打造中国医疗体系创新价值链，实现健康中国 2030 愿景

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摘要

目前 “健康中国 2030 ”战略的实施已进入最后冲刺阶段，讨论如何推进大健康行业的发展显得尤为重要。

过去十年，中国在健康领域已经取得举世瞩目的成就，打造了生物医药产业的创新生态系统，并建立了覆盖城乡居民的医疗卫生服务体系和医疗保障体系。

中国正处在向创新型经济转型的关键时期，让普通民众享受到科技创新的成果和红利至关重要。在健康领域，我们建议中国进一步打造鼓励创新的生态系统，并构建一条贯穿中国医疗体系的创新价值链。

随着中等收入群体比重的不断提升，对高质量、创新、高效和个性化医疗服务的需求也在攀升。同时，慢性病发病率增高和人口老龄化也增加了医疗系统的负担。很多疾病还存在未被满足的医疗需求，例如肥厚型心肌病（HCM）和很多自身免疫性疾病，患者仍急需效果更理想的治疗方案[1,2]。

此外，打造鼓励创新的生态系统还面临一些挑战，需要进一步加快“同类首创（first-in-class）”和“同类最佳（best-in-class）”新药的审评审批，优化国家医保药品目录谈判机制以体现对创新药品价值的认可。国家医保谈判药品仍面临“进院难”，“双通道”管理机制在零售药店的落地过程中存在一定困难，国际最先进的创新疗法在中国获批后，还需要加大对临床医生教育和

培训的投入。

百时美施贵宝非常支持中国进一步鼓励创新和提升患者用药可及性，我们愿意贡献自己的力量，并就此提出如下建议作为未来政策举措的参考：

- **优化药品价格形成机制和医保支付标准形成机制：**与行业内企业开展充分沟通和讨论，进一步完善针对创新药的价值评估体系，引入商业医保等多方共同支付机制，提升患者对创新疗法的支付能力。
- **简化创新药品进院流程：**取消对医院采购自费药品的部分限制，同时加快国家医保谈判药品的采购进度。
- **推进国家医保谈判药品“双通道”管理机制在零售药店的实施：**确保地方按照国家的指导意见，将定点零售药店纳入医保谈判药品的供应保障范围，取消额外的准入限制，对于有特殊管理要求的药品允许其在指定的定点药店销售，同时推进医保电子处方平台的建设和管理。
- **在中国多层次的医疗卫生服务体系中打造一条创新价值链，打通新药上市后直达患者的创新通道：**加大对临床医生教育和培训的投入，使更多医生能够将国际最先进的创新疗法应用于患者临床治疗。

一、前言

2016 年，中国发布了《“健康中国 2030”规划纲要》，勾画了进一步完善国家医疗体系，实现全民健康愿景的宏伟蓝图。“健康中国 2030”战略实施至今，中国在健康领域已经取得举世瞩目的成就，建立了覆盖城乡居民的医疗卫生服务体系和医疗保障体系，建立起基本与国际接轨的生物制药和医疗器械监管制度。[3] 2015 年至 2022 年，国内重大慢性病过早死亡率降幅达 17.8%，表明慢性病防治综合施策取得了显著成效。[4]

同时，“健康中国 2030”战略的实施也较好地满足了国内患者对优质、高效药品和医疗卫生服务不断增长的需求，并极大地促进了中国生物医药产业的快速发展。过去十年，中国逐步形成了生物医药产业的创新生态系统，创新药审评审批提速；国家医保药品目录（NRDL）每年更新，使更多创新药进入医保；国际和本土生物医药企业的研发投入和产出持续增加；海归科学家和专业人才数量不断增长；生物医药产业集群在多地蓬勃发展。

生物医药产业的创新成果也获得了显著提升。2018 年至 2023 年，有 147 种创新药在中国获批。[5, 6] 2015 年至 2019 年，中国的新药上市量占全球的 6%，仅次于美国和日本，位居世界第三，相比 2007 年至 2015 年的占比 2.5%有了大幅增长。[7]

因此，确保生物医药产业创新生态系统与中国医疗卫生服务体系的无缝衔接变得尤为重要，将产业创新成果及时应用于各级医疗机构的日常临床实践，最终使患者获益，挽救更多生命，改善患者生活质量。

此外，由于国民经济水平的提高、居民健康素养水平的提升以及人口结构变化带来的健康挑战，人民群众对优质、高效医疗卫生服务的需求也在持续增长。[8]中国现有的医疗体系主要是为满足全民基本医疗卫生服务需求而

建立的，在深入推进“健康中国 2030”战略的同时，中国可以考虑开始制定“十四五”之后的国家长期医疗卫生政策规划。

中国正处在向创新型经济转型的关键时期，让普通民众享受到科技创新的成果和红利至关重要。在健康领域，我们建议中国进一步打造鼓励创新的生态系统，并构建一条贯穿中国医疗体系的创新价值链。本报告评估了升级中国医疗体系将面临的挑战和机遇，对目前创新价值链上的关键节点和问题进行了分析，并提出了相应的建议。作为一家以“研发并提供创新药物，帮助患者战胜严重疾病”为使命的全球领先的生物制药公司，我们致力于为患者提供全球创新药物，用于治疗多种严重疾病。我们在中国的长期投资，也体现了我们根植中国的长久承诺。非常感谢中国发展研究基金会为我们提供了建言献策的机会，真诚期待与政府和行业专家开展深入沟通和交流。

二、中国创新医疗体系现状概述

1. 对高水平、创新医疗卫生服务的需求持续增长

2019 年，为了全方位干预影响健康的主要因素、保护重点人群、防控重大疾病，国务院发布《关于实施健康中国行动的意见》，[9]具体行动计划实施三年后已取得积极成效，极大提高了人民群众的健康意识和健康水平。例如，2019 年至 2022 年，中国居民健康素养水平从 19.2%提升至 27.8%，平均预期寿命从 77.3 岁提高至 77.93 岁。[10] [11]

与此同时，近年来中国医疗卫生领域也出现了新的变化和挑战，因此需要政府部门重点关注并采取新的应对策略。一方面，中国人口持续快速老龄化。到 2022 年底，中国 65 岁及以上人口将占总人口的 14.9%。[12] 这种人口结构的变化推升了慢性病发病率，增加了医疗系统的负担。随着中等收入群体的扩大和人民生活水平的提高，人们在医疗健康相关项目上的消费意愿和

能力也明显增强。2023 年，中国人均医疗保健支出达到 2460 元，比六年前增长 69.5%。[13] [14]在满足基本医疗卫生需求的基础上，中国人对高水平、创新医疗卫生服务的需求在持续增长。[15]

另一方面，影响中国人口健康的疾病谱也在持续变化。心脑血管疾病、癌症和慢性呼吸系统疾病是威胁人民健康的首要因素，许多其它慢性病也严重影响患者的生活质量。例如肥厚型心肌病（HCM）尽管是一种相对罕见的心血管疾病，通常由遗传因素引起，但对患者而言，需要应对劳力性呼吸困难、胸痛、心悸和晕厥等症状。在年轻人和运动员中，肥厚型心肌病是导致心脏性猝死 (SCD) 的主要原因。因此，对更多慢性病的预防和治疗，也需要得到政府的重视。[16]

在关注这些疾病的同时，还需要解决目前仍广泛存在的未被满足的医疗需求。例如，前文提及的肥厚型心肌病，目前对高风险肥厚型心肌病患者的治疗方式是创伤性的，并且只能控制症状，治标不治本。此外，患者常伴有一系列临床症状，需要选择最适合的药物或手术进行个体化治疗。[17]另一类疾病如自身免疫性疾病，虽然部分疾病已经有相对稳定的治疗方法，但患者仍在不断寻求疗效更好的创新解决方案。[18]例如，北京协和医学院 2023 年开展的一项研究表明，许多中重度银屑病患者会在接受生物制剂治疗 52 周后停止治疗，其中疗效不佳是最大的原因，其次是经济因素。[19]中国健康促进与教育协会最近开展的另一项研究也表明，中国只有 25% 的特应性皮炎患者对治疗效果满意。[20]

同样，许多罕见病也缺乏有效的治疗手段，主要原因是医学界对疾病缺乏足够的认识，而每种罕见病的患者人数很少（因此开发相应治疗方法的经济动力也不足）。[21]中国在 “健康中国 2030 ”战略中已明确提出要完善罕见病

的用药保障政策。[22]近年来罕见病新药的审批审批已加速，更有多款罕见病药物被纳入国家医保药品目录，但考虑到中国仍有 2,000 万罕见病患者，在这一领域还有很多患者需求未被满足。[23]

中国政府在提高人民健康水平、防控重大疾病方面付出的努力和取得的成就举世瞩目，中国医疗卫生体系的能力也获得了极大提升，我们将积极支持中国政府大力鼓励医疗创新，为患者提供高水平、创新医疗产品和服务的举措，这将有助于满足中国人民现有的和不断变化的健康需求。我们希望中国医疗卫生体系在满足人民群众基本医疗卫生服务需求的同时，继续加强治疗和管理重大、复杂疾病的能力，希望进一步打通患者获得创新疗法的快速通道。

2. 中国医药卫生体制改革在鼓励创新方面取得显著进展

鼓励创新一直是中国医药卫生体制改革的一项重要任务。2015 年，为提高监管效率，加快新药上市，中国政府启动了药品审评审批制度改革，加快创新药审评审批，旨在推动医药行业实现从仿制药主导型向创新驱动型增长模式的转变。2020 年，国家药品监督管理局发布了新修订的《药品注册管理办法》，规定了四种药品加快上市注册程序，即突破性治疗药物程序、附条件批准程序、优先审评审批程序和特别审批程序，进一步加快了新药上市注册速度。[24] 2023 年，国家药品监督管理局批准的创新药数量从 2020 年的 20 个增加到 40 个。[25] [26]国家药品监督管理局在 2024 年药品监管工作重点任务中，也提出要继续深化审评审批制度改革，积极支持医药研发创新，推动构建支持创新药械研发、生产、销售、临床应用良性循环的产业生态。[27]

为加快国外创新药在中国上市的进程，中国也在逐步建立与国际接轨的药品监管制度，例如提高药品注册过程中对境外临床试验数据的接受程度，

鼓励国内临床试验机构参与国际多中心临床试验（MRCT）。2017 年，国家药品监督管理局正式成为国际人用药品注册技术要求协调会（ICH）成员后，开始着力推动中国的药品注册技术要求与国际接轨。

这些改革举措促使跨国公司开始在中国和全球同步研发和注册新药，让国际创新药物更早进入中国市场，使中国患者受益。过去，新药在美国注册后进入中国市场需要七到八年时间，[28]目前这一差距已缩短至一至两年。[29]

为鼓励创新，国家医保局也建立了以新药为主体的医保准入和谈判机制，创新药进入医保的速度也明显加快，进一步提升了患者用药可及性。过去，新药在上市后五年左右才能进入医保，现在 80%以上的创新药能在上市后两年内纳入国家医保药品目录。[30]2023 年国家医保药品目录更新时，有 25 种新药参与谈判，其中 23 种成功被纳入医保目录。[31]

3. 打造创新价值链面临的主要挑战

中国已在加快创新药审评审批和进入国家医保目录两个方面取得显著进展，由于人口基数大、影响人口健康的因素持续变化等原因，中国医疗卫生体系仍面临诸多挑战，使得患者无法及时和充分获得最新医疗创新的成果。百时美施贵宝始终致力于将全球创新产品引入中国市场，我们将积极支持和配合中国政府，提升中国医疗卫生体系的创新水平和创新药物的可及性。我们在本章节列举了在现有医疗卫生体系中打造创新价值链面临的主要挑战，并将在下一章节提出相应建议。

3.1 “同类首创”和“同类最佳”新药的审评审批有待进一步加强，从而力争使中国成为全球新药首发上市的国家之一

过去十年，中国生物医药产业的创新能力不断增强，新药获批数量持续增加。中国可以在更多疾病领域继续发力，加强“同类首创”和“同类最佳”新

药的研发能力，成为全球新药首发上市的国家之一。2022 年，在国家药品监督管理局批准的 21 个创新药中，只有 3 个是“同类首创”新药。[32]值得关注的是，多数在研新药高度集中于少数几个疾病领域。例如，2021 年超过一半的化学药物新药临床申请（IND）属于抗肿瘤药物。[33]我们期待国家药品监督管理局能够继续鼓励“同类首创”和“同类最佳”新药的研发，以满足国内患者多样化的医疗需求。

中国目前有 2000 万罕见病患者，因此罕见病治疗领域也亟需突破性创新。关注罕见病药物的研发和供应有助于促进中国医药产业的创新，鼓励本土企业和跨国公司开展更多合作。百时美施贵宝正在加速实施公司的“中国 2030 战略”，加快引入全球领先的“同类首创”和“同类最佳”新药。在过去几年内，我们在中国市场上市了一系列创新药品，包括用于治疗多种中国高发瘤种的全球首个 PD-1 抑制剂欧狄沃 Opdivo（nivolumab），以及全球首创用于治疗 β-地中海贫血的红细胞成熟剂利布洛泽 Reblozyl®（luspatercept）。预计到 2030 年，百时美施贵宝将与全球 100%同步引进数十款全球创新产品，涵盖肿瘤学、免疫学、心血管及神经科学等领域。

细胞和基因治疗（CGT）是另一个值得关注的新药研发领域，目前还需要适当放宽政策限制，从而加强此类创新疗法的国际合作和国内患者可及性。以 CGT 为代表的精准医疗技术是医学攻克罕见病和肿瘤等重大疾病的前沿技术，CGT 也已成为全球医药研发领军企业竞争和未来医药行业创新的关键赛道。中国已经加大了对治疗肿瘤的细胞疗法 CAR-T 的政策支持力度，中国在这一领域的临床试验注册量已达到全球领先水平。[34]

如果中国可以考虑适当调整对外商投资 CGT 领域的政策限制，将极大地促进中国在该领域的技术进步。CGT 疗法的目的不是修改个人的遗传信

息，而是通过对特定疾病的治疗来恢复或改善患者健康。我们完全理解中国政府对患者和国家安全的重要考量，希望能够协助包括商务部、科技部、国家药品监督管理局和国家卫生健康委员会在内的监管部门，共同探讨适当放开外商投资 CGT 临床研究和产品研发限制政策的可行性。我们建议监管部门依据各类 CGT 技术的风险等级和风险控制能力，对《外商投资准入特别管理措施（负面清单）》中提到的“人体干细胞、基因诊断与治疗技术”进行细化和分类。不同风险等级的 CGT 产品，可以允许不同程度的外商投资。相信这些措施可以为中国患者带来更多创新药物，同时提升中国作为革命性药物创新中心的地位。

3.2 药品价格和医保支付标准形成机制有待进一步完善，从而鼓励“同类首创”和“同类最佳”新药进入国家医保目录

为应对高昂的药品价格和医院的过度医疗，2017 年中国全面取消了公立医院的药品加成政策，以促使药品价格回归合理水平。2018 年，国家医保局正式启动国家医保药品目录准入谈判，开辟了患者获得创新药物的新途径。据统计，通过卫生经济学评价方法，2023 年药品谈判的平均降价幅度约为 61.7%，预计未来两年将为患者减负超 400 亿元。[35]

目前国家医保谈判参考的是最低国际参考价(IRP)，从以往的谈判结果来看，谈判后的药品价格通常远低于最低国际参考价。而致力于研发突破性疗法的企业会更欢迎鼓励创新的价格形成机制。

根据德勤发布的报告《衡量 2022 年药物创新的回报》，开发一种新药的平均成本为 23 亿美元，比 2021 年增加了 2.98 亿美元，而每款新药的平均研发周期长达 6.74 年。[36]完全创新的新药（指从发现靶点开始的同类首创新药）进入到上市注册环节的最终成功率仅为 1.2%。[37]因此，虽然在短期内通过医

保谈判实现的大幅降价能减轻患者使用创新药的负担，但大幅降价也会使创新药企难以收回高昂的研发成本，影响其持续创新的能力。

一个鼓励创新的医疗体系应该能够激励有创新能力的企业加大投入研发“同类首创”和“同类最佳”新药，从而推动行业创新，促进临床和学术研究，造福患者。鉴于“同类首创”和“同类最佳”新药的研发成本高、成功率低，政府激励创新的政策应着重保护企业的知识产权，并允许企业在充分考虑药品对患者价值的基础上行使自主定价权。以美国为例，美国实行药品市场自由定价制度，因此成为全球最具创新力的生物医药企业首选的新药上市国家。2022年，美国市场创新药销售额达到药品总销售额的67%。包括来自中国的创新药在内，都会在美国首发上市，且单剂量瓶的价格远高于中国。去年11 月，3 款由中国药企研发的创新药在美国首发上市，其价格都远高于中国。[38]

3.3 创新药品“进院难”

尽管国家药品监督管理局新药审评审批提速后已有很多创新药获批上市，但患者的用药可及性仍有待提高。许多已纳入国家医保目录的创新药，仍存在“进院难”的问题，未纳入国家医保目录的创新药则面临更多困难。过去五年，全国 3300 家三甲医院中只有 10%的医院采购了国家医保目录中的创新药。[39] 2021 年，这一比例只有 5.4%。[40]此外，尽管国家鼓励医院采购罕见病药物，但罕见病药物进院依旧面临很多挑战。[41]

3.4 国家医保谈判药品“双通道”政策实施过程中的挑战

为解决创新药品“进院难”问题，2021 年中国政府出台了国家医保谈判药品“双通道”政策，患者在定点零售药店购买纳入“双通道”的谈判药品，可以享受与在定点医疗机构相同的报销政策。但进入国家医保目录的谈判药品不

会自动被纳入“双通道”管理药品范围。在某些地区，国家医保谈判药品进入“双通道”，企业需要与当地医保部门、医疗机构和零售药店进行大量沟通协调。“双通道”政策在很多地区落地时进展缓慢，主要原因包括医院的参与积极性不高，医保电子处方平台建设任务量大，以及药剂师不熟悉电子处方系统的操作方法。[42] [43]

3.5 现有医疗卫生服务体系的资源和能力有限

为提升基本医疗卫生服务的公平性和可及性，中国政府在过去十年以提升基层医疗服务能力为重点，逐步构建起较完善的分级诊疗制度。一个运行良好的多层次的医疗卫生服务体系可以确保不同地区的患者都能够获得优质的医疗服务，包括市场上最先进的医疗解决方案。

在基层医疗卫生服务能力持续提高的同时，很多基层医疗卫生机构仍面临经费紧张、药品供应不足和缺乏有经验的医务人员等困难。[44]截至 2022 年底，基层医务人员仅占全国总数的 31.6%，而医院医务人员占比为 60.7%。[45] 虽然政府提倡基层医疗卫生机构承担慢性病患者的健康管理工作，但基层医务人员的慢性病诊断和治疗能力仍有待提高，特别是偏远和农村地区。[46] 某些特定疾病多发于偏远地区，因此对患者的疾病管理构成了严峻挑战。例如，β-地中海贫血症患者多集中于广东和广西两省，许多是生活在偏远地区的少数民族。[47]这些地区往往缺乏训练有素的医务人员和高水平的医疗服务，因此加剧了医疗卫生服务不平等问题。

三、政策建议

百时美施贵宝非常赞赏并积极支持中国深化医药卫生体制改革和鼓励创新的重要举措，包括加快有临床价值的创新药上市，推进分级诊疗和推动公立医院高质量发展，促进多层次医疗保障体系发展，和提升先进医疗技术和

药物的可及性。中国正处在向创新型经济转型的关键时期，生物医药产业和医疗卫生服务体系的高质量发展将为中国打造世界领先的创新生态系统奠定坚实的基础。

作为一家致力于研发创新药物的全球领先的生物制药公司，百时美施贵宝全力支持中国创新型经济的发展。我们正在加快引入全球创新产品，提升患者用药可及性，也非常注重在中国的创新研发。我们坚信，中国鼓励创新的政策举措将为患者带来更多创新治疗选择。我们建议中国进一步打造鼓励创新的生态系统，并构建一条贯穿中国医疗体系的创新价值链，我们将从以下四个方面提出具体建议作为参考：

1. 优化药品价格形成机制和医保支付标准形成机制，进一步鼓励创新

创新药特别是“同类首创”和“同类最佳”新药的价格形成机制和医保支付标准，将对患者、生物医药行业和提供治疗服务的医疗卫生体系造成直接影响。

1.1 优化药品价格形成机制，充分听取行业建议

我们关注到中国已经开始在试点地区探索新的药品价格形成机制，逐渐与发达经济体，如经合组织（OECD）国家的价格接轨。近日国务院印发的《浦东新区综合改革试点实施方案（2023－2027 年）》中提到，允许生物医药新产品参照国际同类药品定价，以支持创新药和医疗器械产业发展。[48] 我们期待看到更具体的规则和措施落实这一政策。

我们建议国家监管部门与行业内企业开展充分沟通和讨论，听取行业建议，共同努力优化药品价格形成机制。完善以市场为主导的药品价格形成机制将有利于促进生物医药行业的健康发展和持续创新。

1.2 完善针对创新药的价值评估体系

结合国际经验和中国国情，制定更科学的成本-效果阈值（CET）规则，以适应各种不同的医疗需求。依据国际经验，多数国家会设定一个成本-效果阈值范围，并根据疾病严重性、未满足的需求、罕见性、社会获益和其它因素进行灵活调整。我们建议继续完善成本-效果阈值规则，明确成本-效果阈值调节因素，并对不同情景下的阈值调整保留一定灵活性。政府部门还可以结合国际经验和中国国情，针对罕见病以及其它特殊疾病领域，适当上调成本-效果阈值上限。

我们建议将全球“同类首创”和“同类最佳”新药纳入国家医保药品目录时，避免使用最低国际参考价（IRP），或进一步完善国际参考价的应用方式。如选择继续应用国际参考价，我们建议在充分考虑各国政策环境、市场竞争格局、产品生命周期、税收政策等因素的基础上合理应用国际参考价。

随着国家医保药品目录准入机制的不断完善，需要针对高值药品建立更为全面的创新价值评估体系。除了优化成本-效果阈值规则和国际参考价的应用方式，我们建议采用多维度的价值评估方式，除了药物的临床效果，还要充分考虑其对患者生活质量和医疗成本的影响，以及更广泛的社会效益。

2. 探索创新支付方式，引入商业医保等多方共同支付机制

过去三年，中国各地政府大力发展普惠型商业健康保险，健全多层次医疗保障体系，更好地满足了人民群众多层次、多样化的健康保障需求。据统计，截至 2023 年 11 月，各省、自治区、直辖市共推出 284 款城市定制型商业医疗保险（惠民保）产品。[49]对于一些没有被纳入医保的重疾领域药物，百时美施贵宝也在积极争取将其纳入个人商保或惠民保。截至2023年8月，我们的免疫肿瘤产品已经进入了 147 个城市的惠民保。[50]我们希望地方政府

在设计惠民保和其它商业健康保险产品时，能够考虑将治疗重大疾病的创新药纳入保障范围，让更多“同类首创”和“同类最佳”新药惠及患者。

引入商业医保等创新支付方式的多方共同支付机制，能够促进高值创新药的准入，有效提升患者用药可及性。例如，超过基本医保支付标准年费上限的部分，可以由商业医保和企业共同支付。商业保险公司和生物医药企业还可以联合开发定制型商业医保产品，以涵盖罕见病和特定地区或年龄人群的高发疾病。

3. 实现医保谈判与药品进院的“无缝对接”

我们建议采取措施确保创新药被纳入国家医保目录后，能够快速进入医院为患者所用。

3.1 推进自费药进院

尽管中国加快了创新药（包括很多“同类首创”和“同类最佳”新药）的审批速度，但未被纳入国家医保目录的创新药在进入医院时仍面临更多困难。由于医院渠道占据了中国 70%的处方药市场份额，[51]创新药品“进院难”也造成患者用药难。因此，我们建议可以考虑取消对医院采购自费药品的部分限制。

3.2 加快国家医保谈判药品的采购进度

已纳入国家医保目录的创新药，也存在“进院难”问题。一些省份和城市已出台政策，要求医院提高药事会频次，加快国家医保谈判药品的采购进度。例如，广东省卫健委近期发布《广东省医疗机构药品目录管理指南》，要求各医保定点医疗机构自新版国家医保药品目录正式公布后三个月内召开药事会，对协议期内国家医保谈判药品做到“应配尽配”。[52]2023 年 12 月，上海在发布当地基本医疗保险药品目录时，也要求全市定点医疗机构在《上海药品

目录》发布后 1 个月内，及时召开药事会议。[53] 我们建议在全国范围内推广类似政策，确保医疗机构根据最新国家医保目录调整药品采购目录，提高国家医保谈判药品的患者可及性。

我们建议适当调整和放宽对医疗机构使用国家医保谈判药品（包括罕见病药物）的考核指标，提高医疗机构采购相关药品的积极性。从长远来看，我们还建议被纳入国家医保目录的药品能够自动进入定点医疗机构的采购程序。

为加深医疗机构和医务人员对国家医保谈判药品的了解，公立医院负责药事的部门可以及时提供对相关药品报销政策的解读和说明，并就临床用药事项提供指导意见。

3.3 完善 “双通道” 政策

加快落实“双通道”政策需要同步推进医保电子处方平台的建设和管理。我们支持地方政府加快建设覆盖省级区域的统一电子处方流转平台，将更多医疗机构和零售药店接入电子处方流转系统，并为相关医务人员和药剂师提供培训。为了提高医疗机构的参与积极性，建议采取一些激励措施，如将电子处方的使用和流转纳入医院绩效考核。我们也建议将互联网医院作为推进“双通道”政策实施的一个重要渠道，允许病人凭借医疗机构出具的电子处方在网上购药。

4. 在中国多层次的医疗卫生服务体系中打造“上市后创新价值链”

打造“上市后创新价值链”是为了打通新药上市后直达患者的创新通道，覆盖了医疗卫生服务体系的诸多环节，包括临床医生和患者能够及时接触和了解创新疗法，患者所在地区的医疗机构具备提供治疗的医疗资源和医护人

员，以及患者能够持续接受治疗。

4.1 加强患者教育，帮助患者了解不同的治疗方案

近年来，政府积极支持个性化、精准化医疗技术的发展，大量未被满足的医疗需求也促使生物医药企业不断研发新药。但在新药上市后的很多环节，还需要进一步采取措施，最终使患者能够享受科技进步和医药创新的成果。我们建议政府继续加强对更多慢性病及其治疗手段的患者教育，各级各类临床学会和医疗机构可以发挥重要作用。随着影响中国人口健康的疾病谱的不断变化，政府也可以考虑将更多慢性病纳入国家慢性病综合防控体系。此外，我们还建议及时更新各种疾病的国家临床治疗指南，加快“同类首创”和“同类最佳”新药获批后的临床应用。

4.2 继续加强临床医生教育和培训，提升医疗服务水平

中国致力于建设优质高效的医疗卫生服务体系，通过完善分级诊疗制度，促进优质医疗资源均衡布局和扩容下沉，医疗卫生服务公平性和可及性明显提高，服务质量和效率持续改善。在此基础上，我们建议进一步加大对临床医生教育和培训的投入，使更多医生能够将国际最先进的创新疗法应用于患者临床治疗。当更多临床医生将“同类首创”和“同类最佳”新药应用于临床实践，就能拯救更多生命，改善更多患者的生活质量，因此这样的投入也将收获长期回报。例如，β-地中海贫血是一种需要进行长期输血治疗的疾病，目前很多三甲医院的医生还不了解最新的治疗方案能够修复患者自身造血功能，并减少因铁过载导致的脏器损伤和死亡风险。这种治疗新选择能够减轻输血依赖型 β-地贫患者的输血负担，为缓解血源紧张带来积极的社会意义。因此，我们相信帮助更多医生提升应用创新疗法的能力，将会极大改善众多患者的健康结果，有助于实现提高全民健康水平的最终目标。

四、结语

中国经济的快速发展极大改善了国民的经济水平和健康水平。与此同时，中国的医疗体系也面临人民群众不断变化和增长的医疗需求。收入增加、人口老龄化和慢性病发病率的提高也使人们对优质、创新医疗服务的需求与日俱增。

为了更好满足人民群众日益增长的健康需求，中国持续推进医疗卫生服务体系建设，并取得了非凡的成就。我们相信，通过完善药品价格形成机制，推动创新药加快进入医院和零售渠道，同时加大医疗人才培养力度，中国将进一步升级医疗创新生态系统。

百时美施贵宝始终致力于与中国政府共同努力，打造鼓励创新的生态系统，提升患者对创新药物的可及性。我们将坚定支持“健康中国 2030”战略和中国的医药卫生体制改革。我们期待与相关政府机构、专家和合作伙伴开展进一步探讨和交流。

参考文献

[1] 36 氪. 自免，真能成为中国第二大疾病市场吗？[EB/OL]. (2023-11-14)[2024-03-07]. https://36kr.com/p/2517376522785032
[2] 科学网. 专家：中国肥厚型心肌病明确诊断能力仍需提升 [EB/OL]. (2022-12-11)[2024-03-07].https://news.sciencenet.cn/htmlnews/2022/12/490969.shtm
[3] 国家药品监督管理局. 《药品注册管理办法》将进一步推动我国医药创新[EB/OL]. (2022-04-01)[2024-03-07]. https://www.nmpa.gov.cn/xxgk/zhcjd/zhcjdyp/20200401120001748.html?type=pc&m=
[4] 搜狐新闻. "健康中国"势在必行[EB/OL]. (2023-09-02)[2024-03-07]. https://news.sohu.com/a/717072672_550962
[5] 人民日报. 中国创新药发展提速[N]. (2023-04-18)[2024-03-07]. http://paper.people.com.cn/rmrbhwb/html/2023-04/18/content_25976279.htm
[6] 中国食品药品国际交流中心. 2023 年度药品审评报告显示：注册申请和审批量均创新高 全年共 40 个创新药获批上市[R]. (2024-03-01)[2024-03-07]. https://www.ccfdie.org/cn/yjxx/yphzp/webinfo/2024/03/1708466965756739.htm
[7] 中国医药创新促进会，中国外商投资企业协会药品研制和开发行业委员会（RDPAC）. 构建中国医药创新生态系统[R]. (2023-01)[2024-03-07]. https://cnadmin.rdpac.org/upload/upload_file/1614646546.pdf
[8] 澎湃新闻. 蓝皮书：老年人、孕产妇等群体的健康照护服务需求将不断增长[N]. (2023-04-15)[2024-03-07]. https://m.thepaper.cn/newsDetail_forward_22713999
[9] 中华人民共和国国务院. 国务院关于实施健康中国行动的意见[EB/OL].(2019-07-15)[2024-03-07]. https://www.gov.cn/zhengce/content/2019-07/15/content_5409492.htm
[10] 中华人民共和国国务院. 2022 年全国居民健康素养水平达到 27.78%[EB/OL].(2023-08-21)[2024-03-07]. https://www.gov.cn/lianbo/bumen/202308/content_6899405.htm#:~:text=2022%E5%B9%B4%E6%88%91%E5%9B%BD%E5%B1%85%E6%B0%91%E5%81%A5%E5%BA%B7,1.24%E5%92%8C1.76%E4%B8%AA%E7%99%BE%E5%88%86%E7%82%B9%E3%80%82
[11] 新华社. 我国人均预期寿命提高到 77.93 岁[N]. (2022-07-05)[2024-03-07].https://www.gov.cn/xinwen/2022-07/05/content_5699370.htm#:~:text=%E6%96%B0%E5%8D%8E%E7%A4%BE%E5%8C%97%E4%BA%AC7%E6%9C%88,%E5%8F%96%E5%BE%97%E6%98%8E%E6%98%BE%E9%98%B6%E6%AE%B5%E6%80%A7%E6%88%90%E6%95%88%E3%80%82
[12] 经济日报. 主动健康消费成趋势[N]. (2023-04-16)[2024-03-07]. http://paper.ce.cn/pc/content/202304/16/content_272602.html
[13] 国家统计局. 2023 年居民收入和消费支出情况[EB/OL]. (2024-01-17)[2024-03-07].https://www.stats.gov.cn/sj/zxfb/202401/t20240116_1946622.html
[14] 国务院. 2017 年居民收入和消费支出情况[EB/OL]. (2018-01-18)[2024-03-07].https://www.gov.cn/xinwen/2018-01/18/content_5257974.htm
[15] 36Kr. High End Medical Market Report. [N]. (2019-06-26)[2024-03-07]. https://36kr.com/p/1723891433473

36 氪. 高端医疗市场报告：229 万需求人群促使行业快速发展，近百个品牌角逐[N]. (2019-06-26)[2024-03-07].https://36kr.com/p/1723891433473
[16] Hong Y, Su WW, Li X. Risk factors of sudden cardiac death in hypertrophic cardiomyopathy. [J]. Current Opinion in Cardiology 2020, 15-21
[17] China International Exchange and Promotive Association for Medical and Health Care. 2023 Guideline for Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy [J]. Chinese Circulation Journal 2023, 38:1
[18] 搜狐新闻. 自身免疫性疾病患病率逐年增加，2025 年市场规模或将达 1522 亿美元！[N]. (2021-01-30)[2024-03-07].https://www.sohu.com/a/447639206_120060272
[19] Yu H, Heng G, Kun C. Disease burden and unmet medical needs in Chinese patients with moderate-to-severe psoriasis: a systematic review [J]. Chinese Journal of Dermatology 2023, 965-972
[20] 36 氪. 自免，真能成为中国第二大疾病市场吗？[N]. (2023-11-14)[2024-03-07].https://36kr.com/p/2517376522785032
[21] World Economic Forum. Rare diseases: how can we improve diagnosis and treatment? [EB/OL]. (2023-03-03)[2024-03-07]. https://www.weforum.org/agenda/2023/03/rare-diseases-changing-the-status-quo/
[22] 中华人民共和国国务院. “健康中国 2030”规划纲要[S].(2016-10-25)[2024-03-07]. https://www.gov.cn/zhengce/2016-10/25/content_5124174.htm
[23] 第一财经. 罕见病目录已公布两批，业界缘何还在倡议罕见病立法[N]. (2023-11-15)[2024-03-07].
https://m.yicai.com/news/101904455.html
[24] 国家药品监督管理局. 国家药监局关于实施《药品注册管理办法》有关事宜的公告[S]. (2020-03-31)[2024-03-07].
https://www.nmpa.gov.cn/yaopin/ypggtg/20200331145501259.html?type=pc&m=
[25] 国家药品监督管理局. 2023 年度药品审评报告[R].(2024-02-04)[2024-03-07].
https://www.cde.org.cn/main/news/viewInfoCommon/9506710a7471174ab169e98b0bbb9e23
[26] 国家药品监督管理局. 2020 年度药品审评报告[R].(2021-06-21)[2024-03-07].
https://www.cde.org.cn/main/news/viewInfoCommon/876bb5300cce2d3a5cf4f68c97c8a631
[27] 国家药品监督管理局. 2024 年全国药品监督管理工作会议召开[EB/OL]. (2024-01-10)[2024-03-07].
https://www.nmpa.gov.cn/yaowen/ypjgyw/hyxx/zhhyxx/20240110172910106.html
[28] 南方新闻网. 进击全球市场：中国生物医药企业面临创新考验[N]. (2021-06-16)[2024-03-07].
https://news.southcn.com/node_7e25f16d1c/583491e77a.shtml
[29] ibid.
[30] 人民日报. 医保谈判不是随意砍价[N]. (2024-01-09)[2024-03-07].
http://paper.people.com.cn/rmrb/html/2024-01/09/nw.D110000renmrb_20240109_2-05.htm
[31] 每日经济新闻. 6 成临床试验属重复研究，创新药研发也“内卷” 药企差异化开发迫在眉睫[N].(2021-05-08)[2022-02-22]. http://www.nbd.com.cn/articles/2021-05-08/1737554.html
[32] 国家药品监督管理局. 2022 年度药品审评报告[R]. (2023-09-06)[2024-03-07].
https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20230906163722146.html?type=pc&m=
[33] 人民日报. 肿瘤研究占据新药一半以上，专家：避免同质化竞争[N]. (2023-05-17)[2024-03-07].

https://m.peopledailyhealth.com/articleDetailShare?articleId=38c638a4b93b453183a349eb55d1f096
[34] 清华大学五道口金融学院，国家金融研究院. CAR-T 细胞疗法行业图谱[R]. (2023-05-25)[2024-03-07].
https://www.pbcsf.tsinghua.edu.cn/__local/9/29/C1/96B3FD4E82E57ADABE5676E0DC4_0EEC9FEC_339B72.pdf
[35] 中国科技网. 2023 年国家医保药品目录调整结果公布，新增 126 种药品[N]. (2023-12-12)[2024-03-07].
http://www.stdaily.com/index/kejixinwen/202312/bbc6becd290b4faf9727b8bea4faf416.shtml
[36] Deloitte. Seize the digital momentum - Measuring the return from pharmaceutical innovation [R]. (2023-01)[2024-03-07]. https://www.deloitte.com/global/en/Industries/life-sciences-health-care/analysis/measuring-the-return-from-pharmaceutical-innovation.html
[37] 中国医学科学院医学生物学研究所. 中国创新药悲歌？First in class 还未萌芽，“伪创新”却成严打对象…
[N]. (2021-07-08)[2024-03-07]. https://www.imbcams.ac.cn/tqzx/hyzx/qtzx/content_3362
[38] South China Morning Post. China’s new cancer drug Toripalimab is approved in the US but will cost 30 times more [N]. (2023-11-29)[2024-03-07].https://www.scmp.com/news/china/science/article/3243209/cocaine-price-hike-chinas-new-cancer-drug-approved-us-will-cost-30-times-more
[39] 全文发布：毕井泉关于全链条支持生物医药创新的六方面意见[EB/OL]. (2023-12-28)[2024-03-07]. https://mp.weixin.qq.com/s/TzEWB1zTguK57GIA4E0W-w
[40] ibid.
[41] 网易. 罕见病国谈药存在医疗机构配备进展较慢、地域覆盖水平较低和可负担水平较差的特点[N]. (2023-10-19)[2024-03-07].
https://www.163.com/dy/article/IHDHANA005509P4E.html
[42] 中国外商投资企业协会，药品研制和开发行业委员会（RDPAC）. 历年国家医保谈判药品落地情况分析报告 [R]. (2022-12)[2024-03-07].
https://cnadmin.rdpac.org/upload/upload_file/1678348940.pdf
[43] 新华社. 破解“因药就医”医保电子处方流转进展几何？[N]. (2023-07-29)[2024-03-07].
http://www.news.cn/politics/2023-07/29/c_1129775319.htm
[44] 第一财经. 基层医疗服务：乡村振兴的健康基石 [N]. (2023-11-02)[2024-03-07].
https://m.yicai.com/news/101893476.html
[45] 第一财经. 医生薪资改革下一步：基层如何留住医生？医生劳务价值如何体现？[N]. (2023-11-08)[2024-03-07]. https://m.yicai.com/news/101899678.html
[46] 新浪财经. 毕井泉：建设基层医疗卫生队伍 做好慢病全周期管理[N]. (2023-12-20)[2024-03-07].
https://finance.sina.cn/2023-12-20/detail-imzyqwnh2287526.d.html?vt=4&cid=76524&node_id=76524
[47] 中国医学会围产医学分会、中国医学会妇产科学分会产科学组. 关于孕产妇地中海贫血管理的专家共识[J]. 中国围产医学杂志, 2020 577-584.
[48] 中华人民共和国国务院. 浦东新区综合改革试点实施方案（2023－2027 年）[EB/OL]. (2024-01-22)[2024-03-07]. https://www.gov.cn/zhengce/202401/content_6927503.htm
[49] 中国证券网. 报告显示：我国惠民保产品数量已超 280 款[N]. (2023-12-17)[2024-03-07].

https://news.cnstock.com/news,bwkx-202312-5164949.htm
[50] 财新. 百时美施贵宝陈思渊：加速创新，与健康中国 2030 共振[N]. (2023-08-21)[2024-03-07]. https://weekly.caixin.com/2023-08-21/102094976.html
[51] 开源证券. 电子处方流转平台建设进程加快，处方有望加速外流 ——行业点评报告[R]. (2023-12-02)[2024-03-07].
https://pdf.dfcfw.com/pdf/H3_AP202312041613222918_1.pdf?1701681522000.pdf
[52] 21 世纪经济报道. 14 省份出台新规，创新药入院“最后一公里”加速贯通？[N]. (2024-01-22)[2024-03-07].
https://www.21jingji.com/article/20240122/herald/c534f05efbd102352aa3b36b0d296ae3.html
[53] 上海市医疗保障局. 上海市基本医疗保险、工伤保险和生育保险药品目录（2023 年）[S]. (2023-12-29)[2024-03-07].
https://ybj.sh.gov.cn/qtwj/20231229/f6a38afbfa1446338696d4e88a8861a3.html

Developing an innovation value chain throughout China's healthcare system towards the Healthy China 2030 aspiration

Bristol Myers Squibb

Executive Summary

Promoting Big Health is especially relevant as China advances to the final stage of the "Healthy China 2030" strategy.

BMS applauds China's remarkable achievements over the past decade in building an innovation ecosystem for its biopharmaceutical industry and establishing a health services system and a medical insurance system with near universal coverage in urban and rural areas.

As China pivots to an innovation-intensive economy, it is crucial that as many Chinese citizens as possible can benefit from the dividends of science. For healthcare, we believe it is critical for China to further develop a pro-innovation ecosystem and improve its innovation value chain throughout the country's healthcare system.

With a growing middle class, Chinese patients increasingly seek high-quality, innovative, effective, and highly personalized medical treatment. The concomitant trend of an aging population places further strain on the healthcare system as the prevalence of chronic diseases increases. At the same time, demand for more satisfactory treatments for diseases like hypertrophic cardiomyopathy (HCM) and autoimmune diseases remains unmet. [1] [2]

In addition, certain challenges continue to obstruct further development of a pro-innovation ecosystem. These include a need for accelerated reviews and approvals of "first-in-class" and "best-in-class" medicines and adjustments to NRDL negotiation practices for better reflection of medicinal value. Other challenges include delays in hospital admission of NRDL-listed medicines, difficulties for pharmaceutical companies under the "dual channel" retail scheme, and limited investment in physician education and training on the most advanced and innovative therapies once they are launched in China.

BMS believes that China will continue to make progress in expanding patient access to innovative treatments. We would like to contribute to this progress by sharing some suggestions for future action:

- **Optimize the mechanisms for price formation and medical insurance payments** by holding discussions with industry players, taking further steps towards the adoption of a value-based assessment framework for innovative medicines, and enhancing patients' ability to pay for innovative therapies via commercial medical insurance.
- **Streamline the hospital admission process for innovative medicines** by removing barriers to hospital procurement of out-of-pocket drugs and accelerating the admission of negotiated ones.
- **Reform implementation of the "dual channel" retail scheme** by ensuring local adherence to the central directive that retail pharmacies can distribute NRDL-negotiated drugs, removing additional steps for inclusion, permitting sales of some restricted drugs at specialized pharmacies, and optimizing the digital prescription system.
- **Build a post-market innovation value chain throughout China's multi-tiered medical services system** by strengthening investments in physician education and training on advanced and innovative therapies and increasing the number of physicians trained to help patients through innovative clinical solutions.

I. Introduction

In 2016, China released the "Healthy China 2030" Plan as a national blueprint to further develop the country's healthcare system to achieve the national goal of "Health for All." Since then, China has achieved remarkable success in establishing a health services system and a medical insurance system with near universal coverage in urban and rural areas. Great progress has been made in developing a regulatory system for biopharmaceuticals and medical devices in line with international standards.[3] The premature mortality rate of major chronic diseases decreased by 17.8% between 2015 and 2022, indicating the significant impact of measures taken to prevent and control major chronic diseases.[4]

At the same time, the implementation of the "Healthy China 2030" Plan has helped meet the enormous needs of Chinese patients for high-quality and more effective medicines and healthcare services, stimulating the rapid development of China's biopharmaceutical industry. In the past 10 years, China has gradually formed an innovation ecosystem for its biopharmaceutical industry. Key advancements include the accelerated process for new drugs to be launched and included in the National Reimbursement Drug List (NRDL), which is being updated on an annual basis, the increasing amount of research and development (R&D) investment and output from both domestic and international biopharmaceutical companies, the growing number of returning scientists and professionals to China, and the continued development of biopharmaceutical industry cluster parks.

As a result, 147 innovative drugs were approved between 2018 and 2023.[5] [6] China

accounted for 6% of all new drugs launched globally from 2015 to 2019, ranking third in the world after the U.S. and Japan. This was a significant increase from the period 2007 to 2015, when China accounted for only 2.5% of global new drug launches.[7]

The incorporations of the innovation ecosystem into China's healthcare system will be key to bring tangible benefits to patients that can change and/or save lives by having the timely adoption of innovative industry outputs into daily clinical practice and by medical institutions at different levels.

More importantly, Chinese citizens are seeking higher-quality and more effective healthcare services as a result of its increasing level of economic development, enhanced health literacy and the evolving health challenges facing the population.[8] China's existing healthcare system is mainly designed for meeting the basic healthcare needs of the entire population. It is now undergoing a transition to meet both basic needs and rising demand for more advanced and innovative medical solutions. The time is right for China to consider national healthcare policy planning and development beyond the 14th Five-Year Plan (FYP) when further advancing the "Healthy China 2030" Plan.

As China's pivots to an innovation-intensive economy, it is crucial that as many Chinese citizens as possible can benefit from the dividends of science. For healthcare, we believe it is critical for China to further develop a pro-innovation ecosystem and improve its innovation value chain throughout the country's healthcare system. This paper assesses the challenges and potential to elevate China's healthcare system and examines the blockages along the entire innovation value chain. We also developed a set of recommendations in accordance with the identified challenges. As a company that adopts a patients-centered and innovation-driven approach to healthcare, we are focused on delivering innovative treatments, including for a wide range of diseases, through a streamlined regulatory process. Our decades-long investment in China shows our long-term commitment to the country. We sincerely thank CDF for creating an excellent platform allowing us to contribute our perspective. We look forward to further discussions with the Chinese government on our ideas and recommendations.

II. Situational Analysis

1. Emerging needs for better and more innovative healthcare services

In 2019, China's State Council issued opinions on implementing the "Healthy China 2030" agenda with a focus on addressing key causes of China's health issues, protecting key groups prone to disease and preventing and controlling the spread of major diseases.[9] Actions taken in accordance with the opinions have yielded positive results in the past few years, with improved health awareness and outcomes amongst the population. From 2019 to 2022, Chinese citizens' health literacy

improved from 19.2% to 27.8% and their average life expectancy increased from 77.3 to 77.93 years of age. [10] [11]

While these are commendable achievements, recent years have seen the emergence of new trends and challenges in China's healthcare industry which require policymakers' continued attention and adoption of new strategies to ensure they are reflected in future policymaking. China's population continues to age rapidly, with people aged 65 and above comprising 14.9% of the population by the end of 2022.[12] This demographic change continues to raise the rates of chronic diseases in the country, increasing pressure on the healthcare system. Meanwhile, with a growing middle class and improving living standards, people's capacity and willingness to spend on healthcare-related items have markedly grown. In 2023, Chinese citizens spent RMB 2,460 per capita on healthcare, an increase of 69.5% compared to six years ago.[13] [14] The population is looking beyond their basic medical needs and increasingly seeking high-quality innovative medical solutions and services that are highly personalized and effective.[15]

Another trend concerns the wide spectrum of diseases that need to be addressed within the country. While chronic disease categories including cardiovascular and cerebrovascular diseases, cancer and chronic respiratory diseases pose the most significant health threats to the Chinese population, many other chronic diseases also seriously affect patients' well-being and quality of life, which also warrants policymakers' attention. Hypertrophic cardiomyopathy (HCM), for example, is a less common chronic disease often caused by genetic factors. Patients diagnosed with HCM can suffer from exertional dyspnea, chest pain, palpitations, and syncope. HCM is also a leading cause of sudden cardiac death (SCD) among younger people and athletes.[16]

With growing attention to these existing diseases, significant unmet medical needs in China will need to be addressed. For example, current treatments for high-risk HCM patients can be invasive, which only focus on symptom control instead of addressing the underlying pathophysiology. In addition, patients with HCM present with a range of clinical symptoms, and treatment should be personalized involving the selection of appropriate medications or surgical methods. [17] Autoimmune diseases are another example – although some autoimmune diseases can be better managed than diseases like HCM, patients continue to look for more effective and innovative medical solutions.[18] According to a study carried out by the Peking Union Medical College in 2023, among Chinese patients affected by moderate to severe psoriasis, discontinuing biological therapies was common after 52 weeks of receiving treatment of biologics, with the lack of efficacy being the largest reason, followed by economic factors.[19] Another recent study carried out by the China Association of Health Promotion and Health Education suggested that only 25% of atopic dermatitis patients in the country considered their treatments satisfactory.[20]

Similarly, there is a continuing lack of treatment options for many rare diseases due to insufficient knowledge of the diseases by the medical community and limited numbers of patients for each rare disease type (hence low monetary incentives to develop corresponding treatments).[21] Under the "Healthy China 2030" strategy, the Chinese government aims to enhance the provision of rare disease drugs.[22] Although policymakers have accelerated the review and inclusion of rare diseases in the NRDL, more work is needed to support the 20 million people in China affected by rare diseases.[23]

We commend the Chinese government's efforts towards improving the population's health and controlling the spread of key diseases. While the capacity of the current healthcare system has been greatly strengthened, we appreciate the government's continued work to encourage the development and delivery of innovative medical treatments and effective medical products and services. These efforts will help address both the population's existing and evolving medical needs. BMS hopes that the country's healthcare system will strive to take care of the basic health needs of the population while improving the management of more complex diseases. We hope for patients to have more rapid access to more innovative treatments.

2. Notable progress on accelerating innovation as part of China's healthcare reform

Fostering innovation has been a major focus of China's ongoing healthcare reform. These efforts accelerated in 2015 when a new drug review and approval system was initiated to improve regulatory efficiency and reduce lags in launching new drugs. The government established accelerated drug approvals for breakthrough therapies and innovative medicines, aiming to shift the growth model of the pharmaceutical industry from generics-led to innovation-driven. In 2020, the National Medical Product Administration (NMPA) announced new the *Drug Registration Regulation*, outlining four expedited procedures for drug approval, including Breakthrough Therapy, Conditional Approval, Priority Review, and Special Approval, further accelerating the market approval of novel medicines.[24] In 2023, the NMPA approved 40 innovative drug applications), up from 20 in 2020.[25] [26] The calls to deepen drug review and approval reform were highlighted in NMPA's 2024 work plan, in a bid to support pharmaceutical research and development, and innovation and promote an industrial ecology that embraces the full lifecycle of a medicine.[27]

Efforts have been made to increase alignment with international standards to promote quicker entry of international innovative medicines into the Chinese market. This includes increasing acceptance of overseas clinical trial data during drug registration and promoting China's participation in multi-regional clinical trials (MRCT). In 2017, China joined ICH, further committing to international alignment in pharmaceutical technical standards and guidelines.

These developments have enhanced the ability of multinational companies to

synchronize research and development and registration of key products in China and overseas. They have facilitated the earlier entry of international innovative medicines in the Chinese market which benefits patients. In the past, it took seven or eight years for a new drug already registered in the U.S. to enter the Chinese market.[28] Now, the delay has been reduced to between one and two years.[29]

Innovative medicines are now brought to the Chinese market more quickly. Chinese regulators have allowed for their more rapid inclusion in the NRDL. That means faster patient access. The time taken for new medicines to be included in the NRDL has been greatly reduced with an average of 80% of new medicines now listed in the NRDL within two years of marketing approval.[30] In the past, it took around five years for innovative drugs to be included in NDRL. In 2023, NRDL negotiations featured 25 innovative medicines, with 23 successfully entering the list.[31]

3. Remaining challenges in the Innovation Value Chain

China has made tremendous achievements in improving its healthcare system and accelerating innovative drug approvals. However, given the country's large population and the evolving health difficulties facing them, the government recognizes that challenges remain in China's healthcare system that limit the potential of the progress that has been made so far, and continues to roll out policies to allow Chinese patients to fully benefit from healthcare innovation. We have been dedicated to bringing the most innovative medical solutions to the market and would like to work with the government to strengthen efforts towards increasing innovation and efficiency of the current healthcare system. Based on our experience in the Chinese markets, we would like to highlight the following challenges in China's healthcare system and will discuss our suggestions in the following section.

3.1 Further promoting the accelerated review and approval for "first-in-class" and "best-in-class" innovative drugs to make China a leading new drug first-launch country

China's pharmaceutical industry has become increasingly innovative over the past decade, with a significant increase in approvals for innovative medicines. However, more efforts are needed to accelerate the development of "first-in-class" and "best-in-class" medicines in additional disease areas and build China into a leading market where the world's most advanced drugs are first launched. In 2022, of the 21 innovative drugs that were approved by the NMPA, only three were first-in-class medicines.[32] It is worth noting that the development of many new drugs has been highly focused on a small number of disease areas and mechanisms. For example, over half of the INDs of chemical drugs were cancer drugs in 2021.[33] We hope the NMPA will continue to encourage innovation around first-in-class and best-in-class medicines that are tailored to the different medical needs of Chinese patients.

Rare diseases are an important area where breakthroughs should be sought, given the enormous potential benefits to the country's 20 million rare disease patients. A

focus on developing and providing rare disease drugs would foster innovation in China's pharmaceutical industry and encourage more collaboration between Chinese companies and multinationals. BMS seeks to contribute to this effort through the launch and implementation of our 2030 China strategy, which aims to accelerate the introduction of world-leading first-in-class and best-in-class medicines into the Chinese market. In the past, these have included Opdivo (nivolumab), the first PD-1 Inhibitor globally to have demonstrated superior survival benefit, and Reblozyl® (luspatercept) for treating beta thalassemia. We will continue these efforts as we pursue our goal of simultaneously launching dozens of innovative therapies in China and in other global markets by 2030. These products will cover a wide range of disease areas, including oncology, immunology, cardiovascular, and neuroscience.

Another key development area worth noting is cell and gene therapies (CGT), which need more accommodating rules to enhance patient accessibility and strengthen international cooperation for innovative medicines. These precision therapeutics are at the forefront of medical advancements for treating rare and critical diseases like cancer. CGT is a critical track for global research-based flagship developers and the pharmaceutical innovation of the future. We are happy to see that, with growing policy support for CAR T, a cell therapy for cancer, China has now become a global leading player in this field in terms of clinic trial registrations.[34]

This massive progress could be further accelerated if China could consider adjusting the CGT investment restrictions for foreign participation. The focus of CGT is primarily directed at the treatment of specific diseases and seeks to restore or improve the patient's state of health rather than to modify an individual's genetic information. We fully appreciate the government's major concerns over patient and national security and we welcome multi-party regulators (including the Ministry of Commerce (MOFCOM), the Ministry of Science and Technology (MOST), the National Medical Products Administration (NMPA), and the National Health Commission (NHC)) to explore possibilities for foreign investment in CGT clinical research and product development that aim to protect people's health. We hope that the government will refine and categorize the content of "human stem cell, gene diagnosis, and treatment technology development and application" in the *Negative List* for foreign investment by referring to the degree of risk control capacity of such advanced CGT treatment. Different risk levels of CGT products allow variable foreign capital participation levels. We believe that these steps could increase the availability of innovative medicines for Chinese consumers and strengthen China as an innovation hub for revolutionizing medicines.

3.2 Improve pricing and payment model that rewards for "first-in-class" and "best-in-class" drugs in the Basic Medical Insurance negotiation mechanism

In an effort to rationalize drug spending due to high drug prices and overuse at the

hospital level, the National Healthcare Security Administration (NHSA) announced a new pricing plan, shifting from a cost-plus approach to a value-based pricing mechanism. In 2018, the NHSA launched national price negotiations to forge new pathways to innovative medicines. Leveraging health economic tools, these negotiations secured an average price reduction for drug purchases of around 61.7% in 2023. This is expected to reduce the burden on patients by over RMB 40 billion over the next two years.[35]

According to the 2022 report 'Measuring the Return from Pharmaceutical Innovation' released by Deloitte, the average cost to develop a new drug is USD 2.3 billion (an increase of USD 298 million from 2021) and the average research and development period is 6.74 years.[36] The final success rate of fully innovative new drug development (first-in-class drugs, starting with target discovery) is only 1.2%.[37] As a result, significant price reductions achieved through negotiations have made innovative medicines more affordable in the short term but heavily cut-down prices may make it difficult for innovative drug companies to recoup high research and development costs.

A pro-innovation healthcare system tends to incentivize the most capable businesses to invest in R&D for "first-in-class" and "best-in-class" pharmaceuticals. A healthy and supportive system propels industry innovation, advances clinical and academic research, and benefits patients. Given the high research and development costs and low success rates of "first-in-class" and "best-in-class" drugs, incentive policies should be designed in a way that protects the intellectual property rights of the businesses and grants them the autonomy to independently determine pricing with full consideration of the drug's value to patients. As a preferred launch site with market-driven drug pricing mechanism for the world's most innovative biopharmaceutical companies, innovative drug sales accounted for 67% of total drug sales in the U.S. market in 2022. As a result, innovative drugs, including those from China, were first launched in the U.S. with a much higher single-dose vial cost than in China. Another two Chinese-made cancer drugs also saw similar price bumps in the U.S. market in the same month.[38]

Therefore, a pricing mechanism that rewards innovative medicines is highly appreciated by companies with breakthrough therapies. The BMI negotiation involves significant price cuts based on the lowest international reference prices (IRP) where the NRDL negotiated price generally falls significantly lower than the lowest IRP, as seen from past negotiation results.

3.3 Delays in the hospital admission process

Although more innovative drugs have been approved by the NMPA and at a faster pace, this does not necessarily translate to their greater accessibility to patients. Several factors limit hospitals' adoption of drugs added to the NRDL, and the challenge is even greater for drugs not yet included in the list. In the past five years, only 10% of the 3,300 tier-3 hospitals across China have procured innovative drugs

listed in the NRDL.[39] In 2021, this figure was only 5.4% of innovative drugs.[40] Meanwhile, hospital inclusion of rare disease medicines continues to run into challenges, despite the government encouraging hospitals to procure these drugs.[41]

3.4 Challenges in participating in the "dual channel" scheme

To address the issues associated with new drug inclusion at hospitals, the Chinese government introduced the "dual channel" policy in 2021, allowing patients that are prescribed innovative drugs at hospitals to purchase and reimburse them at designated pharmacies. Inclusion in the NRDL does not automatically lead to a drug's inclusion in the dual channel scheme. In some regions, if a pharmaceutical company wishes to include a drug in the scheme, considerable efforts need to be made to communicate and coordinate with the local government department, medical institutions, and pharmacies. Rollout of the dual channel policy has also seen slow progress in many regions due to the lack of incentives for hospitals to participate in the scheme, the low adoption and fragmentation of the digital prescription transfer platforms, and pharmacists' unfamiliarity with the digital prescription system. [42] [43]

3.5 Limited resources and capabilities of the current medical service system

To promote more equitable access to medical care, the Chinese government has piloted and implemented a series of initiatives over the past decade to establish a three-tiered diagnosis and treatment system, with a focus on capacity-building at primary level medical intuitions. A well-functioning tiered medical care system can ensure that patients across different localities have access to quality healthcare, including the most advanced medical solutions available in the market.

Although these efforts have greatly strengthened China's primary healthcare, the country's primary medical institutions remain underfunded and continue to be challenged by a limited supply of drugs and a shortage of skilled health workers.[44] At the end of 2022, medical staff at the primary level only accounted for 31.6% of the national total while 60.7% were employed at hospitals. [45] Though the government encourages chronic diseases to be managed at the primary level, primary medical professionals' capabilities for treating chronic diseases need to be strengthened, especially for those in remote and rural areas. [46] Consequently, diseases affecting patients concentrated in these areas pose particularly grave challenges. Beta thalassemia, for example, mostly affects patients in Guangdong and Guangxi provinces, many of whom are also members of ethnic minorities living in remote areas. [47] The lack of quality medical care and well-trained medical workers in these regions exacerbates the issue of health inequality in these areas.

III. Policy Recommendations

BMS applauds China's healthcare system reform and its focus on promoting innovation, improving efficiency to reduce lags in launching new drugs, and encouraging high-quality development of a multi-tiered medical services system to

enhance public access to cutting-edge therapies and medications. China is now transforming itself into an innovation-oriented economy. It has built a solid foundation to develop a world-leading innovation ecosystem throughout its biopharmaceutical industry and healthcare system.

As a multinational biopharmaceutical company specializing in the R&D of innovative medicines, we are making every effort to support the development of the Chinese market, accelerate the introduction of innovative medicines, improve patient accessibility, and cultivate research and development. We firmly believe that China's efforts will make it easier for patients to access innovative treatment solutions. We would like to highlight four areas with our perspectives on how China could further develop a pro-innovation value chain to optimize the overall healthcare ecosystem:

1. Adjust the pricing and medical insurance payment mechanism to encourage innovation

The price formation and medical insurance payment mechanism for innovative drugs, especially for first-in-class and best-in-class therapies in the market, has a direct impact on patients, the biopharmaceutical industry, and the healthcare system that delivers treatments.

1.1 Optimize the drug pricing mechanism with more input from industry.

We are pleased to see that China has enabled pilot regions to promote a pricing mechanism that integrates and aligns with global pricing levels of developed economies, such as the OECD regions. The State Council directed Shanghai Pudong to allow new biomedical products to be priced with reference to international drugs of the same kind to support the development of the innovative drug and medical device industries.[48] We look forward to more explicit rules and measures to implement this policy on the ground.

We suggest national regulators have joint discussions with biopharma industry players to bring in the voices of drug developers as part of efforts to optimize the drug pricing mechanism. A more market-oriented pricing mechanism and regulations will encourage healthy development and continuous innovation in the industry.

1.2 Move toward a value-based assessment framework for innovative medicines

Given global experiences in the cost-effectiveness threshold (CET) framework-setting and China's national conditions, a more scientific CET measurement is needed to enhance adaptation to various medical needs. In terms of international practices, most countries set a CET range and adjust according to the severity of the disease, unmet need, disease rarity, social benefit, and other factors. We believe that it would be beneficial if steps were taken to refine China's CET adjustment rules, clarify the determinants of CET adjustment, and retain flexibility under different

scenarios. The government could also appropriately increase the upper limit of CET for rare diseases and other special therapeutic areas based on global examples and domestic conditions.

A waiver or a revised IRP mechanism should be implemented for globally marketed "first-in-class" and "best-in-class" drugs when introduced into the NRDL list. If IRP use for pricing comparison is maintained, we advise only applying it after careful consideration of the policy environment, market competition landscape, product life cycles, and tax policies of different countries.

With continuing improvement in the NRDL access mechanism, an assessment framework capturing a holistic value for innovation will better support the pricing of high-value medicines. In addition to an optimized CET estimation and IRP pricing, China could fully consider multi-dimensional value assessment, which includes not only the clinical benefits of a drug, but also its broader impact on patient quality of life, healthcare costs, and societal benefits.

2. Encourage commercial medical insurance and other innovative approaches to cover payment for innovative drugs

China has made notable progress in expanding local inclusive commercial insurance over the past three years, in an effort to construct a multi-tiered medical insurance system to better meet public medical needs. According to a recent report, as of November 2023, a total of 284 city-level affordable commercial medical insurance products (Huiminbao) have been launched in provinces and cities across the country.[49] We are actively collaborating with local Huiminbao and individual commercial insurance providers to include BMS products for critical illnesses. As of August 2023, our immuno-oncology treatments have been available in 147 Huiminbao products at the city level.[50] We welcome local governments to design the customized scope with innovative drugs in the Huiminbao scheme and other commercial insurance products and enhance patient access to more best-in-class or first-in-class medications.

Other innovative commercial medical insurance approaches that incorporate multi-party payments could also provide joint financial support for innovative drugs and thus tangible access for patients to these therapies. In particular, the cost for innovative drugs that exceed the annual cost caps in the BMI fund could be covered by commercial medical insurance or shared by commercial medical insurance and pharmaceutical companies. There could also be opportunities for insurers and biopharma companies to jointly develop tailor-made insurance products that cover rare diseases and diseases with a higher prevalence in specific regions and age groups.

3. Build a "seamless connection" between medical insurance negotiations and hospital admissions

We believe further measures could be taken to ensure that innovative drugs, once included in the NRDL, could enter hospitals more quickly and become accessible for patients.

3.1 Facilitate inclusion of out-of-pocket drugs in hospitals

While the government has accelerated the approval of innovative drugs (including many first-in-class and best-in-class medicines), drugs that are not included in the NRDL still face significant hurdles to inclusion in hospital supply lists. As China's hospitals contribute to 70% of the provision of prescription drugs in the country, the difficulty for these innovative drugs effectively means lack of accessibility to patients.[51] Therefore, mechanisms need to be explored to remove barriers for hospitals to procure out-of-pocket drugs.

3.2 Accelerate inclusion of negotiated drugs in hospitals

For negotiated drugs, measures also need to be taken to accelerate their inclusion in hospitals. Some regions and cities have already initiated measures to increase the frequency of drug affairs meetings at hospitals to allow for a more rapid rollout of negotiated innovative drugs. For example, the Guangdong Provincial Health Commission recently published a *Guide on Drug Catalogue Management of Medical Institutions in Guangdong Province*, which stipulates that designated medical insurance-covered medical institutions should convene drug affairs meetings within three months after the publication of the latest edition of the NRDL and make every effort to procure the needed negotiated drugs.[52] In December 2023, the Shanghai municipal government also released its local basic medical insurance catalogue notice, which requires designated medical institutions to host drug affairs meetings within one month after the publication of the *Shanghai Drug Catalogue*.[53] We recommend that similar policies be adopted nationally to ensure that hospitals adjust their drug catalogues based on the latest NRDL, and thereby enable patients to benefit from the addition of innovative drugs to the list.

Rigid performance targets for hospitals' cost controls involving negotiated drugs (including rare disease drugs previously set by the NHC) should also be adjusted and loosened to reduce concerns over missing targets as a result of procuring these drugs. In the long run, we would also recommend mandatory national implementation and access of NRDL approved medicines in hospitals.

To increase awareness of negotiated new drugs among hospitals and medical staff, the drug affairs departments of public hospitals need to provide timely interpretation of policies regarding negotiated drugs and guidance on the clinical use of these therapies.

3.3 Improve the "dual channel" policy

The NHSA and NHC released the dual channel policy in 2021 to improve patient access to innovative drugs listed in the NRDL by allowing both hospitals and pharmacies to dispense selected negotiated drugs. In accordance with the central government policy guidance, local governments need to accelerate the

implementation of the policy. For certain medicines that pharmacies are not permitted to sell according to existing regulations (e.g., peptide hormones), the government should consider adjusting the rules and make exceptions for designated pharmacies' sales of these drugs in order to increase patient accessibility.

The dual channel policy can also be strengthened by improving the digital prescription transfer platform system. Regional governments accelerate the development of unified and well-functioning regional digital prescription platforms. More medical institutions and retail pharmacies should be enrolled in the scheme with relevant medical staff and pharmacists provided with relevant training. Incentives should be increased for hospitals to participate in the scheme, such as incorporating such participation in hospitals' performance reviews. Internet hospitals are another important channel to consider for inclusion in the scheme to allow patients to purchase drugs online with digital descriptions issued by hospitals.

4. Develop the "post-market innovation value chain" throughout China's multi-tiered medical service system

The "post-market innovation value chain" covers physician and patient awareness of innovative treatment, patient access to medical institutions with resources and physicians that can provide proper treatments and prescribe appropriate therapies, and the ability of patients to continue their prescribed treatments.

4.1 Enhance patient education about different treatment options

Policymakers have been promoting personalized and targeted healthcare in recent years with pharmaceutical companies continuing to develop new drugs to address unmet medical needs in the market. However, more steps need to be taken in the post-marketing processes for drugs to ensure that patients can fully benefit from these scientific and medical advances. The government could increase patient education for a wider range of chronic diseases and available treatment options. Medical associations and institutions can play an important role in this process. With the evolving spectrum of diseases in China, the government could consider including the management of more chronic diseases in its policy framework. At the same time, we would recommend that national clinical practice guidelines be updated in a timely manner to include the newly approved "first-in-class" and "best-in-class" drugs.

4.2 Continue to enhance education and training of physicians to improve healthcare capabilities

With persistent progress towards improving its healthcare capabilities and resolve disparities in access to quality healthcare between provinces and between rural and urban regions, China is making strides to enable all citizens easy access to high-quality medical resources. Building upon existing efforts, we would suggest increasing investments in physician education and training on the most advanced and innovative therapies once they are introduced in China. Greater chances of

saving or improving lives, as well as a longer-term return on investment, could be realized when more physicians use first-in-class and best-in-class medicines in clinical practice. For diseases such as beta thalassemia that require long-term disease management, many physicians in class-three hospitals are still not aware of the new treatment option that could repair patients' own hematopoietic function and reduce the risk of organ damage and death caused by iron overload. This new treatment would benefit more patients with beta thalassemia and help reduce blood supply pressures in many cities. We believe that increasing the number of physicians capable of helping patients through innovative clinical solutions will lead to significantly improved health outcomes and help China achieve its goal of fostering a healthier population.

IV. Conclusions

China's rapid development has delivered significant improvements to the prosperity and wellbeing of its citizens. As a result of these profound changes, China's healthcare system is experiencing an evolving mix of needs and expectations. Rising incomes have increased demand for quality and innovation in medical treatments, while an aging population is accompanied by the growing prevalence of chronic diseases.

China has made admirable progress in cultivating a healthcare system that fosters and applies innovation to keep pace with the changing needs of its population. BMS has full confidence in China's capacity to advance its innovation ecosystem through further improvements to its pricing, procurement, retail, and talent training systems. BMS shares China's ambitions for expanding patient access to innovative treatment. We are committed to supporting the Healthy China 2030 strategy and China's healthcare reform efforts. We stand ready to discuss our recommendations with relevant government agencies in more detail.

References

[1] 36Kr. Can autoimmune diseases really become the second largest disease market in China? [EB/OL]. (2023-11-14)[2024-03-07]. https://36kr.com/p/2517376522785032

[2] ScienceNet. Expert: China's ability to diagnose hypertrophic cardiomyopathy still needs improvement [EB/OL]. (2022-12-11)[2024-03-07]. https://news.sciencenet.cn/htmlnews/2022/12/490969.shtm

[3] National Medical Products Administration. Policy interpretation on the effect of the Measures for the Administration of Drug Registration on pharmaceutical innovation [EB/OL]. (2022-04-01)[2024-03-07]. https://www.nmpa.gov.cn/xxgk/zhcjd/zhcjdyp/20200401120001748.html?type=pc&m=

[4] Sohu News. “Healthy China” is indispensable [EB/OL]. (2023-09-02)[2024-03-07]. https://news.sohu.com/a/717072672_550962

[5] People's Daily. China accelerates the development of innovative drugs [N]. (2023-04-18)[2024-03-07]. http://paper.people.com.cn/rmrbhwb/html/2023-04/18/content_25976279.htm

[6] China Center for Food and Drug International Exchange. Notice on the implementation of the 2023 Drug Review Report [S]. (2024-03-01)[2024-03-07]. https://www.ccfdie.org/cn/yjxx/yphzp/webinfo/2024/03/1708466965756739.htm

[7] R&D-based Pharmaceutical Association Committee. Building China’s Pharmaceutical Innovation Ecosystem. [R]. (2023-01)[2024-03-07]. https://cnadmin.rdpac.org/upload/upload_file/1614646546.pdf

[8] The Paper. Demand for health care services for the elderly, pregnant women and other groups will continue to grow according to Blue Book [N]. (2023-04-15)[2024-03-07]. https://m.thepaper.cn/newsDetail_forward_22713999

[9] State Council of the PRC. Opinions on promoting the “Healthy China” Action” [S].(2019-07-15)[2024-03-07]. https://www.gov.cn/zhengce/content/2019-07/15/content_5409492.htm

[10] State Council of the PRC. Monitoring the health literacy of Chinese residents in 2022 [EB/OL].(2023-08-21)[2024-03-07]. https://www.gov.cn/lianbo/bumen/202308/content_6899405.htm#:~:text=2022%E5%B9%B4%E6%88%91%E5%9B%BD%E5%B1%85%E6%B0%91%E5%81%A5%E5%BA%B7,1.24%E5%92%8C1.76%E4%B8%AA%E7%99%BE%E5%88%86%E7%82%B9%E3%80%82

[11] The Xinhua News Agency. My country's average life expectancy has increased to 77.93 years [N]. (2022-07-05)[2024-03-07]. https://www.gov.cn/xinwen/2022-07/05/content_5699370.htm#:~:text=%E6%96%B0%E5%8D%8E%E7%A4%BE%E5%8C%97%E4%BA%AC7%E6%9C%88,%E5%8F%96%E5%BE%97%E6%98%8E%E6%98%BE%E9%98%B6%E6%AE%B5%E6%80%A7%E6%88%90%E6%95%88%E3%80%82

[12] China Economic Net. Active healthy consumption becomes a trend [N]. (2023-04-16)[2024-03-07]. http://paper.ce.cn/pc/content/202304/16/content_272602.html

[13] National Bureau of Statistics. Households' Income and Consumption Expenditure in 2023. [M]. (2024-01-17) [2024-03-07]. https://www.stats.gov.cn/sj/zxfb/202401/t20240116_1946622.html

[14] State Council. Households' Income and Consumption Expenditure in 2017. [EB/OL]. (2018-01-18) [2024-03-07] https://www.gov.cn/xinwen/2018-01/18/content_5257974.htm

[15] 36Kr. High End Medical Market Report. [N]. (2019-06-26)[2024-03-07]. https://36kr.com/p/1723891433473

[16] Hong Y, Su WW, Li X. Risk factors of sudden cardiac death in hypertrophic cardiomyopathy. [J]. Current Opinion in Cardiology 2020, 15-21
[17] China International Exchange and Promotive Association for Medical and Health Care. 2023 Guideline for Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy [J]. Chinese Circulation Journal 2023, 38:1
[18] Sohu News. The market size for autoimmune treatments may reach US$152.2 billion in 2025 amidst increasing prevalence of autoimmune diseases. [N]. (2021-01-30)[2024-03-07]. https://www.sohu.com/a/447639206_120060272
[19] Yu H, Heng G, Kun C. Disease burden and unmet medical needs in Chinese patients with moderate-to-severe psoriasis: a systematic review [J]. Chinese Journal of Dermatology 2023, 965-972
[20] 36Kr. Can auto-immune diseases really become China's second largest disease market? [N]. (2023-11-14)[2024-03-07]. https://36kr.com/p/2517376522785032
[21] World Economic Forum. Rare diseases: how can we improve diagnosis and treatment? [EB/OL]. (2023-03-03)[2024-03-07]. https://www.weforum.org/agenda/2023/03/rare-diseases-changing-the-status-quo/
[22]State Council of the PRC. Outline of the "Healthy China 2030" Plan [S].(2016-10-25)[2024-03-07]. https://www.gov.cn/zhengce/2016-10/25/content_5124174.htm
[23] Yicai News. Two batches of rare disease catalogs have been published. Why is the industry still advocating for rare disease legislation? [N]. (2023-11-15)[2024-03-07]. https://m.yicai.com/news/101904455.html
[24] National Medical Products Administration. Announcement on the adjustment of drug registration information [S]. (2020-03-31)[2024-03-07]. https://www.nmpa.gov.cn/yaopin/ypggtg/20200331145501259.html?type=pc&m=
[25] National Medical Products Administration. 2023 Annual Drug Review Report [R].(2024-02-04)[2024-03-07]. https://www.cde.org.cn/main/news/viewInfoCommon/9506710a7471174ab169e98b0bbb9e23
[26] National Medical Products Administration. 2020 Annual Drug Review Report [EB/OL].(2021-06-21)[2024-03-07]. https://www.cde.org.cn/main/news/viewInfoCommon/876bb5300cce2d3a5cf4f68c97c8a631
[27] National Medical Products Administration. Announcement on the 2024 National Drug Supervision and Administration Work Conference [EB/OL]. (2024-01-10)[2024-03-07]. https://www.nmpa.gov.cn/yaowen/ypjgyw/hyxx/zhhyxx/20240110172910106.html
[28] Southern News Network. Entering the global market: Chinese biopharmaceutical companies face the test of innovation [N]. (2021-06-16)[2024-03-07]. https://news.southcn.com/node_7e25f16d1c/583491e77a.shtml
[29] ibid.
[30] People's Daily. Negotiating medical insurance is not about haggling [N]. (2024-01-09)[2024-03-07]. http://paper.people.com.cn/rmrb/html/2024-01/09/nw.D110000renmrb_20240109_2-05.htm
[31] The Xinhua News Agency. Analyzing the new version of the National Medical Insurance Drug Catalog [N]. (2023-12-13)[2024-03-07]. http://www.news.cn/politics/2023-12/13/c_1130025807.htm
[32] National Medical Products Administration. 2022 Annual Drug Review Report [R]. (2023-09-06)[2024-03-07]. https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20230906163722146.html?type=pc&m=

[33] People's Daily Health. Cancer research accounts for more than half of new drugs, according to experts [N]. (2023-05-17)[2024-03-07]. https://m.peopledailyhealth.com/articleDetailShare?articleId=38c638a4b93b453183a349eb55d1f096
[34] Tsinghua University PBC School of Finance. CAR-T cell therapy industry map [R]. (2023-05-25)[2024-03-07]. https://www.pbcsf.tsinghua.edu.cn/__local/9/29/C1/96B3FD4E82E57ADABE5676E0DC4_0EEC9FEC_339B72.pdf
[35] Science and Technology Daily. 126 new drugs added to the 2023 National Medical Insurance Drug Catalog. [N]. (2023-12-12)[2024-03-07]. http://www.stdaily.com/index/kejixinwen/202312/bbc6becd290b4faf9727b8bea4faf416.shtml
[36] Deloitte. Seize the digital momentum - Measuring the return from pharmaceutical innovation [R]. (2023-01)[2024-03-07]. https://www.deloitte.com/global/en/Industries/life-sciences-health-care/analysis/measuring-the-return-from-pharmaceutical-innovation.html
[37] Institute of Medical Biology, Chinese Academy of Medical Sciences. First in class has not yet emerged, but "pseudo-innovation" has become the target of severe crackdowns [N]. (2021-07-08)[2024-03-07]. https://www.imbcams.ac.cn/tqzx/hyzx/qtzx/content_3362
[38] South China Morning Post. China's new cancer drug Toripalimab is approved in the US but will cost 30 times more [N]. (2023-11-29)[2024-03-07].https://www.scmp.com/news/china/science/article/3243209/cocaine-price-hike-chinas-new-cancer-drug-approved-us-will-cost-30-times-more
[39] BioShanghai. Full Article Release: Bi Jingquan's Six Sections of Opinions on Full-Chain Support for Biomedical Innovation [EB/OL].(2023-12-28)[2024-03-07]. https://mp.weixin.qq.com/s/TzEWB1zTguK57GIA4E0W-w
[40] ibid.
[41] NetEase. Domestic drugs for rare diseases have the characteristics of slow progress in medical institution deployment, low level of geographical coverage, and poor affordability. [N]. (2023-10-19)[2024-03-07]. https://www.163.com/dy/article/IHDHANA005509P4E.html
[42] China Association of Enterprises with Foreign Investment, R&D-based Pharmaceutical Association Committee (RDPAC). Implementation analysis report of drugs negotiated by national medical insurance. [R]. (2022-12)[2024-03-07]. https://cnadmin.rdpac.org/upload/upload_file/1678348940.pdf
[43] The Xinhua News Agency. China strengthens the supervision of medical advertisements. [N]. (2023-07-29)[2024-03-07]. http://www.news.cn/politics/2023-07/29/c_1129775319.htm
[44] Yicai News. Primary medical services are an indicator of rural revitalization success. [N]. (2023-11-02)[2024-03-07]. https://m.yicai.com/news/101893476.html
[45] Yicai News. The next step in doctor salary reform: How to retain doctors at the grassroots level? [N]. (2023-11-08)[2024-03-07]. https://m.yicai.com/news/101899678.html
[46] Sina Finance. Build grassroots medical and health teams to do full-cycle management of chronic diseases. [N]. (2023-12-20)[2024-03-07]. https://finance.sina.cn/2023-12-20/detail-imzyqwnh2287526.d.html?vt=4&cid=76524&node_id=76524
[47] Perinatal Medicine Branch of the Chinese Medical Association, Obstetrics Group of the Obstetrics and Gynecology Branch of the Chinese Medical Association. Expert consensus on the management of thalassemia during pregnancy [J]. Chinese Journal of Perinatology, 2020 577-584.

[48] State Council of the PRC. Pudong New Area Comprehensive Reform Pilot Implementation Plan (2023-2027) [EB/OL]. (2024-01-22)[2024-03-07]. https://www.gov.cn/zhengce/202401/content_6927503.htm
[49] China Stock Network. China Commercial Medical Insurance products exceeds 280. [N]. (2023-12-17)[2024-03-07]. https://news.cnstock.com/news,bwkx-202312-5164949.htm
[50] Caixin Weekly. BMS China GM calls for accelerating innovation and resonating with "Healthy China 2023". [N]. (2023-08-21)[2024-03-07]. https://weekly.caixin.com/2023-08-21/102094976.html
[51] Kaiyuan Securities. Electronic prescription circulation platform development is underway, the outflow of prescriptions is expected to accelerate. [R]. (2023-12-02)[2024-03-07]. https://pdf.dfcfw.com/pdf/H3_AP202312041613222918_1.pdf?1701681522000.pdf
[52] 21st Century Business Herald. 14 provinces have introduced new regulations to speed up the "last mile" of innovative drug registration. [N]. (2024-01-22)[2024-03-07]. https://www.21jingji.com/article/20240122/herald/c534f05efbd102352aa3b36b0d296ae3.html
[53] Shanghai Municipal Health Commission. Notice on the Issuance of the “Shanghai Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2023)". [S]. (2023-12-29)[2024-03-07]. https://ybj.sh.gov.cn/qtwj/20231229/f6a38afbfa1446338696d4e88a8861a3.html