估、审批、疫苗政策等方面进行了重大改革，这些改革使日本的制度更加透明，更加支持创新，更有利于生物制药的研发。这些改革减少了监管造成的延迟和日本众所周知的“药物滞后”（即创新药物没有及时上市）。

然而，自 2016 年以来，政策和商业环境明显恶化。日本政府进行了 50 多项定价规则变更，多次对专利药品降价，并在专利期限内提早批准了某些仿制药，这些也得到了中央社会保险医疗协议会（Chuikyo）的批准。这些措施降低了可预测性，并使日本的生物制药创新生态系统处于竞争劣势。日本现在被视为一个负增长市场，生命科学投资持续下降，与全球的积极趋势形成鲜明对比。

如图 9 所示，其结果是日本在早期产品管线中的份额下降，新临床试验停滞不前，以及“药物滞后”现象的回归，即越来越多的用于未满足医疗需求的创新药物没有及时在日本推出，或者根本没有推出（即“药物损失”）。日本政府认识到了这些挑战，并于 2023 年 12 月决定实施变革，这是自 2016 年以来做出负面决定后，朝着更恰当地评估创新药物的方向迈出的第一步。日本需要进一步改革，以发挥其蓬勃发展的生物制药创新生态系统的潜力。

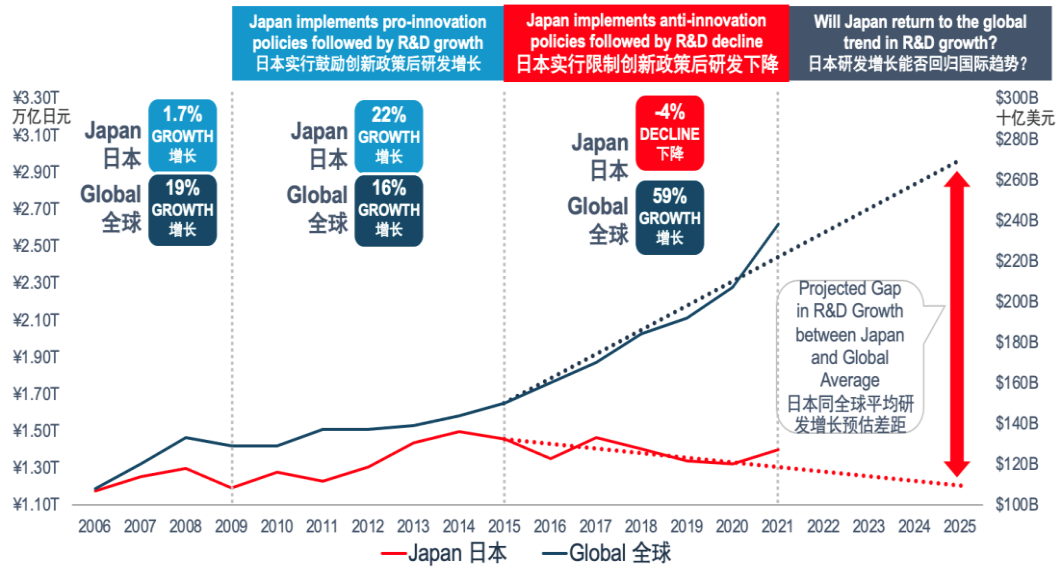

图 9：相对于全球趋势，支持和反对创新政策的历史时期对日本的研发投资产生了影响[21]

案例分析：英国

患者的可及性在很大程度上取决于公共健康保险的承保范围和报销。在英国，即使药物在公共健康保险范围内，患者也面临可及性限制，因为国家卫生与临床优化研究所 （NICE） 经常建议只有一部分批准的用途才应当在

[21] 资料来源：日本总务省，《2022 年研究与开发调查报告》；Evaluate Pharma， 2022 到 2028 年全球展望（2022 年）。

国民保健署 （NHS） 中报销。NICE 使用基于质量调整生命年阈值的成本效益分析提出建议。因此，在 2017 年 1 月 1 日至 2021 年 12 月 31 日期间，全球推出的新药中，只有 39%被 NICE 推荐用于医保，只有 13%被推荐用于所有批准的用途（见图 10）。

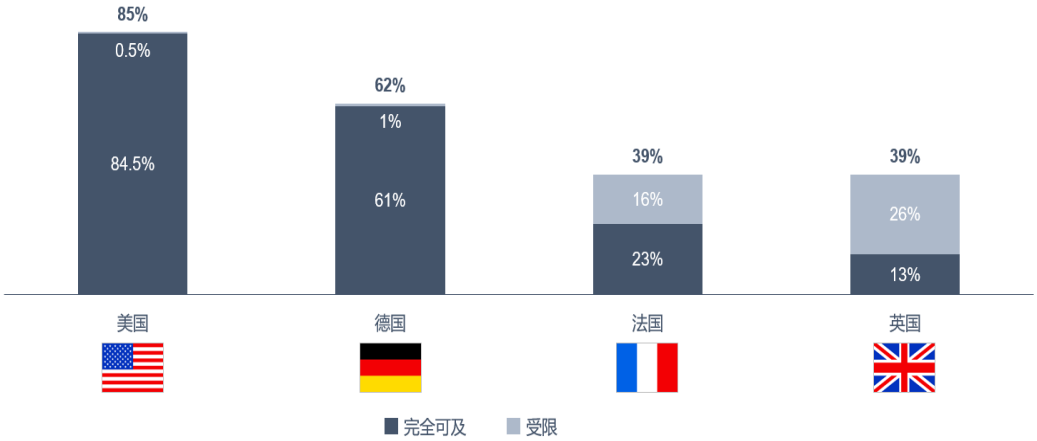

图 10：按国家划分的完全可及与限制可及性的公共保险计划报销的新药百分比[22]

与美国、德国或法国的患者相比，英国患者在公共健康保险所涵盖的新药中面临更高比例（66%）的可及性限制。由于癌症治疗的高度持续创新，对癌症患者的影响可能特别明显。在英国，很少有患者能在限制情形下获得 NICE 推荐的新癌症药物（图 11）。

[22] 资料来源：PhRMA 对 IQVIA MIDAS®以及国家监管和公共保险报销数据的分析。2023 年 11 月。

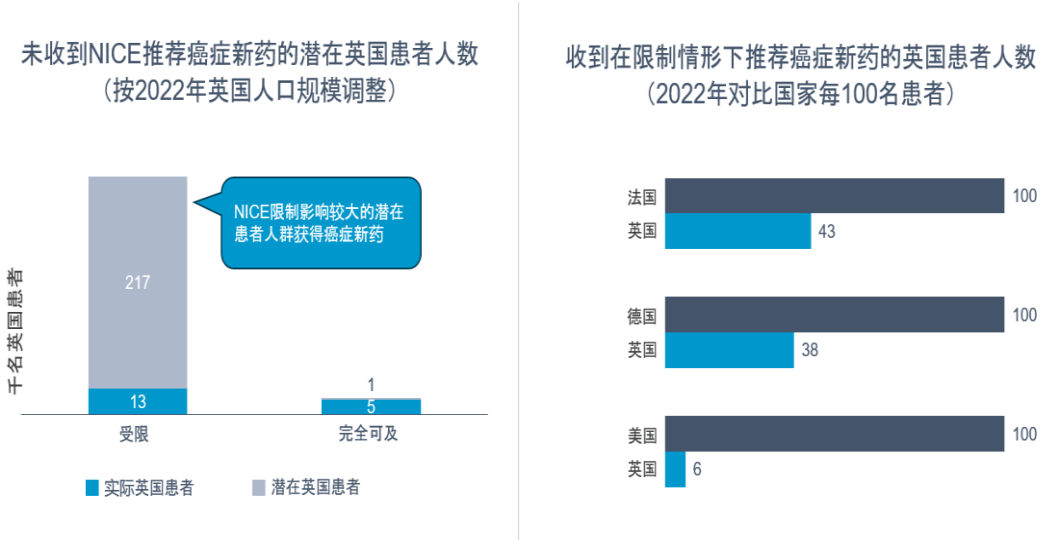

图 11：NICE“优化”推荐严重限制了英国患者获得癌症新药的机会[23]

建议

中国已在加强其医疗保健体系和为广大人口提供医疗保险方面取得了很大进展。国家药监局的持续改革加快了监管审批时间，并促成一批又一批的新药品上市。国家医保目录的更新更加频繁，现在每年更新一次，增加了涵盖的新药数量。

与此同时，国家医保目录的新药定价和报销程序仍然缺乏足够的透明度，与全球最佳实践偏离。产品选择和评估标准似乎是基于狭义的价值和预算影响维度，而没有明确说明如何确定和应用这些标准。此外，在确定报销价格时，仍然存在重大的实施挑战，例如报销百分比低、进入医院的限制和额外的成本控制法规，这些因素仍在限制患者获得创新和救命药物的机会。

为了更好地优化国家医保目录的定价和报销流程，我们建议：

1、改进临床评估、经济评估和谈判过程，将创新药物纳入国家医保目

[23] 资料来源：PhRMA 对 IQVIA MIDAS®以及国家监管和公共保险报销数据的分析。2023 年 11 月。

录，以反映临床、经济和社会效益和成本，而不是关注最低的国际参考价格和成本效益门槛。

2、提高行业和其他利益攸关方对这一过程的了解度和参与度，包括评估和预算影响分析标准，以及适当选择参照药的标准。

3、灵活应对特定治疗领域和罕见病的挑战，为企业提供寻求创新支付安排的新途径。

4、支持评估的个人专家组的遴选标准应更加科学和透明。

5、确保国家医保局与生产企业之间的谈判基于明确的条件和标准化的文件，企业应当有足够的时间准备需提交的文件，而且在谈判之前、期间和之后应当提供开放的沟通渠道，以便解决任何问题。

6、加快国家医保目录的实施（例如，谈判药品进入医院），以改善患者获得创新药物的机会。

c、商业健康保险

除了公共定价和报销制度外，包括商业健康保险在内的多层次医疗保障体系有可能增加患者获得创新药物的机会并减轻自付费用。在中国，自 2015 年推出至 2021 年，城市商业补充健康保险（“商业补充险”）计划已成为一项受欢迎的商业健康保险计划，受到政府、保险业和医药行业的关注，并已发展到 1.1 亿参保人，总保费达 120 亿元人民币。

尽管有此增长，我们也观察到商业补充险产品对创新药物的覆盖范围有限。平均而言，商业补充险的报销清单仅涵盖 20 个创新药品牌，涉及 19 种疾病。

案例分析：珠海

2018 年 12 月，珠海市人力资源和社会保障局启动了珠海市商业补充险

项目，这是一个政府支持的政企合作项目。政府对产品设计给予全面指导，提供行政支持并促进参保。

作为一项健康保险，珠海的商业补充险旨在提供广泛的承保范围、相对较低的保费以及高赔付率。此外，珠海的商业补充险还为确诊患有重大疾病的患者提供一次性支付的重大疾病保险福利。该计划还涵盖筛查等健康管理服务，并与生物制药公司合作开展创新药物的患者援助计划，以提高低收入患者的药品可及性。

截至 2023 年，该项目参保人数达到约 110 万人，位居广东省第一、全国前列。自成立以来，投保人覆盖率一直在 35%-45%之间，自 2020 年以来稳步上升（图 12）。保费保持稳定，保费资金池持续扩大。

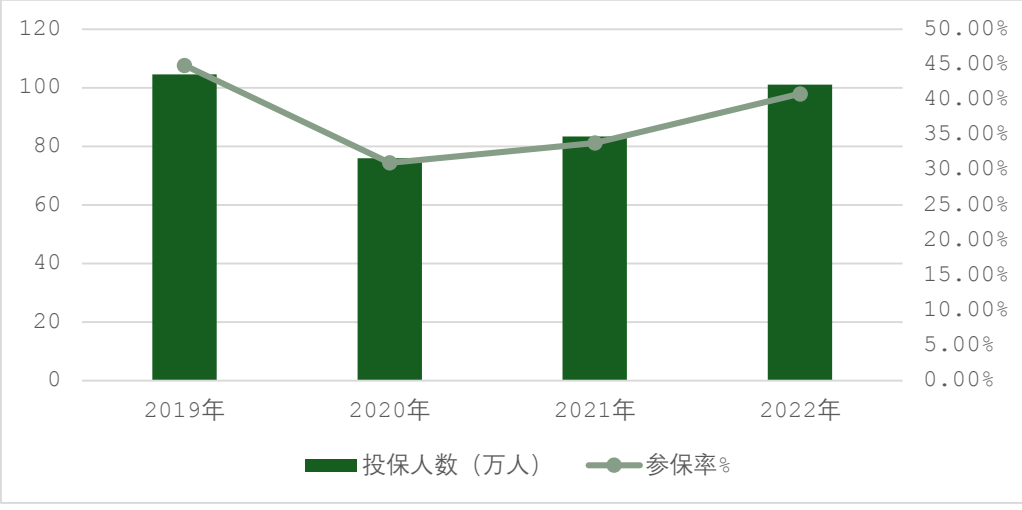

图 12：2019-2022 年珠海商业补充险参保情况

该项目四年累计支付赔偿金 4.34 亿元，累计惠及 1.89 万人，报销共计 5.94 万笔（图 13）。用于恶性肿瘤的自费非国家医保目录药物的报销率为 74%，使更大比例的患者能够获得这些药物。此外，珠海市政府近日宣布，该项目将扩大非国家医保目录罕见病药物以及通过港澳药械通提供的新药的

覆盖范围，报销率为 60%（最高费用为人民币 30 万元）。[24]

总体而言，珠海的商业补充险项目运行顺利，自成立以来实现了小幅预算盈余。此外，该项目的癌症筛查服务已通过早期检测成功节省了约 990 万元人民币的医疗费用。

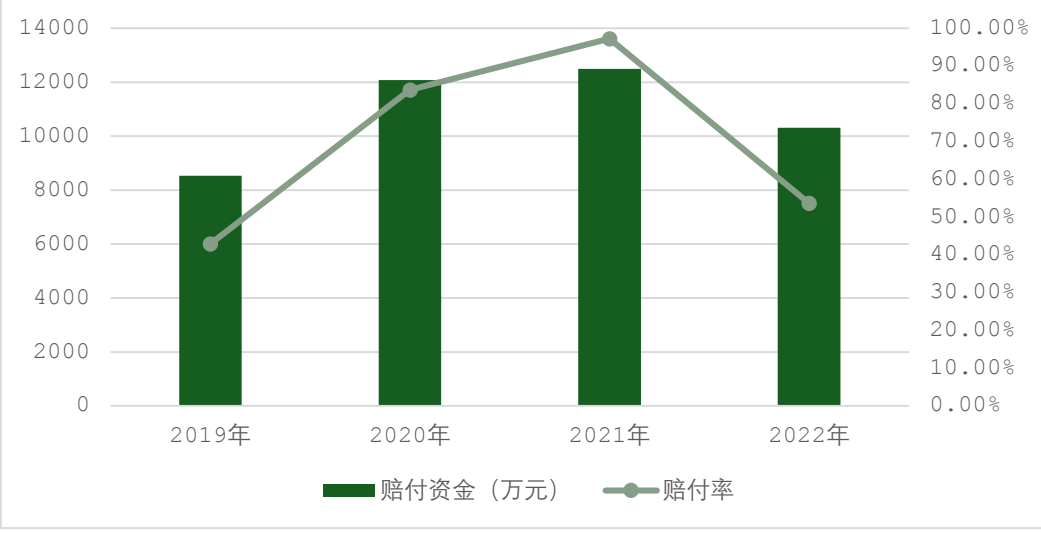

图 13：珠海商业补充险的赔付水平，2019-2022 年

建议

珠海的例子表明，得到政府大力支持和推动的商业补充险计划有可能为公众提供本来难以获得的创新药物。为改善商业健康保险的政策环境，扩大患者获得创新药物的机会，我们对商业补充险的可持续发展提出以下建议：

1、优化商业补充险产品设计，通过允许已有症状的人群和老年人群参与等方式，确保包容性。

2、加强药企与保险公司合作，加强有关数据共享、支付模式探索、基于科学的特种药目录设计等主题的对话。

[24] 来源：珠海市人民政府，https://www.zhuhai.gov.cn/xw/xwzx/bmkx/content/post_3567423.html。2023 年 8 月。

3、鼓励提高创新药物覆盖面，包括设计产品以应对区域疾病风险，使商业补充险的报销责任与国家医保目录保持一致，包括解决未满足医疗需求的高价值药物，设计分层的商业补充险产品以满足不同的患者需求，以及增加商业补充险对创新药物的报销。

4、提高政企参与率，允许基本医疗保险个人账户资金用于自己或家人的商业补充险，在政府支持下通过多种渠道推广商业补充险，提高参与率，降低平均运营成本，建立税收优惠，促进商业补充险参与。

5、建立更完整的数据体系：鼓励与保险公司共享数据，同时考虑数据安全，并要求保险公司披露商业补充险相关数据。

6、发布中央一级的政策文件，支持和规范商业补充险发展，明确相关部委和部门的职责。

7、让当地基本医疗保险部门支持商业补充险的可持续发展，指导商业补充险的设计，使商业补充险能够发挥其对基本医疗保险的补充作用。

结束语

我们今天看到的生物制药创新方面的进展，正在彻底改变我们诊断、治疗、治愈和预防疾病的方方面面，挽救患者的生命并改善各种慢性和罕见病患者的生活质量。在新的医学时代，许多从前被认为是致命的疾病现在都已变得可控，并且有可能治愈。随着研究人员不断探索改变患者生活的新领域，前景前所未有的光明。在恰当的政策环境下，生物制药创新可以充分发挥其潜力，让中国和世界各地的患者享受更健康、更长寿的生活。

Biopharmaceutical Innovation: Fostering Research, Development and Patient Access

PhRMA Enterprise Report submitted to the China Development Forum
March 2024

Executive Summary

Biopharmaceutical research and development (R&D) is key to improving patients' health and saving lives. Over the last decade, the global biopharmaceutical industry has more than doubled its annual investment in the search for new treatments and cures, including USD 262 billion in 2023.[1] While these investments build upon previous medical advances, they are just beginning to yield results on the latest breakthroughs, opening the door to entirely new ways to address some of the most complex diseases of our time.

China's R&D pipeline has made tremendous advances in the past decade, with over 10-fold growth in the number of medicines in preclinical and clinical development and is now second only to the United States. We expect to see many more innovative medicines approved in China, and at a faster rate, in the coming years.

While there has been considerable progress in recent years with regard to access to new medicines in China, still only 24% of new medicines launched globally in the past 10 years are available in China, versus 85% in the United States and 38% on average for OECD countries. Further, only 15% of global new medicines are reimbursed under the National Reimbursement Drug List (NRDL) in China.[2] Thus, there is considerable potential for China to increase patient access to innovative medicines.

Alongside these trends, an aging population and expectations for better health and longevity have accelerated the demand for health care in China. For example, there are an estimated 200 million adults with obesity in China, with an additional 100 million expected in the next 10 years;[3] these individuals may greatly benefit from cutting-edge obesity treatments. Sustained growth of the biopharmaceutical sector will require a supportive policy environment to enable innovative medicines to

[1] Evaluate, https://www.evaluate.com/thought-leadership/pharma-reports/world-preview-2023-pharmas-age-uncertainty.
[2] PhRMA, Global Access to New Medicines Report, https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report.
[3] Wall Street Journal, https://www.wsj.com/health/pharma/ozempic-is-taking-off-with-the-worlds-largest-obese-population-hint-it-isnt-the-u-s-a7c2498c.

reach patients and to incentivize continued research in the next generation of treatments and cures.

Innovative biopharmaceutical companies look for stable and predictable pro-innovation policy environments when making decisions regarding medicines development and launch. Such policies include: 1) strong intellectual property (IP) to protect their innovations; 2) predictable and science-based regulatory pathways that ensure timely market access; and 3) a payment system that rewards innovation and allows for further investment in the next generation of medicines. These three areas are all necessary for the sustainable development of a vibrant innovation ecosystem that provides patients faster access to lifesaving therapies.

This paper provides data and experience from global biopharmaceutical markets that demonstrate the relationship between pro-innovation public policies and greater investment in and availability of innovative medicines. Where markets are open, innovation is valued and IP is protected and enforced, biopharmaceutical innovators have the predictability and certainty that they need to collaborate with partners, compete successfully and accelerate the launch of new medicines.

I. Global Trends on R&D and Access to New Medicines

a. R&D Pipeline

We are in a new era of medicine where breakthrough science is transforming care and our approach to treating patients. Robust investment in R&D by biopharmaceutical companies is resulting in advances and discoveries unlike anything seen before. The application of genomics to develop personalized medicines is enabling physicians to tailor treatments to the unique needs of patients while immunotherapies are harnessing patients' own immune systems to fight off various conditions, including cancer and rare diseases. Today, there are more than 8,000 medicines in clinical development around the world addressing pressing unmet medical needs, including:

Decades of research unlocking the nature and origin of **cancer** have led to an unprecedented amount of targeted treatment approaches and improved prognoses for many cancer patients. A range of game-changing new treatment approaches—such as personalized medicines, CAR-T cell therapies, immune checkpoint inhibitors and many others—have become available to patients with cancer. From 2000 to 2016, new cancer treatments were associated with preventing nearly 1.3 million deaths in the United States. There are currently 1,600 vaccines and treatments for cancer in clinical development.[4]

Older adults are disproportionately affected by **chronic diseases,** such as diabetes, arthritis and heart disease. Nearly 95% have at least one chronic disease, and nearly 80% have two or more.[5] Chronic diseases can often limit an older adult's ability to work and perform daily activities, cause them to lose their independence and lead to the need for long-term care. The combined costs of managing chronic diseases account for two-thirds of all health care costs in the United States.[6] Currently, there are over 400 medicines in clinical trials for chronic diseases affecting older patients that hold promise to improve lives and save healthcare costs.[7]

China's R&D pipeline has made tremendous advances, with over 10-fold growth in the past decade in the number of medicines in preclinical and clinical development, and among countries is now second only to the United States. (See Figures 1 and 2). We thus expect to see many more innovative medicines approved in China, and

[4] PhRMA, Medicines in Development for Cancer: 2023 Report, https://phrma.org/resource-center/Topics/Medicines-in-Development/Medicines-in-Development-for-Cancer-2023-Report.
[5] National Council on Aging, www.ncoa.org/article/the-inequities-in-the-cost-of-chronic-disease-why-it-matters-for-older-adults.
[6] Kaiser Family Foundation, www.kff.org/interactive/medicare-spending/.
[7] PhRMA, Medicines in Development 2023 Report: the Leading Chronic Diseases Impacting Older Americans, https://phrma.org/resource-center/Topics/Medicines-in-Development/Medicines-in-Development-for-Chronic-Illness-Older-Americans-2023-Report.

at a faster rate, in the coming years.

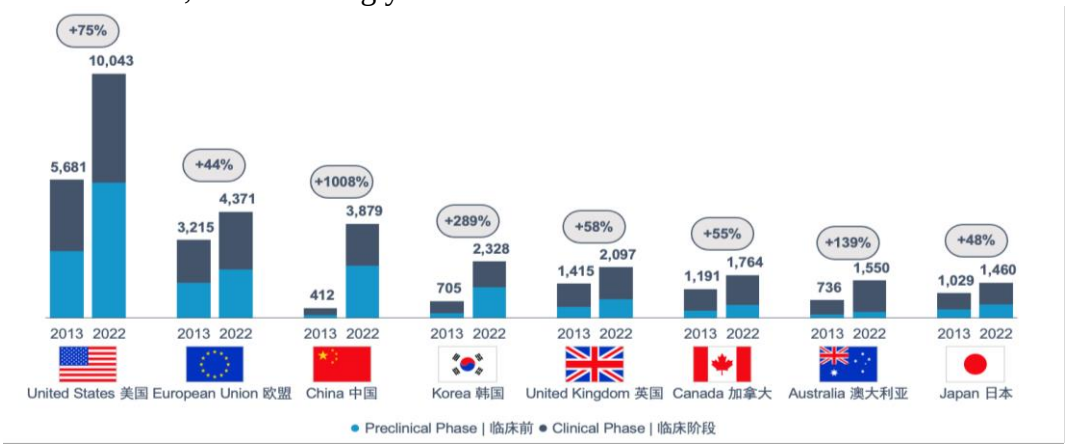

Figure 1: Number of Medicines in Preclinical and Clinical Development by Geography (2013 vs. 2022)[8]

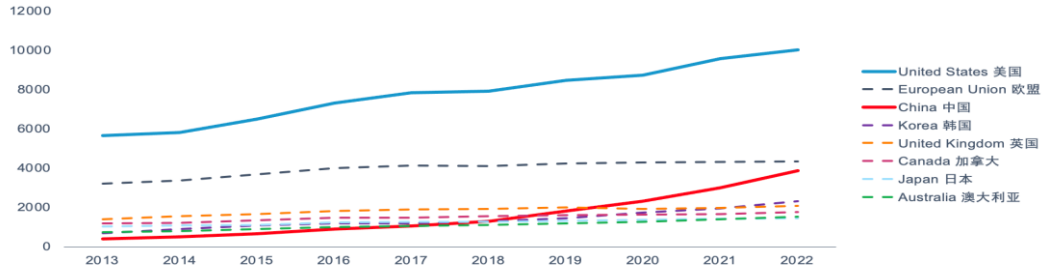

Figure 2: Number of Medicines in Development by Geography and Year, 2013-2022[9]

b. Access to New Medicines

A recent analysis examining access to and public reimbursement of new medicines across 72 different markets indicates that a record number of new medicines are launching globally, but patients in most countries — including many developed countries — can access only a small share. While the launch of new medicines declined over time in most G20 countries, the launch of new medicines in China doubled from 2017 to 2021, marking the largest improvement among G20 countries. Even so, as shown in Figure 3 below, only 24% of new medicines launched globally in the past 10 years are available in China, versus 85% in the United States and 38%

[8] Source: PhRMA analysis of Informa data on pipelines and clinical trials. August 2023.
[9] Id.

on average for G20 countries. In addition, China has made 15% of new medicines launched globally from 2012 to 2021 reimbursable by the NRDL, compared to public reimbursement rates of 85% in the United States and 28% on average for G20 countries. Thus, there remains considerable potential for China to increase patient access to innovative medicines.

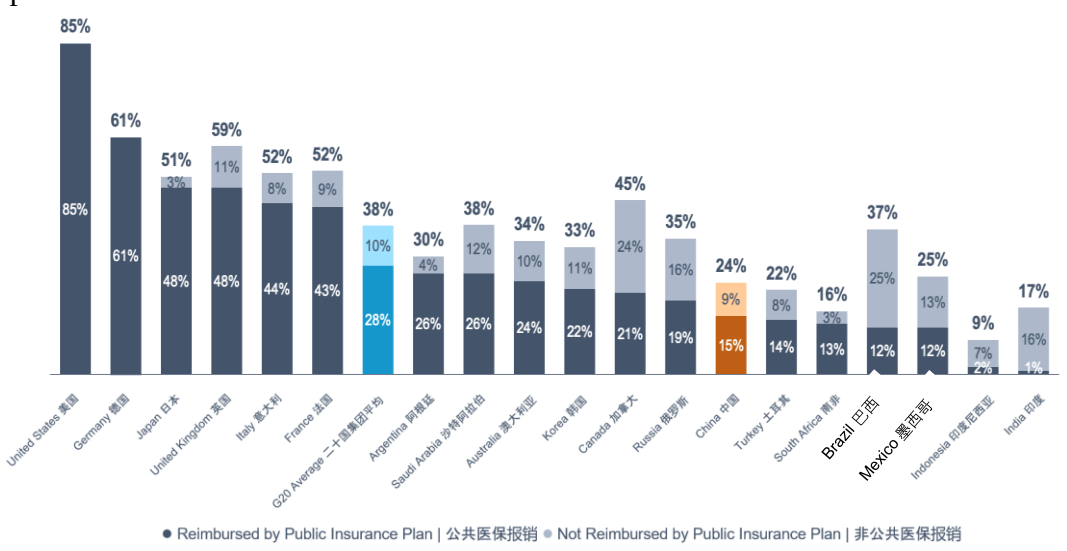

Figure 3: Percentage of New Medicines Approved and Publicly Reimbursed (of all 460 new medicines launched from 2012 to the end of 2021)[11]

II. Markets Need Pro-Innovation Policies to Foster R&D and Timely Patient Access to New Medicines

Bringing innovative medicines to the market involves lengthy, risky and costly development processes. On average, it takes 10-15 years and USD 2.6 billion (RMB 17.7 billion) to develop one new medicine, including the cost of many failures.[10] Further advancing investment in biopharmaceutical R&D and patient access depends on a policy ecosystem that promotes innovation.

A successful biopharmaceutical innovation policy ecosystem is comprised of three core components that are closely related and *equally* necessary for growth and sustainability:

Intellectual Property System: A robust IP system drives biopharmaceutical innovation by providing the necessary incentives to invest substantial capital and other resources in researching, developing and launching innovative medicines. To bring valuable new medicines to patients, biopharmaceutical innovators must be

[10] PhRMA, Research & Development Policy Framework, https://phrma.org/policy-issues/Research-and-Development-Policy-Framework.

able to effectively secure and enforce patents, receive regulatory data protection (RDP) for clinical information demonstrating the safety and efficacy of a medicine for marketing approval, and protect trade secrets and confidential commercial information. Only with strong IP protection and enforcement will innovators have the predictability and certainty that they need to collaborate with partners, compete successfully and accelerate the launch of new medicines.

Regulatory System: An effective regulatory system establishes and consistently applies clear, science-based, and impartial rules to assess the safety, efficacy and quality of products, from preclinical and clinical development to post-market surveillance and risk management. Such features will enable the regulatory system to produce consistent and predictable approval decisions within reasonable timeframes and allow for simultaneous global development. Successful regulatory systems adopt harmonized guidelines and eliminate market-specific requirements when possible.

Pricing and Reimbursement System: The pricing and reimbursement system should reflect the holistic value that innovative medicines provide to patients and society and enable companies to continue investing in the next generation of treatments and cures. This includes timely, transparent, predictable and evidence-based systems that meaningfully engage stakeholders. Commercial health insurance (CHI) is part of a multi-layered medical security system that improves access and reduces out-of-pocket costs for patients.

With these systems in place, China can further strengthen its innovation ecosystem to sustain its growth in R&D and ensure patients have access as these medicines are approved.

III. The Impact of Public Policies on R&D Investment and Patient Access: Case Studies

The following provides case studies from biopharmaceutical markets that demonstrate the relationship between pro-innovation public policies and the strong development and availability of innovative medicines. Where markets are open, innovation is valued and IP is protected and enforced, biopharmaceutical innovators have the predictability and certainty that they need to collaborate with partners, compete successfully and accelerate the launch of new medicines. Conversely, a lack of supportive policies or policies that work against innovation can hinder patient access and investment in R&D. In such cases, levels of R&D and patient access can suffer.

a. Regulatory Data Protection

Major markets around the world with highly innovative biopharmaceutical industries typically have strong IP protection and enforcement systems. Distinct from patents, RDP provides a period of exclusivity for clinical data generated to

demonstrate the safety and efficacy of biopharmaceutical products for marketing approval. In many cases, RDP may complement patents on innovative medicines, while in other situations RDP may be the only protection available. Strong enforcement of RDP is therefore critical for fostering R&D of new medicines and for advancing efforts to stimulate local and global biopharmaceutical innovation.

RDP is particularly important for large molecule drugs (i.e., biological products). Produced using material from living organisms, biologics are complex and challenging to manufacture and may not be protected adequately by patents alone. Unlike generic versions of traditional chemical compounds, biosimilars are not identical to the original innovative medicine, which can lead to greater uncertainty about whether an innovator's patent right will cover a biosimilar version. Without the certainty of some substantial period of market exclusivity, innovators will not have the incentives needed to conduct the expensive, risky and time-consuming work to discover and bring new biologics to market.

RDP provides powerful incentives to invest in R&D and launch new medicines. As Figures 4 and 5 illustrate, markets that have RDP have on average 31.5% of global medicines available to patients, versus 11.1% for markets without RDP. Of this increase, RDP contributes 9.2% higher availability, corresponding to 45% of the difference.[11] In practical terms, this means half of the difference in availability between markets with and without RDP can be attributed to RDP.[12]

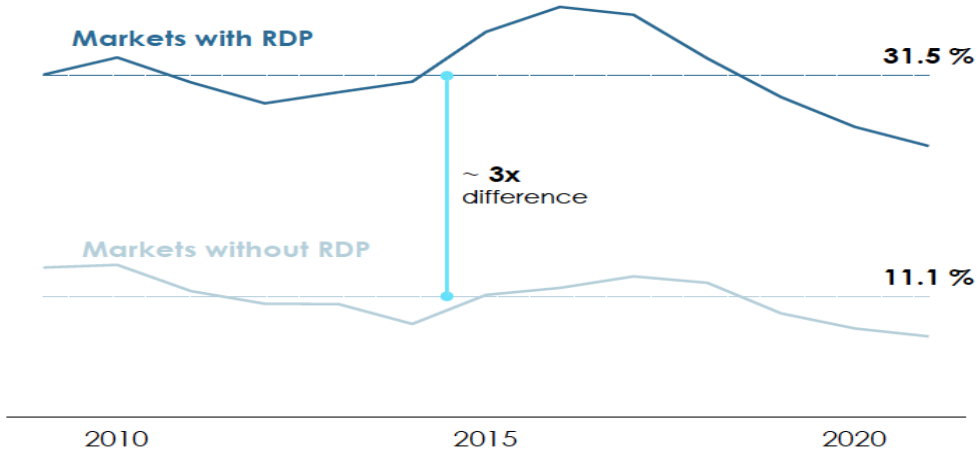

Figure 4: Availability of Innovative Medicines in Markets with and without RDP[13]

[11] Source: Copenhagen Economics based on data from IQVIA, WHO and World Bank.

[12] Copenhagen Economics, Regulatory Data Protection: How adopting regulatory data protection can increase medicines availability, innovation and investment (2023), https://copenhageneconomics.com/publication/regulatory-data-protection-how-adopting-regulatory-data-protection-can-increase-medicine-availability-innovation-and-investment/.

[13] Source: Copenhagen Economics based on data from IQVIA.

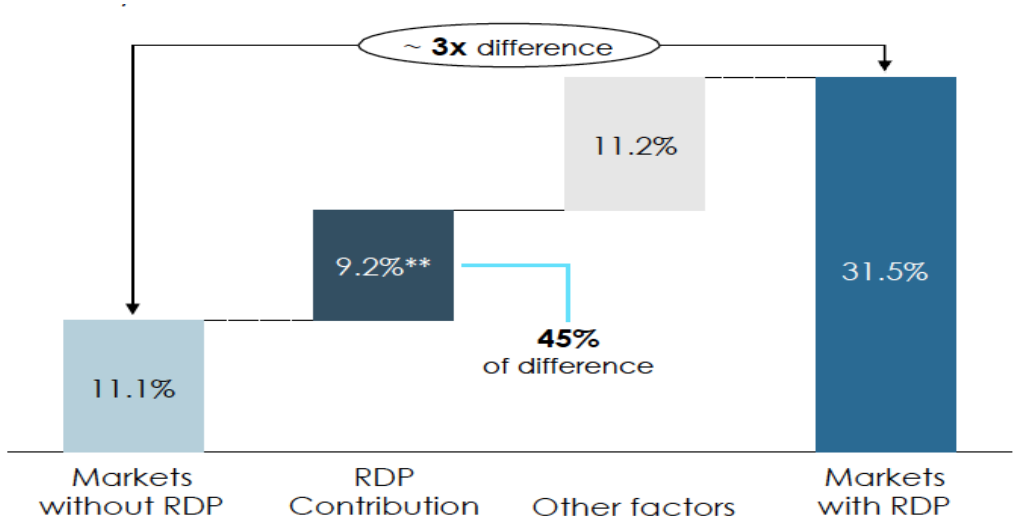

Figure 5: Percentage Availability and Percentage Point Increase in Availability of Innovative Medicines Associated with RDP[14]

RDP is also correlated with greater clinical trial activity. Markets without RDP have an average of 4 clinical trials per million capita versus 21 in markets with RDP (Figure 6). Evaluating the isolated effect of RDP shows an increase of 2.8 clinical trials per million capita (Figure 7). This amounts to a 70% increase above the baseline number of clinical trials in markets without RDP.

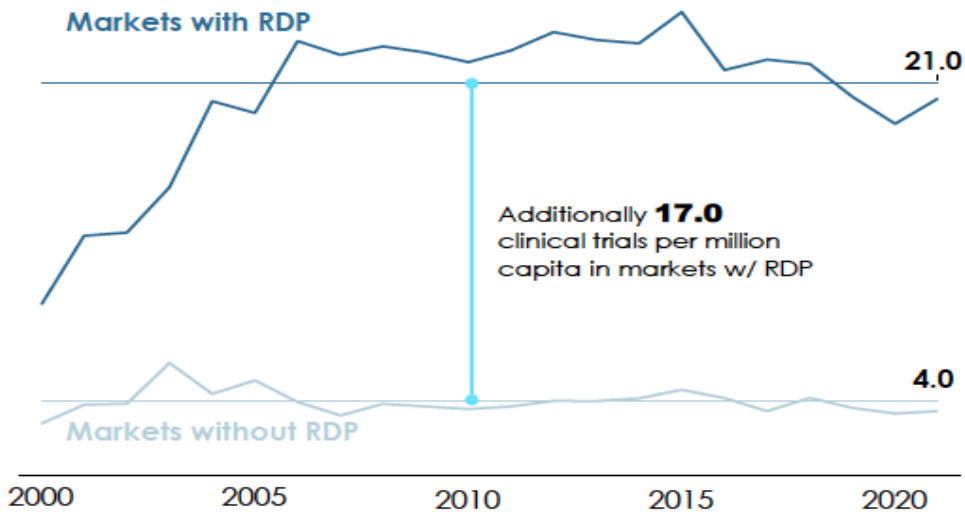

Figure 6: Average Number of Clinical Trials in Markets with and without RDP[15]

[14] Source: Copenhagen Economics based on data from IQVIA, WHO and World Bank.
[15] Source: Copenhagen Economics based on data from IQVIA.

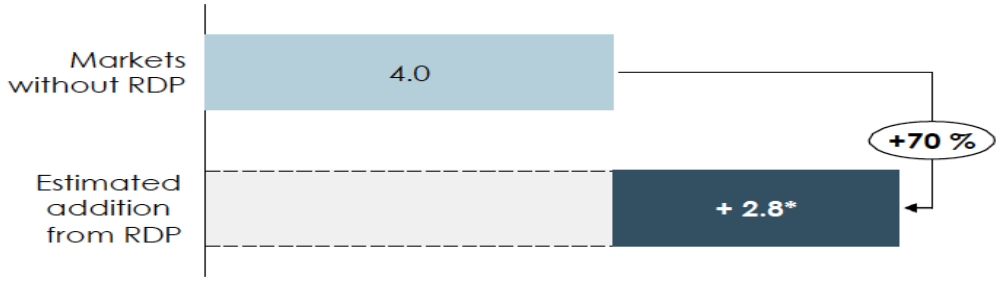

Figure 7: Clinical Trials Per Million Capita and Estimated Increase Associated with RDP[16]

Case Studies: Croatia and Japan

Empirical evidence from Croatia and Japan aligns with the estimated impact of RDP availability on clinical trials (Figure 8). In Croatia, clinical trials per million capita increased by 1.5 from 2007-2012 after the introduction of RDP. Japan also saw an increase of 3.5 clinical trials per million capita after it introduced RDP from 2007-2017. The increase in clinical trials occurs after several years, likely due to the time it takes to plan clinical trials. It is noteworthy that after Japan introduced RDP, it subsequently adopted restrictive pricing policies, which negatively impacted the number of clinical trials in the country after 2016 (see section III.b).

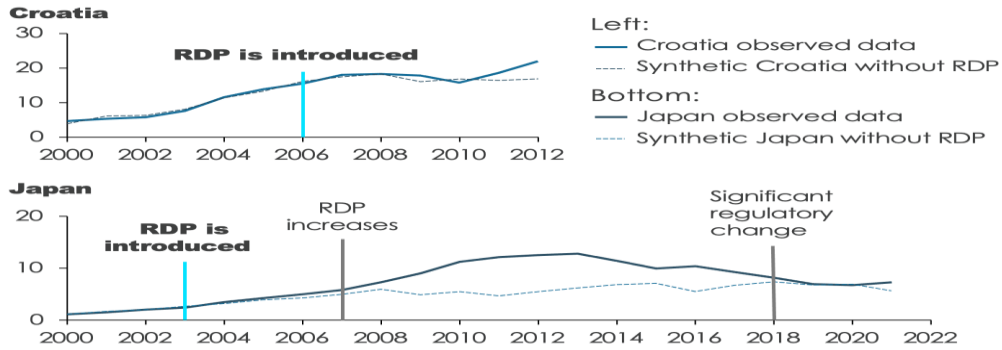

Figure 8: Observed Effect of RDP on Clinical Trials after Implementation in Croatia and Japan[17]

Recommendations

China has made commitments to provide RDP, including in its accession to the WTO, its signature of the *TRIPS Agreement* and in the *China-Switzerland Free Trade Agreement*. The *TRIPS Agreement* has long provided that signatories must protect the test and other data submitted to regulatory authorities to secure approval

[16] Copenhagen Economics, Regulatory Data Protection: How adopting regulatory data protection can increase medicines availability, innovation and investment (2023), https://www.wsj.com/health/pharma/ozempic-is-taking-off-with-the-worlds-largest-obese-population-hint-it-isnt-the-u-s-a7c2498c.

[17] Source: Copenhagen Economics based on data from IQVIA, World Bank, WHO, WGI, and National Statistics

of new medicines against both unfair commercial use and disclosure. Despite proposals to implement RDP in China both in 2018[18] and in 2022,[19] RDP is still unavailable in China.

To increase confidence and predictability for the biopharmaceutical industry, we recommend that China move quickly to provide RDP at levels consistent with international best practices, including:

1. RDP for small molecules and biologics that are new to China with a term of protection consistent with the highest international standards;[20]
2. RDP for improved and new uses of drugs, which is consistent with the rules in markets such as the United States and Switzerland, for a change to a previously approved active ingredient in a small molecule drug, provided there is new clinical data from the applicant; and
3. RDP terms that are measured from the date of approval of a marketing authorization by the National Medical Products Administration (NMPA).

We note that prior proposals for RDP would have limited the availability or duration of RDP for drugs previously approved outside of China, a practice inconsistent with that of major markets globally. Such an approach would also be contrary to China's innovation goals, making it more difficult for both foreign and domestic innovative manufacturers to benefit from the incentives that RDP offers for innovation, which may in turn impact decisions to develop and/or launch products in China. Given the problems associated with a "new-to-the-world" approach, it is critical that RDP be made available equally to all innovative products launched in China.

b. Pricing and Reimbursement

A timely, transparent and evidence-based pricing and reimbursement system ensures that an innovator's investment is rewarded and funds future R&D. Key features of such a system include:

- *Transparency and Due Process*—Proposed laws, regulations and procedures concerning how medicines are selected, assessed, priced and reimbursed should be published with timely opportunities for comment prior to adoption. Specific determinations and decisions should be fair, evidence-based, reasonable and consistent, with meaningful engagement of stakeholders and supported by written rationales. Decisions should be subject to an appeals process with an independent review of the available evidence.

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[18] *NMPA Measures on the Implementation of Drug Clinical Trial Data Protection* (draft for public comments) (2018).

[19] *Revised Implementing Regulations for the Drug Administration Law* (draft for public comments) (2022).

[20] For example, the United States grants five years of RDP for small molecule drugs that contain new active moieties and 12 years of RDP for biologics, with both periods starting on the date of first approval in the United States. 21 U.S.C. §355; 42 U.S.C. §262. The European Union grants small molecule drugs and biologics ten years of RDP from the date of first authorization in Europe, with the possibility of an additional year based on approval of an additional indication.

- *Value Assessment*—The value assessment framework should be holistic and recognize multiple domains of value, including therapeutic benefit, unmet need, broader socioeconomic benefits and contribution to medical innovation. Value assessment should also focus on the outcomes that matter to patients, recognizing individual patient needs and varying responses to treatments.
- *Pricing and Reimbursement*—The reimbursement amount should recognize the assessed value of a product through premium pricing over the appropriate comparator medicines and be maintained during the period of IP protection with predictable rules for price adjustment that creates incentives for early access and continued innovation (e.g., new indications and formulations).
- *Flexibility*—Innovative pricing and payment models, as well as the infrastructure needed to support them, should be permitted to accelerate patient access while managing uncertainty with regard to real-world clinical outcomes and budget impact.

Only when innovation is adequately rewarded can innovators invest in the development and launch of the next generation of treatments and cures. On the other hand, restrictive pricing reimbursement policies can have negative impacts on R&D and patient access.

Case Study: Japan

Over a decade ago, Japan made important reforms in the areas of drug pricing, evaluation and approval, and vaccine policy that made its system more transparent, more supportive of innovation and more conducive to biopharmaceutical research and development. These reforms reduced regulatory delays and Japan's well-known "drug lag" in which innovative medicines were not launched in a timely manner.

However, the policy and commercial environment has significantly deteriorated since 2016. The Japanese Government has pursued, and the Central Social Insurance Medical Council (Chuikyo) has approved, more than 50 changes to pricing rules, repeated price cuts to patented medicines and prematurely approved certain generics during the patent term. These shifts resulted in reduced predictability and put Japan's biopharmaceutical innovation ecosystem at a competitive disadvantage. Japan is now viewed as a negative growth market and life sciences investment continues to decline in contrast to the positive global trend. As depicted in Figure 9, the result has been a decrease in Japan's share of the early-stage pipeline, stagnation in new clinical trials and a return of the "drug lag" in which innovative medicines to treat unmet medical needs are increasingly not launched in Japan in a timely manner – or a "drug loss" in which they are not launched at all. The Japanese government recognized these challenges and decided in December 2023 to implement changes that represent a first step toward more appropriately valuing innovative medicines after negative decisions since 2016.

Further reforms are needed for Japan to reach its potential for a thriving biopharmaceutical innovation ecosystem.

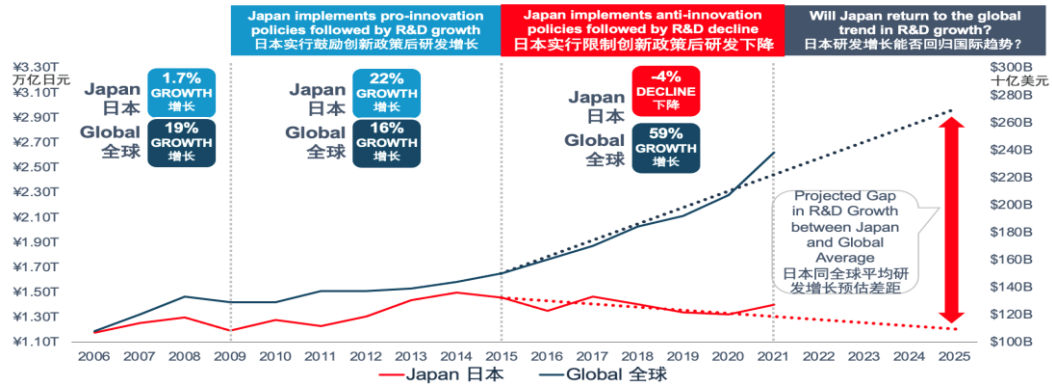

Figure 9: Historical periods of pro- and anti-innovation policies have impacted R&D investment in Japan relative to global trends[21]

Case Study: United Kingdom

Patient access depends heavily on coverage and reimbursement by public health insurance. In the United Kingdom, patients face access restrictions even when a medicine is covered by public health insurance because the National Institute for Health and Care Excellence (NICE) often recommends that only some approved uses should be reimbursed by the National Health Service (NHS). NICE makes recommendations using cost-effectiveness analyses that are based on quality-adjusted life year thresholds. As a result, only 39 percent of new medicines launched globally between January 1, 2017, and December 31, 2021, are recommended by NICE for coverage and only 13 percent are recommended for all approved uses (see Figure 10).

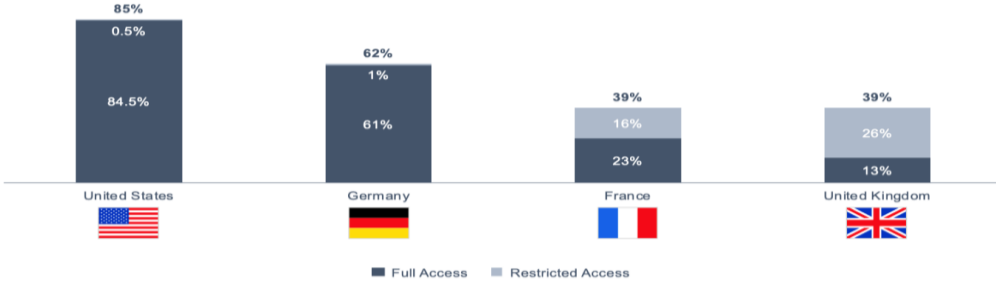

Figure 10: Percentage of New Medicines Reimbursed by Public Insurance Plans with Full vs Restricted Access by Country[22]

[21] Source: Japanese Ministry of Internal Affairs and Communications, Report on the Survey of Research and Development, 2022; Evaluate Pharma World Preview 2022 Outlook to 2028, 2022.
[22] Source: PhRMA analysis of IQVIA MIDAS® and country regulatory and public insurance reimbursement data. November 2023.

Patients in the United Kingdom face access restrictions on a higher share (66%) of new medicines covered by public health insurance than do patients in the United States, Germany or France. The impact on cancer patients can be particularly stark due to the high degree of ongoing innovation in cancer treatments. Far few patients in the United Kingdom access new cancer medicines that are recommended by NICE with restrictions (Figure 11).

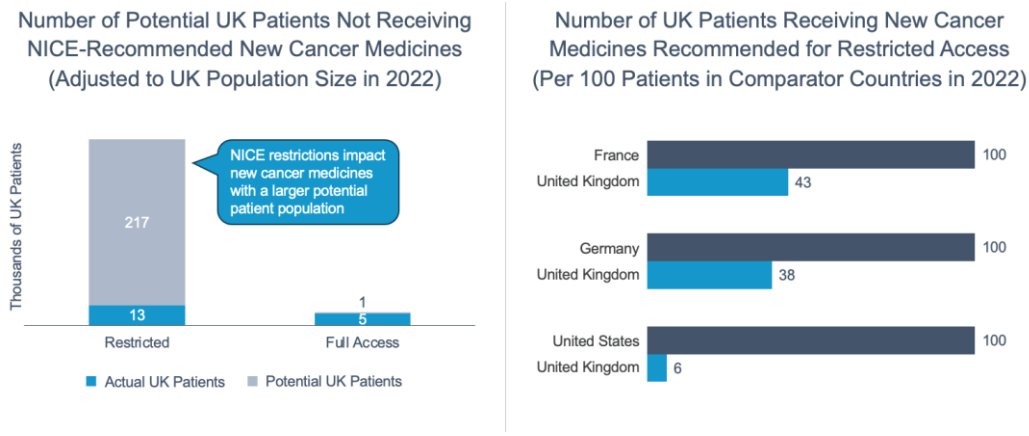

Figure 11: NICE "Optimized" Recommendations Seriously Restrict Patient Access to New Cancer Medicines in the UK[23]

Recommendations

China has made progress in strengthening its health care system and providing health insurance to its vast population. Sustained reforms by the NMPA have led to faster regulatory approval timelines and waves of new product launches. More frequent and now annual updates to the NRDL have increased the number of new medicines covered.

At the same time, the NRDL pricing and reimbursement process for new medicines continues to lack sufficient transparency and diverges from global best practices. The product selection and assessment criteria appear to be based on narrowly defined dimensions of value and budget impact, without clarity on how these criteria are determined and applied. Furthermore, when reimbursed prices are established, there remain major implementation challenges, such as low reimbursement percentages, hospital listing restrictions and additional cost control regulations that continue to restrict patient access to innovative and life-saving medicines.

To better optimize the NRDL pricing and reimbursement process, we recommend:

1. Improving the clinical assessment, economic assessment and negotiation process

[23] Source: PhRMA analysis of IQVIA MIDAS® and country regulatory and public insurance reimbursement data. November 2023.

for including innovative medicines in the NRDL to reflect the clinical, economic and societal benefits and costs – as opposed to focusing on the lowest international reference prices and cost-effectiveness thresholds.
2. Greater clarity and engagement with industry and other stakeholders regarding the process, including assessment and budget impact analysis criteria, and standards for appropriate comparator selection.
3. Flexibility to address challenges for particular therapy areas and rare diseases, and new pathways for companies to pursue innovative payment arrangements.
4. Selection standards for individual expert groups that support these assessments that are more scientific and transparent.
5. Ensuring negotiations between the National Healthcare Security Administration and the manufacturer are based on clear conditions and standardized documentation, with sufficient time for companies to prepare submissions and open communication channels before, during and after negotiations to resolve any issues.
6. Accelerating NRDL implementation (e.g., hospital listing of negotiated drugs) to improve patient access to innovative medicines.

c. Commercial Health Insurance

Along with the public pricing and reimbursement system, a multi-layered medical security system, including CHI, has the potential to enhance patient access to innovative medicines and alleviate out-of-pocket costs. In China, since its launch in 2015 until 2021, City Supplementary CHI (CSCHI) has become a popular CHI scheme, attracting attention from the government, the insurance industry and the pharmaceutical industry, and has grown to 110 million policy holders with total premiums of RMB 12 billion.
Despite this growth, we also observe that CSCHI products provide limited coverage for innovative medicines. On average, CSCHI reimbursement lists covered only 20 innovative medicine brands for 19 diseases.

Case Study: Zhuhai

In December 2018, the Zhuhai Municipal Human Resources and Social Security Bureau launched Zhuhai's City Supplementary Commercial Health Insurance (CSCHI) program as a government supported public-private partnership. The government provides overall guidance on the product design, offers administrative support and promotes enrollment.
As a health insurance, Zhuhai's CSCHI aims for wide coverage, relatively low premiums and a high compensation rate. In addition, Zhuhai's CSCHI features one-time payment of critical illness insurance benefits for patients diagnosed with a major illness. The program also covers health management services such as screening and collaborates with biopharmaceutical companies on patient assistance

programs for innovative medicines to enhance access for low-income patients.
As of 2023, the number of insured reached around 1.1 million people, ranking first in Guangdong province and among the top in China. The policy holder coverage level has been between 35%-45% since its inception with a steady increase since 2020 (Figure 12). Premiums have remained stable and the premium funding pool has continued to expand.

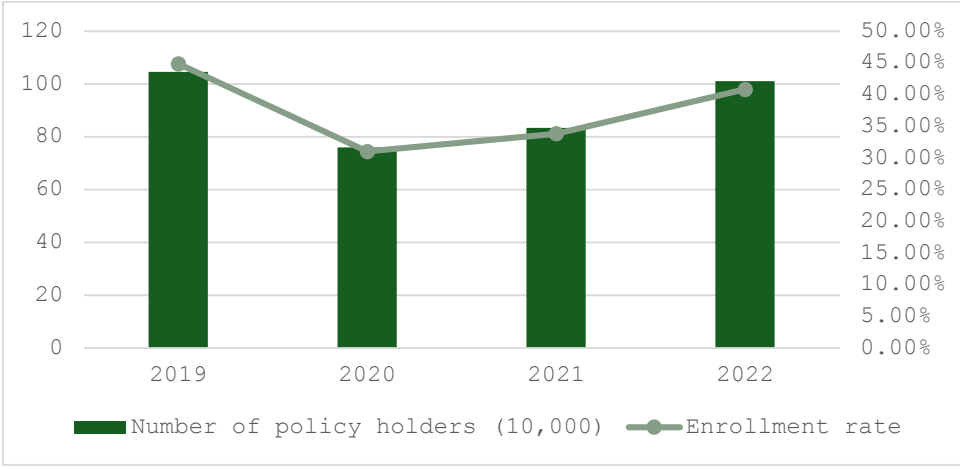

Figure 12: 2019-2022 Zhuhai CSCHI Participation

The program has paid a total of RMB 434 million in compensation over four years, benefitting a total of 18,900 people, with a total of 59,400 reimbursements (Figure 13). The reimbursement rate for self-paid non-NRDL medicines for malignant tumors is 74%, putting these medicines in reach for a larger proportion of patients. Furthermore, the Zhuhai government recently announced that the program will expand coverage of non-NRDL rare diseases medicines, as well as new medicines made available through the Greater Bay Area Medical Device and Medicines Pathway, at a reimbursement rate of 60% (up to RMB 300,000 in cost).[24]

Overall, Zhuhai's CSCHI program has been operating smoothly, achieving a slight budgetary surplus since its establishment. In addition, the program's cancer screening service has been successful in saving an estimated RMB 9.9 million in health care costs due to early detection.

[24] Source: Zhuhai Municipal Government, https://www.zhuhai.gov.cn/xw/xwzx/bmkx/content/post_3567423.html. August 2023.

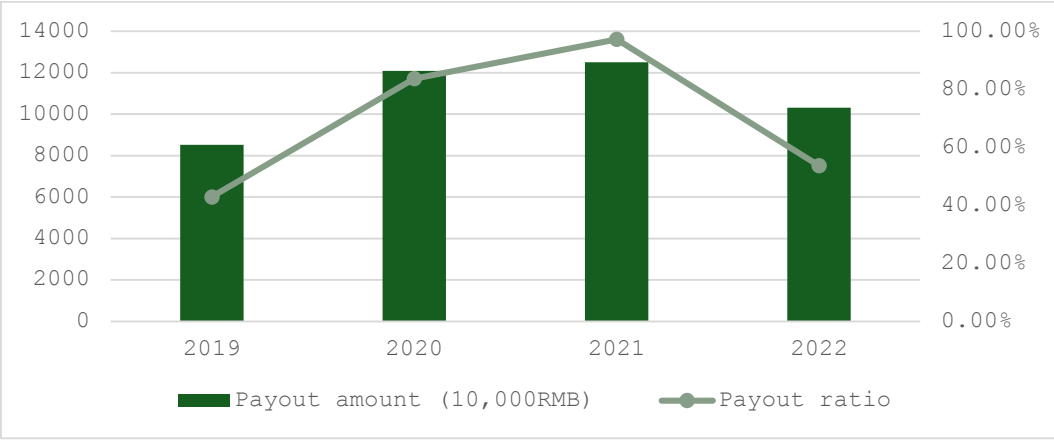

Figure 13: Compensation Level of Zhuhai CSCHI, 2019-2022

Recommendations

The example of Zhuhai shows that CSCHI programs that are strongly supported and promoted by the government have the potential to provide the general public access innovative medicines that would otherwise be difficult to attain. To improve the policy environment for CHI and expand patient access to innovative medicines, we have the following recommendations related to the sustainable development of CSCHI:

1. Optimizing CSCHI product design to ensure inclusivity through allowing, for example, people with existing conditions and elderly populations to participate.
2. Strengthening collaboration between pharmaceutical companies and insurance companies with greater dialogues on issue such as data sharing, payment model exploration and science-based specialty medicine list design.
3. Encouraging improvements to innovative medicine coverage, including designing products to address regional disease risks, aligning CSCHI reimbursement responsibilities with the NRDL, including high-value medicines to address unmet medical needs, designing tiered CSCHI products to meet diverse patient needs and increasing CSCHI reimbursement for innovative medicines.
4. Increasing government and enterprise participation rates by allowing Basic Medical Insurance (BMI) personal account funds to be used for CSCHI for oneself or family members, promoting CSCHI through multiple channels with government support to increase participation rates and reduce average operating costs, and establishing taxation benefits to promote CSCHI participation.
5. Establishing more complete data systems: encouraging data sharing with insurance companies while accounting for data security and requiring CSCHI-related data disclosures from insurance companies.
6. Publishing central-level policy documents to support and regulate CSCHI

development and clarify the responsibilities of relevant ministries and departments.
7. Having local BMI departments support CSCHI's sustainable development, guide CSCHI design and enable CSCHI to fulfill its supplementary role to the BMI.

Conclusion

The progress in biopharmaceutical innovation we see today is revolutionizing how we diagnose, treat, cure and prevent disease, saving patients' lives and improving quality of life across a broad range of chronic and rare conditions. In this new era of medicine, many diseases previously regarded as deadly are now manageable and potentially curable. The future has never been brighter as researchers explore new frontiers that can transform patients' lives. With the right policy environment, biopharmaceutical innovation can reach its full potential, allowing patients in China and throughout the world to enjoy healthier and longer lives.