促进合理用药，提升医疗体系效率，建设健康中国

诺华集团

摘要

诺华非常荣幸参加 2016 年中国发展高层论坛(CDF)，并就具体领域建言献策。在中国积极推动“十三五规划”制定工作、谱写 2016－2020 年中国经济社会发展宏伟蓝图的背景下，此次论坛的召开意义非凡。诺华非常荣幸就深化中国医药卫生体制改革、建设健康中国的议题，分享有关提高医疗卫生服务体系效率、更好满足患者需求的国际经验和教训，我们认为这也切合了十三五规划的重点工作之一。

随着中国深化医药卫生体制改革的推进，改革成果也在逐步显现，如医疗卫生服务可及性、服务质量、服务效率和群众满意度显著提高，人均预期寿命有所增长。中国正在全面实施“健康中国 2020”战略，贯彻落实全面建设小康社会的国家规划蓝图。然而中国社会如今正面临着人口老龄化加剧，慢性病高发的严峻形势，在此形势下，建立完善合理用药体系，提高医疗资源合理配置显得尤为重要。

诺华基于对中国现行药物政策及其面临挑战的观察，将就以下四个领域分享经验并建言献策，与中国合力推进合理用药。

1. 建立以循证医学为基础的药物使用政策

科学系统地收集分析流行病学研究调查数据和临床证据有助于更好理解病患的疾病负担和实际需求，以及各种治疗手段的效果，从而建立合理高效的药物政策体系。

诺华建议政府鼓励科研机构，如中国医学科学院肿瘤医院(CICAMS)等针对四种重点慢性病（高血压、糖尿病、癌症和心脑血管疾病）开展全国性的流行病学调查研究，并实时更新疾病数据库用以深入了解病患疾病负担。对

药物临床数据的系统分析也有助于制定临床诊疗规范，为评估疗效和优化诊疗路径提供明确依据。加深对中国疾病现状的了解，重视对现有治疗手段的成本效益分析，将有助于推进药物的合理使用，全面提高医疗卫生服务体系的效率。

2. 鼓励引进和使用成本效益较高的创新药物

创新疗法的研发和普及可有效预防、控制、治疗慢性疾病，最终降低慢性疾病的医疗负担。诺华非常赞赏中国政府出台一系列政策加快创新药品的审评审批，并为临床急需的创新药物开辟快速审评审批通道。

诺华建议中国政府尽快落实近期出台的有关快速审批实施方案，以确保治疗肿瘤等高发慢性疾病的创新药物能通过快速审评审批通道尽早引进中国。同时，及时将这些药物纳入医保目录并根据其临床效益定期调整报销额度，将极大地鼓励更多创新药物的引进以满足中国患者的需求。此外，创新药物的定价机制应遵循市场形成的原则，并着重考虑药物价值和预期的健康产出。

3. 建立以患者为中心的服模式，提升疾病管理能力

在各级医疗机构之间建立以患者为中心的医疗服务模式，提升疾病管理能力，能够有力促进合理用药政策体系的建设。

诺华建议加强疾病诊断和药品处方之后的过程管理，通过减少住院次数、缩短住院时间，改善病人体验并降低医疗费用。合理用药体系建设应与优化慢病管理模式相结合，诺华建议在三级医疗服务体系内的各级医疗机构之间（上至三甲医院，下至社区卫生服务中心）建立目标明确、权责清晰的分工协作机制，这将大大提升基层医疗机构的服务水平。鼓励通过公私合作模式（PPP）开展医生培训和患者教育项目，建立现代医院管理制度，这些措施将有效增加对慢病治疗的资金支持，提高健康产出，从长远来看最终将降低医疗费用。

4. 加强对仿制药的质量监管，保障药品安全与有效性

质量合格的仿制药是确保慢性病得到安全有效治疗的重要基石。因此，诺华非常赞赏中国最近发布的一系列征求意见稿，通过开展质量一致性评价逐渐缩小仿制药与原研药之间的质量差别，我们也很支持国家食品药品监督

管理总局（CFDA）作为仿制药质量一致性评价的监管方以确保患者的用药安全。

诺华建议 CFDA 尽快出台落实仿制药质量一致性评价的实施细则。此外，在药品招标过程中通过质量分层奖励优质仿制药，依据国际公认和有科学依据的标准进行分组。

一、简介

2016 年是中国“十三五规划”的开局之年，今年举办的中国发展高层论坛重要性不言而喻。诺华很荣幸被再次邀请参会并就相关领域建言献策。

“十三五规划”的一项重要内容是制定落实“健康中国 2020”战略。这是卫生领域以提高人民群众健康为目标，贯彻落实全面建设小康社会新要求、实现包容性发展的国家战略。这一战略也与诺华的使命，即“以创新的方式改善和延长人类生命”不谋而合。我们热切希望与政府部门合作，为建设健康中国建言献力。

由于中国政府几十年来坚持不懈的努力和与医疗产业的合作，中国医疗卫生事业的发展取得了瞩目成就。尤其在“十二五”期间，医疗卫生服务可及性、服务质量、服务效率和群众满意度显著提高，全国居民健康水平总体上达到中高收入国家水平。中国人均预期寿命到 2015 年预计将比 2010 年提高 1 岁（比 1990 年提高 6 岁[1]）；婴儿死亡率由 2008 年的 14.9‰下降到 2014 年的 8.9‰；居民个人卫生支出占卫生总费用比重自 2010 年以来下降了 3 个百分点[2]。

然而中国社会和决策层也正面临着人口老龄化加剧和慢性病高发的严峻形势。2013-2023 年间，中国 65 岁以上老龄人口预计将增长 12.4%达到 1.816 亿人[3]。40 岁及以上慢性病患病人数至 2030 年将增长两倍甚至三倍，其中糖尿病的发病率将位居首位，肺癌发病率将增长五倍[4]。此外糖尿病和心血管疾病导致的慢性心力衰竭等其它并发症，会产生“隐形”费用从而加重疾病负担。为了减轻沉重的疾病负担和由此造成的经济负担，中国政府从 2008 年起开始逐步加强慢性病防控管理工作。2012 年国家卫生和计划生育委员会（NHFPC）与其它 14 个部门联合发布了《中国慢性病防治工作规划（2012-2015 年）》。这是中国首个慢性病防治计划，明确了慢性病防治的重点领域，并提出在中国 30%的癌症高发区开展早期筛查和治疗。同时中国政府还颁布了《中国烟草控制规划》、《预防接种工作规范》、《全民健康

1 http://press.thelancet.com/ChinaGBDChinese.pdf
2 http://www.npc.gov.cn/npc/xinwen/2015-12/22/content_1955662.htm
3 6th National Census Data
4 http://www.worldbank.org/content/dam/Worldbank/document/NCD_report_en.pdf

生活方式行动实施方案》。国务院办公厅最近印发了《关于推进分级诊疗制度建设的指导意见》，明确规定以高血压、糖尿病、肿瘤、心脑血管疾病等四种慢性病为突破口，开展分级诊疗试点工作。在现有政策基础上，十三五规划提出了医疗卫生领域的六个重点发展方向，包括深化医药卫生体制改革，加强传染病、慢性病、地方病等重大疾病综合防治，积极开展应对人口老龄化行动等。

为了实现全医疗卫生体系慢性病防治目标，全面提高居民健康水平，诺华建议通过促进合理用药来优化疾病管理模式。合理用药是通过最大限度地发挥药物的疗效以改善健康结果，提高患者生活质量，提升整个医疗卫生服务体系的效率，从而减轻国家医疗负担。

本报告将对中国药物政策体系的现状加以阐述，并为制定健康中国战略规划建言献策。

二、中国药物政策体系的现状及主要挑战

十三五规划将慢性病防治列为重点方向之一，本章节将根据中国药物政策体系的现状，列出可能影响慢病防控和患者健康结果的主要挑战。

这些主要挑战包括：1.缺乏流行病学调查数据和实时患者诊疗信息；2.患者所需的创新药物利用不足；3.现行疾病管理体系仍有不足；4.安全高质量仿制药使用不足。

2.1 缺乏流行病学调查数据和实时患者诊疗信息

20 世纪中期中国政府开始把慢性病管理的重点从治疗向防控转移，从而大幅提升了国家慢性病防控工作的成效。进一步提高整个医疗卫生系统的资源利用率和整体效率，关键是对临床数据、药品疗效和患者依从性的系统分析。

但是目前中国依然缺乏系统地收集和分析流行病学调查数据及患者诊疗信息的机制，这直接关系到能否对国家疾病的流行情况做出准确评估，同时在循证的基础上制定清晰的指导意见有效配置医疗资源。缺乏充分、可靠的流行病学及临床数据就很难对疾病控制结果做出清楚与可信的评估。

但即便以现有的数据来看，中国的疾病控制结果仍然不尽如人意。在其它国家依据对上述信息的系统整理和分析，制定了规范化的诊疗指南，同时也为提高不同医疗方案的效率提供了有用的信息。例如根据这些临床数据，我们了解到德国的高血压控制率为 85%，加拿大是 66%，美国是 51.8%，而中国 2011 年的数据显示只有 9.3%[5]。

2.2 患者所需的创新药物利用不足

中国的慢性病发病率及死亡率正不断上升，与全球其他市场相比，创新药物在中国的可及性仍然有限。很多创新药物还未在中国上市。据相关统计，2008 年及以后全球研发成功的新药，截至 2013 年只有 20%在中国上市[6]。

造成创新药物利用不足的原因有很多，较突出的一个原因是药品注册上市时间过长，目前从有待审批的药品注册申请数量来看，就意味着中国药品注册上市相比全球普遍滞后平均 5 年时间，可能会间接导致很多患者出现并发症甚至死亡。2012 年慢性病患者死亡率占全国死亡率的 86.6%，远超 68%的全球平均数据[7]。

另一个原因则是药品招标采购流程过于繁琐复杂，进一步延误了创新药品的上市。2009 年后国家医保目录一直没有更新，加上招标过程中唯低价是取的做法都使得中国的病患无法及时获得创新的治疗药物。

2.3 现行疾病管理体系仍有不足

中国医疗卫生费用占国内生产总值的比重从 1995 年的 3.5%增长到 2013 年的 5.6%，但是相对于全球其它经济合作与发展组织国家(OECD)来说这一数据仍然很低[8]。随着人口老龄化和城镇化建设的发展，以及慢性非传染性疾病发病率的升高，居民对医疗卫生服务的需求也在不断增加，此时更需要持续的公共财政投入和社会投资来开发高质量的创新药物以满足医疗需求。

目前公共医疗领域面临的一个主要挑战是接受过慢性病防治培训的专业医疗服务人员严重短缺，既影响了疾病防控的效率，又造成了医疗资源的浪

5 Prevalence, Awareness, Treatment, and Control of Hypertension in China; APR 2014. Hypertension. 2009, 53: 450-451
6 Lichtenberg, 2013, NBER Working Paper No. 18235
7 WHO. “Global Health Observatory (GHO) Data”: http://www.who.int/gho/ncd/mortality_morbidity/en/
8 World Bank. “Health expenditure, total (% of GDP) Data”: http://data.worldbank.org/indicator/sh.xpd.totl.zs

费。其次，只有少数机构能够为病情趋于稳定的患者提供高质量的医疗、护理和康复服务。这些机构和其它国家的同类机构相比，更倾向于超额接收病人并延长他们的住院时间。

此外，现行医疗卫生体系主要是按医疗项目收费和报销医保费用的，因此也鼓励了开大处方、多用药和增加辅助治疗的行为。2008 年国家卫生计生委成立了合理用药专家委员会，开始致力于解决不合理用药的问题，重点是抗生素的使用。虽然慢性病治疗中的不合理用药已经造成了巨大的资源浪费，但尚未得到足够的重视。

2.4 高质量仿制药使用不足

目前在中国市场销售的仿制药质量参差不齐，部分质量较差的仿制药对患者构成了安全隐患。政府主管部门已经意识到必须采取措施全面提升仿制药的质量。CFDA 已经开始建立相关制度开展仿制药质量一致性评价工作，对已获批在中国上市的仿制药进行质量检验。

但是由于质量一致性评价的办法无法提供足够的保障，患者仍不能确定所用仿制药的实际质量。例如，要求企业仅通过自检进行溶出曲线试验，评价体系就会因为潜在的利益冲突存在一定风险。

三、政策建议

作为医药卫生体制改革的重要举措，“健康中国 2020”战略，旨在未来五年内全面提高人民健康水平。为了实现这一目标和应对上述提及的挑战，诺华建议以循证医学证据为基础推动和完善合理用药政策体系建设，实现医疗资源的有效配置，提高治疗效果。

我们的具体建议主要包括：1.建立以循证医学为基础的药物使用政策；2.鼓励引进和使用成本效益较高的创新药物；3.建立以患者为中心的服模式，提升疾病管理能力；4.加强对仿制药的质量监管，保障药品安全与有效性

3.1 建立以循证医学为基础的药物使用政策

全面、准确的患者诊疗信息是制定合理用药政策的基石。真实可信的数据能够帮助决策者全面了解疾病流行的现状，从而制定相应政策以满足患者的实际需求，同时提高整个医疗卫生服务体系的效率。

3.1.1 针对重点慢性病开展全国性的流行病学调查

我们建议中国开展更多流行病学调查，重点弥补现有的数据缺口。搜集和整理流行病学数据可以了解特定疾病或健康状况在不同人群的出现频率及其决定因素。这些科学证据可以为整个医疗卫生产业链的各个环节提供决策依据，包括投资医药研发、确定重点医疗卫生服务指标制定临床诊疗指南。

最近国家癌症中心发布了中国的癌症流行病学数据。该研究在 2011 年评估了中国所有癌症的 5 年癌症患病率，数据来源于我国 177 个肿瘤登记点，是首次对中国的癌症患病率进行系统的分析和评估。

诺华非常支持这样的研究，我们建议政府鼓励肿瘤领域（如中国医学科学院肿瘤医院、北京肿瘤医院和上海交通大学肿瘤研究所）及其它慢性病领域的科研机构针对四种重点慢性病（高血压、糖尿病、癌症和心脑血管疾病）开展更多全国性的流行病学研究，更新疾病数据库以更好地了解病患及其家属的疾病负担。同时国际和国内制药企业也可以为这些研究提供相应支持。

以研究得到的数据为基础，政府、医疗机构（从三甲医院到社区卫生服务中心），保险公司和产业（药企和 IT 供应商）可以联合组织专家资源群策群力，在十三五期间合作研发“国家疾病图谱-大数据库”项目。对这些数据的研究分析将为推动国家慢病防控体系建设，提高国民健康水平提供关键信息。国外就有类似的项目，例如欧洲创新药物计划(IMI)中的“应用大数据获得更佳健康结果”(Big Data for Better Outcomes)项目 [9]，其目标是在保障可持续发展的前提下，将欧洲各国医疗卫生系统的发展重点转变为以健康结果与价值为导向。

3.1.2 系统收集分析临床数据

建立科学体系收集整理临床数据为更好地理解疾病负担奠定了基础。这些数据包括医院用药情况和药物的临床效果，疾病治疗结果包括住院率、生活质量和死亡率。广泛和深入地收集关于现有治疗方案结果的相关信息，并对其经济效益进行评估，能够帮助中国制定更相应的药物政策创造更大效益。

9 https://ec.europa.eu/digital-agenda/events/cf/big-data-value-ppp-lighthouse-projects-in-h2020/item-display.cfm?id=17867

政府部门还可以制定相关政策法规，并提供财政经费来支持临床数据登记信息系统的建设。制药行业也可以与医疗学术团体合作为数据登记提供有力支持。

欧洲已经建立了一系列信息登记系统，包括人口登记系统，特定疾病（比如癌症，糖尿病，心血管疾病）或按疗效付费医保项目的登记系统。通过分享真实数据和最佳诊疗实践，并重点关注健康结果和价值，这些系统提供了有助于疾病管理的工具。例如，瑞典的在线急性冠脉疾病登记系统[10]-SWEDEHEART （瑞典的一个网络系统，根据循证医学证据评估、加强和改善心脏疾病的诊疗）报告称过去几年来，因急性冠脉综合征和接受冠脉或血管植入而住院的每个患者的治疗结果，为心内科专家优化临床治疗提供了至关重要的数据支持。

3.1.3 及时更新和规范临床诊疗指南

规范的临床诊疗指南是建立合理有效药物政策体系的关键。制定指南的依据是“对临床数据的系统回顾和对不同诊疗方案的利弊分析”，其目的是“使患者得到最优化的治疗”。[11]指南的制定主要依靠“科学数据、临床经验、对患者实际价值的判断和选择”。[12]因此制定全面的临床指南需要获得充分的流行病学和临床数据。

及时更新和规范临床诊疗指南能够为健康结果评估和优化治疗手段提供明确依据。例如，欧洲肿瘤医学会(ESMO) 就根据药物的循证医学发现制定了针对不同肿瘤（包括结肠癌、胰腺癌、乳腺癌、内分泌肿瘤、肉瘤等）的指南。这些指南对欧盟国家的健康干预措施产生了重要影响。另一个例子是美国心脏协会(AHA)[13]，为提升病患的治疗效果，该协会根据研究数据，就心脑血管疾病的诊疗防控发布了一系列的临床诊疗标准。同时，AHA 也致力于提升医疗服务人员的业务能力教育、引导病人更好地遵从医嘱以配合治疗。为

10 http://eurheartj.oxfordjournals.org/content/ehj/30/18/2165.full.pdf
11 Graham, R. et al (ed). 2011. “Clinical Practice Guidelines We Can Trust”. Institute of Medicine: http://www.ncbi.nlm.nih.gov/books/nbk209546/
12 Ibid.
13 http://www.heart.org/HEARTORG/HealthcareResearch/Healthcare-Research_UCM_001093_SubHomePage.jsp

了鼓励医院遵循这些诊疗标准，AHA 还开发了一款集信息登记、瞬时基准测试和诊疗手段监测为一体的病患管理网上应用程序。

基于这些国际经验，诺华建议政府根据流行病学和临床数据来制定诊疗标准，并根据批准上市的慢性病新药来不断更新修订这些标准。为促进医疗服务人员遵守诊疗指南，建议将这些指南的传播与相关的培训课程相结合，以确保医疗服务人员，特别是基层医疗服务人员，能够获悉最新的创新药物及疗法。

我们非常赞赏中华医学会在这一方面进行的探索和努力。我们也将一如既往地支持中华医学会的工作，分享我们的临床数据，并合作开展培训项目。

3.2 鼓励引进并使用成本效益较高的创新药物

创新疗法的研发和普及可有效预防、控制并治疗慢性疾病。以肿瘤、心血管疾病为例，创新疗法可提高患者的生存率、减少住院次数、缩短住院时间，进而能够从整体上降低医疗体系的负担。因此，诺华建议中国政府考虑采取有效措施，以确保中国医疗体系能够受益于全球在相关领域的创新实践。对创新疗法的及时获取可降低治疗慢性疾病的整体成本负担并提升患者的生活质量。

3.2.1 加快审批推进创新药物的市场准入

诺华高度赞赏中国政府就推进药品审评审批制度改革推出的系列举措，但目前的药品审批周期与国际水平相比仍然较长。简化审评流程将加快药品审批和国际药品的研发速度，从而使中国患者更快地获益于创新药。

建议中国采取与美国食品药品管理局类似的审批方式[14]来促进创新药的发展，即在中国开展国际临床试验、尽快落实快速审批机制以加快重大疾病治疗创新药的上市。通过数据分析我们发现，这样的实践尤其能使病情较为严重的的患者和多发慢性疾病患者受益。特别对于肿瘤患者而言，及时获取创新药物能使他们很快获得更好的治疗结果。目前，肿瘤是导致中国患者死亡的主要原因，而中国患者可用的创新药却极为有限。

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14 US FDA Guideline on Expedited Programs for serious conditions, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf

3.2.2 以临床证据为基础，定期更新国家医保目录、调整医保报销水平

为了进一步提高创新药物的可及性，诺华建议应及时将创新药列入医保目录，并把高价值的创新药列入地方重大疾病医保报销体系。自 2009 年实施以来，中国的基本药物制度和报销模式已大大提升了创新药物的可及性。但是，中国政府仍需采取定期更新医保目录等措施。诺华认为，治疗慢性疾病的创新药物在获得国家食品药品监督管理局审批通过后，应尽快列入省级医保目录，这样一方面可以保证中国患者能更及时地得到经济有效的创新疗法，另一方面也可以鼓励企业更有针对性地研发用于治疗常见慢性病的优质创新药物。

临床数据分析（参见 3.1.2）可为有关医保方案的政策制定提供支持，包括何种药物应列入国家医保目录、其合理的报销额度等。基于对同类药物进行成本效益的对比，政策制定者可相应地调整药品报销比例。此外，诺华建议中国在制定创新药物的定价标准时充分考虑药品本身为医疗系统创造的价值，其为患者带来的预期健康产出，并遵循自由市场的定价原则。对创新药物成本-价值的研究能够为定价提供事实依据。

诺华非常愿意支持中央和地方政府建立清晰而透明的机制，以加快药品定价和报销政策的制定与出台。加强与国际制药企业，诸如国际医疗评估学会（HTAi）[15]和 HTAsiaLink[16]等国际机构的合作，有助于中国政府借鉴相关的国际经验、并结合本国实际制定更加有效、合理的政策。

3.2.3 鼓励国内外创新主体合作共赢

诺华等很多跨国制药企业目前已经在中国设立了研发和生产基地。为了能使这些资源更好地服务于中国的医疗服务系统，诺华建议将跨国制药企业的研发优势进一步融入到中国的医改进程中。而成功的融合需要对内外资企业提供平等的待遇，比如在中国设有大型研发团队的跨国制药企业的产品应享有与国内企业同等的权力，能够被纳入医保目录。

CFDA 已经发布了一系列加快高质创新药审评审批的政策，通过实行药品上市许可持有人制度，以研发为核心的公司可以在中国加快产品的上市。

15 http://www.htai.org/
16 http://www.htasialink.org/

诺华认为试点上市许可持有人制度是一个非常积极的尝试。为进一步提升中国药品的研发能力，不光是药品生产企业，该制度还允许药品研发机构和科研人员取得药品批准文号。我们支持 CFDA 继续出台类似的政策，同时加强知识产权保护的措施，以进一步鼓励国内外企业的创新积极性。

3.3 通过建立以患者为中心的医疗服务模式提升疾病管理能力

无论是“十三五规划”还是“健康中国 2020” 战略，均强调要在各级医疗机构之间建立以患者为中心的医疗服务模式，以提升医疗服务整体水平。实现这些目标需要完善疾病管理模式，其中包括建立合理用药的政策体系。

3.3.1 分配更多医疗资源用于慢病治疗

药物研发除了需要企业的参与外，来自政府的资金支持也必不可少。二者兼备才可确保有效创新药物的可及性，从而保障医疗体系的效率。

随着疾病负担逐渐从传染病转向慢性病领域，政府资金可主要用于临床数据的收集与分析（参见 3.1.1 和 3.1.2 章节）、加强医疗工作者的能力建设，并提高——特别是与慢性病治疗相关的——医院的管理效率。

3.3.2 加强药物使用的过程管理

过程管理可明显改善健康产出，并通过降低住院率及过早死亡率来减少医疗费用的产生[17]。过程管理主要涉及疾病诊断环节和处方开出之后的疾病管理环节。后一环节包括了解患者对药物治疗方案的依从性、查看包括不良反应在内的突发情况，并最终对患者的治疗方案做出必要调整等。然而，在人满为患的三甲医院，由于患者出院后与其主治医师的沟通非常有限，有效的过程管理一般很难实现[18]。

为了优化慢性病的管理模式，诺华建议在三甲医院到社区卫生服务中心的各级医疗机构之间开展有效的合作，在不同级别、不同类别的医疗机构之间建立目标明确、权责清晰的分工协作机制，以大幅提升基层医疗机构的服务水平。此外，要求医生监控患者对既定药物治疗方案的执行情况，并对随

17 Pharmaceutical Innovations to Address Chronic Diseases: http://www.ifpma.org/fileadmin/content/Global%20Health/NCDs/PDF143.pdf
18 “Chronic disease management in China”: http://social.eyeforpharma.com/column/chronic-disease-management-china

时可能发生的不良反应等突发事件给出解决方案。如果能把过程管理的具体措施纳入到药物使用政策中，并把患者的疗效作为医生绩效考核的标准，那么上述目标就可以实现。

美国等其它国家已经证明类似的加强基层医疗机构过程管理的措施是成功的。美国 2003 年通过的《医疗现代化法案》（MMA）规定，医疗处方应包含在由专业医生提供的药物治疗管理服务（MTM）中。这种服务模式尤其使同时患有多种慢性病的患者（如糖尿病、哮喘、高血压、高脂血、充血性心脏衰竭等）受益。这类患者通常需要同时服用多种药物，其年均医药费用很可能超出预期水平[19]。

3.3.3 优化医院管理

“健康中国 2020”战略的核心目标之一是建立起一套现代化的医院管理制度以提高人口健康水平。良好的医院管理制度不仅可以挽救更多生命，在医院预算紧张时还能保障医院的服务水平以满足医疗需求。但是，在中国目前的医院管理制度下，为控制成本，院方更倾向于使用疗效欠佳的低价药，而非疗效更好、可减少长期医疗费用的创新药物。

诺华高度赞赏中国政府为解决这些问题而建立现代医院管理制度的决心。现代化的医院管理制度能引导并促进以价值为基础的医疗体系的建立。高效的现代化医院管理制度应包括如下主要因素，专业医疗护理人员的能力建设、慢性病管理和患者用药安全监督、明确的流程和职责定义，以及对上述所有流程及合规性的定期评估。此外，由政府支持的医院评估和临床认证等项目同样可以进一步提升医疗服务质量。

3.3.4 鼓励通过公私合作模式（PPP）开展医生培训和患者教育项目

加强基层医疗机构的医疗服务水平是加快推进分级诊疗体系建设的关键。诺华已与北京和新疆的地方政府分别开展了针对慢性呼吸系统疾病和高血压的合作项目。下文将分享诺华在这些项目中了解到的实际问题，并综合运用 PPP 模式提出解决方案。这些问题主要是基层医疗机构在实施合理用药政策过程中所遇到的挑战。

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19 https://www.medicare.gov/part-d/coverage/medication-therapy-management/medication-therapy-programs.html

基层医疗机构的医生往往缺少能为患者做出准确诊断的医疗设备。此外，由于医生知识储备不足或资源有限，基层医疗机构往往无法提供针对慢性病治疗最合适的药物。从北京和新疆的项目中诺华了解到，这个问题同样存在于城市的基层医疗服务机构并极大地影响了基层医疗服务机构的服务水平。

采取 PPP 模式，由大医院的医生为社区卫生服务中心的医护人员提供培训，这一方式已被证实能够非常有效地提升基层医疗机构的服务水平。在新疆，诺华为基层医护人员开展了 14 次培训，培训内容包括对最有效药物的相关知识的传播、合理的疾病过程管理的制定等。2012 年试点项目开始时，血压在正常范围内的患者比例仅为 27%，经过三年的努力，2015 年 12 月项目结束时这一指标成功地提升到了 57.3%。

通过该试点项目，当地患者对合理用药、健康生活方式和加强疾病预防必要性的意识也得到了很大提高。

3.4 加强对仿制药的质量监管，保障药品安全与有效性

质量合格的仿制药是慢性病得到安全有效治疗的基础。因此，诺华非常赞赏并支持中国政府最近推出的一系列相关政策，其中包括旨在加强质量管理和减少仿制药与原研药之间质量差别的质量管理指南和“药物质量一致性评价”等。

3.4.1 发布质量一致性评价实施细则

诺华希望 CFDA 尽快出台落实“药品质量一致性评价”的实施细则，包括对具体操作流程和监管机制的说明，以便于中国的制药企业及时采取行动。

目前已公布的征求意见稿提出药品生产企业自身对其产品进行药品质量一致性评价。诺华建议正式文件出台之后应采取适当的措施保证药企递交自检报告的真实性。诺华支持 CFDA 监督“质量一致性评价”项目的审评工作，，以确保该评价的依据是全国统一标准。

此外，为了提升高质量仿制药的有效性和可及性，CFDA 应接受中国国内企业和在中国境内有生产能力的跨国企业递交国际生物等效性试验数据。对于拥有了国际生物等效性试验数据的企业而言可不必在中国重新进行生物等效性试验。

由于优质仿制药价格低廉，并且生物等效性、疗效、安全性方面与达到国际标准的原研药（参比制剂）相一致，因此提高其可及性可以有效降低医疗费用。

3.4.2 奖励优质仿制药

诺华建议在药品招标过程中，优质的仿制药应通过一套质量分层体系给予认定。质量分层应有科学的依据和参考国际公认的标准。原研药/参比制剂应列为一个单独的组别竞标并给予价格保护。

同时，质量分层应在全国设立统一标准，并要求省级层面严格贯彻执行，以确保全国范围内的一致性。

3.4.3 加强质量控制和监督

为保障患者的安全，CFDA 应加强建设统一的质量监管体系，实施对仿制药生产企业的全面监控。诺华建议 CFDA 及省级药监部门开展抽查和定期检查，对原研药和仿制药的质量进行跟踪对比。开展针对仿制药生产企业的抽查可确保其产品质量在通过质量一致性评价后仍能保持较高的标准。此外，CFDA 也可以考虑建立退出机制，将在检查过程中发现的质量不符合标准的产品淘汰出局。

诺华非常认可 CFDA 在提升仿制药质量方面所取得的成绩。为了进一步提升仿制药质量，我们建议将仿制药的质量监管体系与符合国际标准的药品生产质量管理规范（GMP）进行对接，并通过对执行机制的更新来确保其执行效果。由于 GMP 标准针对的不只是最终成品，而是药品的整个生产周期，GMP 也将作为有效机制促进从药品研发和整个生产环节的质量提升。

四、结语

能够借此机会为实现十三五期间深化医药体制改革的目标建言献策，诺华深感荣幸也深表感激。中国政府完全有能力制定合理用药的政策体系，使患者得以享受更好的医疗服务水平，并保障高效医疗体系的可持续性发展。

流行病学数据和临床数据是解决医疗领域最迫切的需求，同时也是促进医药创新的源动力。此外，制定以临床证据为基础的疾病图谱对制定合理的用药政策也非常关键。合理的用药政策体系可以提升患者的生命质量，有助

于建立现代化的医院管理制度，并最终提高中国患者的健康水平，促进中国经济的繁荣发展。

诺华随时准备为中国政府优化药物政策体系提供更多的支持与帮助。人口众多、城乡发展不均衡等因素给中国的医疗服务体系带来了巨大的挑战。在这样的背景下，构建合理的用药政策体系一方面有助于实现“健康中国2020”战略的核心目标，另一方面，在世界各国均面临被世界卫生组织称为“慢性疾病井喷”[20]的特殊时期，还将使中国在国际舞台上树立一个有效提升国家医疗体系效率和可持续性的成功模式。

[20] Reuters. “WHO says chronic diseases kill 3 million annually in China”. Jan 29, 2015: http://www.reuters.com/article/us-china-health-idUSKBN0KS0YL20150119

PROMOTING RATIONAL DRUG USE TO IMPROVE THE EFFICIENCY OF THE HEALTHCARE SYSTEM FOR A HEALTHIER CHINA

NOVARTIS GROUP

EXECUTIVE SUMMARY

Novartis is honored to participate in the 2016 China Development Forum (CDF) and to submit policy recommendations. This year's forum is particularly relevant as the country embarks on the 13th Five-Year-Plan (FYP), laying out the core economic, social and policy goals for 2016-2020. Under the sub-theme, *Deepening Healthcare and Pharmaceutical Sector Reform for a Healthier China*, Novartis is pleased to share international lessons and experience to better address Chinese patients' needs while improving the efficiency of the healthcare system in line with the 13th FYP priorities.

Building on the successes of the healthcare reforms such as higher life expectancy and improved healthcare outcomes, the country is well positioned to fully develop the "Healthy China 2020" strategy, laying the foundation for a "moderately prosperous society." Key to realizing these goals is a rational drug use policy system that more efficiently uses resources in the context of a rapidly aging population and rising prevalence of chronic diseases.

Novartis has identified four key areas that work together to enable rational drug use. Based on the analysis of China's current drug policy system and primary challenges, Novartis would like to offer recommendations and international best practices in these four areas.

1. Establish a drug use policy based on patient data

The availability and analysis of robust epidemiological data and clinical evidence enhance the understanding of the disease burden, unmet medical needs and benefits of different treatments. Enabling this analysis is essential to developing an efficient and rational drug use policy system.

Novartis recommends that the government encourages leading academic institutions such as the Cancer Institute/Hospital of the Chinese Academy of Medical Sciences (CICAMS) to conduct national epidemiological surveys on the four prioritized chronic diseases (hypertension, diabetes, cancer and cardiovascular conditions) and update databases to better understand the disease burden. Systematically collecting and analyzing clinical data will help define standardized clinical practice guidelines, setting a clear reference to assess outcomes and optimize treatment pathways. Better information on China's disease landscape, coupled with a greater emphasis on cost-efficiency analysis of available treatments, could lead to a more rational drug use and greater efficiency throughout the healthcare chain.

2. Encourage the introduction and use of cost-effective innovative drugs

The development and availability of innovative therapies is key to efficiently prevent, manage and treat chronic diseases, reducing the cost-burden of chronic diseases overall. Novartis welcomes the government announcements to optimize and accelerate review and approval procedures for innovative drugs and to introduce fast-track review for innovative drugs for unmet medical needs.

Novartis recommends that the government facilitates fast implementation of the recently announced guidelines on fast-track approval for new drugs that treat high-prevalence chronic diseases, particularly for oncology drugs given their limited availability today. The timely inclusion of such medicines on reimbursement lists and adjustments to their reimbursement rates based on evidence of their clinical benefits would greatly encourage the introduction of better drugs for Chinese patients. Furthermore, price setting for innovative drugs should follow free market mechanisms and take the value of the medicine and the expected health outcome into account.

3. Improve disease management via patient-oriented services

Patient-oriented healthcare services across all levels of the tiered healthcare system lead to better disease management, a key enabling factor for developing a rational drug use policy system.

Novartis recommends strengthening process control following the diagnosis and drug prescription to improve patient experience and reduce costs by decreasing the frequency and duration of hospitalization. To optimize chronic disease management and make it an integral part of a rational drug use system, Novartis suggests establishing mechanisms to facilitate efficient collaboration among healthcare organizations within the tiered service system, from Tier III hospitals to Community Health Centers (CHC). This will strengthen capabilities at the primary level. Encouraging Public-Private Partnerships on physician training, along with a modernized hospital management system, could increase funding for chronic disease treatment and prove crucial to improving outcomes and reducing costs in the medium to long-term.

4. Enhance quality supervision of generics to ensure safety and efficacy

Generic drugs of appropriate quality are a vital cornerstone of safe, effective and cost-efficient treatment of chronic diseases. Therefore, Novartis welcomes the recent release of the draft drug consistency evaluation guidance aimed at closing the quality gap between generics and originators, and supports the CFDA's oversight and supervision of this evaluation to ensure patient safety.

Novartis recommends releasing detailed implementation measures for the drug consistency evaluation. Additionally, to reward innovators, high-quality generics could be recognized through a tiered quality system during the bidding process, with categories based on scientific criteria and internationally accepted standards.

I. INTRODUCTION

The China Development Forum (CDF) 2016 is particularly important as 2016 marks the commencement of the 13th Five-Year-Plan (FYP). Therefore, Novartis is very pleased to be invited again and to have the opportunity to submit recommendations to this year's forum.

One important element of the 13th FYP is the development of the "Healthy China 2020" plan. The Healthy China 2020 plan represents a comprehensive national strategy aimed at inclusive development and building a moderately prosperous society that better addresses the needs of Chinese patients. As this strategy is fully in line with the Novartis mission "to discover new ways to improve and extend people's lives," we are eager to work with the government and to offer our expertise and support.

The Chinese government, in partnership with the healthcare industry, has accomplished remarkable achievements in healthcare through persistent and well-orchestrated efforts during recent decades. In particular during the 12th FYP period, healthcare outcomes have improved broadly across China, reaching levels of a middle-high income country. For instance, since 2010, the life expectancy of Chinese citizens has increased by another full year (and around 6 years in total since 1990[1]); infant mortality rates have been cut to 8.9 per 1,000 in 2014 down from 14.9 in 2008; and out-of-pocket-fees for medical care have decreased by three percentage points since 2010[2].

Chinese society and policy makers, however, are confronted with challenges stemming from the country's rapidly aging population and the rising prevalence of chronic diseases. Between 2013 and 2023, China's population aged 65 and over is estimated to grow by 12.4% to a total of 181.6 million[3]. Chronic disease incidence among Chinese over 40 is expected to double or triple by 2030, with diabetes being the most prevalent disease and lung cancer cases increasing fivefold[4]. Furthermore, the burden to society of diseases such as diabetes or cardiovascular disease carries a 'hidden' cost from the secondary conditions they cause, such as chronic heart

1 http://press.thelancet.com/ChinaGBDChinese.pdf
2 http://www.npc.gov.cn/npc/xinwen/2015-12/22/content_1955662.htm
3 6th National Census Data
4 http://www.worldbank.org/content/dam/Worldbank/document/NCD_report_en.pdf

failure. To reduce this significant disease burden and the resulting economic costs, the government has taken significant steps since 2008 to improve chronic disease management. For instance in 2012, the National Health and Family Planning Commission (NHFPC) and 14 other government agencies issued a *Work Plan for China Chronic Disease Prevention and Control (2012 -2015)*, the first national chronic disease prevention and control plan outlining key chronic diseases and implementing early diagnosis and treatment in 30% of China's highest risk regions. Simultaneously, policies concerning tobacco control, vaccination, and healthy lifestyles have been issued. The government has also lately announced a tiered medical system pilot, starting with four major chronic diseases: hypertension, diabetes, cancer and cardiovascular conditions. The 13th FYP addresses these challenges and builds on the successes mentioned above, defining six focus areas, including deepening healthcare and pharmaceutical sector reform, enhancing prevention and treatment of chronic diseases, and responding to the needs of a growing elderly population.

To meet chronic disease management objectives as well as promote optimal healthcare results throughout the healthcare system, Novartis recommends focusing on optimizing disease management via rational drug use. Rational drug use involves the optimal and comprehensive use of medicines to improve health outcomes, patients' quality of life and ensure greater efficiencies throughout the healthcare chain, thus reducing the societal burden.

In this document, we will examine the present status of China's drug policy system, and put forth our recommendations towards developing a "Healthier China" for all citizens.

II. OVERVIEW OF CHINA'S DRUG POLICY SYSTEM AND PRIMARY CHALLENGES

In line with the 13th FYP healthcare focus on the prevention and treatment of chronic diseases, this section will examine the current drug policy system and major challenges that can potentially impact chronic disease management and patient health outcomes.

These are: 1. Lack of epidemiological and real-life patient data; 2. Limited availability of innovative drugs for patients; 3. Gaps in the current disease management system; and 4. Insufficient access to safe and high-quality generics.

2.1 Lack of epidemiological and real-life patient data

The Chinese government has made great strides to improve chronic disease management, shifting its focus from treatment only to both treatment and prevention since the mid 2000's. To improve efficiency throughout the healthcare management chain, systematic analysis of clinical data, the benefits of medicines and the response to treatment in patients is essential.

However, China currently lacks systematic ways to collect and analyze both epidemiological and clinical data which is essential to assessing accurately the country's disease landscape and establishing clear, evidence-based guidance to allocate resources efficiently. The lack of sufficient, reliable epidemiological and clinical data makes clear and reliable assessments of healthcare outcomes difficult.

Those limited data that are available, however, indicate that healthcare outcomes in China may not be satisfactory. Systematic collection and analysis of such data in other markets have laid the basis for developing standardized treatment guidelines and provided useful information about the efficiency of different medical treatments. For instance, based on such clinical evidence, we know that hypertension control rates reached 85% in Germany, 66% in Canada and 51.8% in the US, compared to only 9.3% in China in 2011[5].

2.2 Limited availability of innovative drugs for patients

While prevalence and mortality due to chronic diseases are on the rise in China, it also has limited availability of innovative drugs compared to other markets. A number of innovative medicines have yet to be approved in China. For example, of the innovative medicines launched in developed markets since 2008, only 20% had been commercialized in China as of 2013[6].

A number of reasons can explain this situation, one of them being the long time required by Chinese regulators to grant marketing authorizations to new medicines.

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5 Prevalence, Awareness, Treatment, and Control of Hypertension in China; APR 2014. Hypertension 2009, 53: 450-451

6 Lichtenberg, 2013, NBER Working Paper No. 18235

The current approval backlog translates into an average five-year delay for new drugs to enter the Chinese market in comparison to other regions in the world, potentially leading to countless preventable health complications for the Chinese people, and likely deaths. In 2012, 86.6% of all deaths in China were due to chronic diseases, above the global average of 68%[7].

Another factor behind the limited availability of innovative drugs is the diffuse and complex tendering and procurement procedures that continue to delay commercialization of these medicines. Failure to update the National Reimbursement Drug List (NDRL) since 2009 and disproportionate focus on the price of medicines in the tendering system additionally hinder progress toward bringing innovative therapies to Chinese patients.

2.3 Gaps in the current disease management system

China's healthcare spending increased from an estimated 3.5% of its gross domestic product (GDP) in 1995 to 5.6% in 2013, but still remains significantly lower when compared to the Organisation for Economic Co-operation and Development (OECD) countries[8]. Growing demand for healthcare services in face of an aging population, urbanization and proliferating lifestyle diseases requires sustained public and private investment to develop innovative and high quality drugs that can address these healthcare needs.

One of the main challenges in the public health sector hampering the efficiency of the disease management system and resulting in wasted resources is the shortage of healthcare professionals sufficiently trained in the treatment of chronic diseases. Furthermore, only few high-quality step-down care facilities exist that offer restorative care for patients with moderate conditions who need medical, nursing, and rehabilitation services. These facilities tend to be overcrowded and keep patients longer than many of their international counterparts.

In addition, most service reimbursement is still done in a fee-for-service system, which encourages prescriptions of unneeded services and drugs as well as of medication with unclear benefit. The Chinese government has started to tackle irrational drug use since the NHFPC established a national Expert Committee on

7 WHO "Global Health Observatory (GHO) Data": http://www.who.int/gho/ncd/mortality_morbidity/en/
8 World Bank "Health expenditure, total (% of GDP) Data": http://data.worldbank.org/indicator/sh.xpd.totl.zs

Rational Drug Use in 2008, with a particular focus on antibiotics. However, irrational drug use related to the treatment of chronic diseases has not received sufficient attention yet despite the huge waste of healthcare resources that it generates.

2.4 Insufficient access to safe and high-quality generics

Today the Chinese market sells generic medicines of different quality levels, some of which pose risk to patients due to lower quality. The Chinese authorities have recognized the need to establish measures to raise the overall quality standard of these products. For example, China Food and Drug Administration (CFDA) has introduced a system to conduct a quality consistency evaluation for generic drugs aimed at proving quality attributes of authorized generics on the Chinese market.

However, patients still cannot be sure to receive generic drugs of adequate quality, because the methodology used for the quality consistency evaluation may not provide sufficient guarantees. For instance, manufacturers are asked to perform dissolution assays only via self-tests, exposing the system to risk due to potential conflict of interests.

III. POLICY RECOMMENDATIONS

The Healthy China 2020 plan aims to improve health outcomes within the next five years as part of the ongoing healthcare reforms. To realize this goal and tackle some of the challenges mentioned in the previous section, Novartis recommends promoting a rational and comprehensive drug use policy that relies on robust clinical evidence, enables efficient use of resources, and improves treatments.

Specifically, Novartis would like to make the following recommendations: 1. Establish a drug use policy that is based on patient data; 2. Encourage the introduction and use of cost-effective innovative drugs; 3. Improve disease management via patient-oriented services; and 4. Enhance quality supervision of generics to ensure safety and efficacy.

3.1 Establish a drug use policy based on patient data

Accurate and comprehensive patient data is the cornerstone of rational drug use policy. Reliable data allow policymakers to fully understand the disease landscape

and thus develop appropriate policies that meet the needs of patients and engender greater efficiency throughout the healthcare system.

3.1.1 Conduct national epidemiological surveys on prioritized chronic diseases

We recommend that China conducts epidemiological research to fill key information gaps. Gathering and managing epidemiological data would provide information on how often specific diseases or healthcare conditions occur in different population groups and the determinants of these conditions[9]. Such scientific evidence could thus inform key decisions throughout the entire healthcare chain, from R&D investments to prioritizing healthcare measures or establishing treatment guidelines.

The recently released report[10] by the National Cancer Center published nationwide cancer epidemiology data that estimate the 5-year prevalence for all cancers combined in 2011 in China. The research bases on data from 177 cancer registries and presents the first systematic analysis of Chinese national data assessing the overall cancer prevalence.

Novartis welcomes very much this piece of work and recommends the government to encourage more academic institutions in the field of cancer, e.g. the Beijing Cancer Hospital or the Cancer Institute of Shanghai Jiaotong University, and in other chronic disease areas to conduct national epidemiological research and update databases to better understand the disease burden for patients and their families. Also, international and domestic pharmaceutical companies can provide support to this initiative.

Once this data is collected, a consortium comprised of representatives of government, hospitals (from Tier III to Community Health Centers [CHC]), insurers and industry (pharmaceuticals and IT providers) could develop a "National Disease Mapping - Big Data" project as part of the 13th FYP by pooling necessary resources and expertise. Analysis of such data would generate useful information that could prove crucial in supporting government efforts aimed at improving chronic disease management and quality of life of Chinese patients. An example of this kind of project is the "Big Data for Better Outcomes" program of the European

9 http://www.who.int/maternal_child_adolescent/epidemiology/en/
10 http://www.ncbi.nlm.nih.gov/pubmed/26458996

Innovative Medicines Initiative (IMI)[11], aiming to catalyze the shift towards value and outcome–based healthcare systems in European countries with a view to guaranteeing the sustainability of these systems.

3.1.2 Systematically collect and analyze clinical data

Developing a scientific system to collect and process clinical data lays the foundation for a better understanding of the disease burden. This would include information on the nature of drug use in hospitals and the clinical effect of these drugs, prognosis of the disease progression including hospitalization, quality of life and mortality. Increasing the depth and breadth of the information available about the outcomes of current treatment patterns combined with assessments of their economic efficiency could inform decisions in China's drug policy system to create significant efficiency gains.

Governments can support systems to collect and process clinical data, so-called registries, by creating a regulatory framework and funding. The pharmaceutical industry can also play an important role by partnering with medical societies to develop such registries.

Europe has created a variety of registries: population-based registries, disease specific (e.g. cancer, diabetes, cardiovascular) or pay-for-performance scheme registries. Based on real data and best practice sharing, these tools improve disease management by focusing on value and patient outcomes. For example, Sweden's online registry for acute coronary care[12], SWEDEHEART (Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies) reports the outcome of every patient hospitalized for acute coronary syndrome or undergoing coronary or valvular intervention and has been key for cardiologists to optimize clinical outcomes in the past years.

3.1.3 Timely update of and standardize clinical practice guidelines

Standardized clinical practice guidelines are a cornerstone of a rational and optimal drug policy system. These guidelines are "intended to optimize patient care" based

11 https://ec.europa.eu/digital-agenda/events/cf/big-data-value-ppp-lighthouse-projects-in-h2020/item-display.cfm?id=17867
12 http://eurheartj.oxfordjournals.org/content/ehj/30/18/2165.full.pdf

on “a systematic review of evidence and an assessment of the benefits and harms of alternative care options”[13]. These guidelines rely on “a combination of scientific evidence, knowledge gained from clinical experience and patient value judgments and preferences”[14]. Access to robust epidemiological and clinical evidence enables these comprehensive clinical guidelines to be developed.

Standardized and timely updated clinical practice guidelines provide a clear reference to assess health outcomes and to optimize treatment pathways. For example, in Europe the European Society for Medical Oncology (ESMO) has established guidelines based on the findings of evidence-based medicine in different types of cancer, such as colorectal, pancreatic, breast, endocrine, sarcomas and others. These guidelines have strong influence on healthcare interventions in European countries. Another example are the activities of the American Heart Association (AHA) [15] that play a crucial role in defining standard practice guidelines for diagnosing, treating and preventing cardiovascular diseases based on recognized scientific studies with the overarching goal to enhance patient health outcomes. AHA also enhances the capabilities of healthcare professionals and educates patients to comply with medical treatments. To encourage hospitals to follow practice guidelines, AHA developed a web-based Patient Management Tool, including an information registry, instantaneous benchmarking and performance improvement mechanisms.

Following international best practices, Novartis suggests that treatment guidelines are generated based on epidemiological and clinical data and updated in a timely manner upon approval of new drugs for chronic diseases. Moreover, to encourage adherence to the recommended prescription behaviors, these guidelines should be publicized and accompanied by educational programs to ensure that physicians, especially at primary healthcare centers, are aware of the most innovative treatments.

13 Graham, R. et al (ed). 2011. “Clinical Practice Guidelines We Can Trust”. Institute of Medicine: http://www.ncbi.nlm.nih.gov/books/nbk209546/
14 Ibid.
15 http://www.heart.org/HEARTORG/HealthcareResearch/Healthcare-Research_UCM_001093_SubHomePage.jsp

We applaud the Chinese Medical Association efforts in this regard and stand ready to support its work by sharing information on clinical outcomes or jointly sponsoring educational campaigns.

3.2 Encourage the introduction and use of cost-effective innovative drugs

The development and availability of innovative therapies are key to efficiently prevent, manage and treat chronic diseases, because they benefit patients via improved survival, as in the case of cancer or cardiovascular treatments and reduce hospitalization or the duration hospital stays, thus reducing the burden to the healthcare system overall. Therefore, China is advised to put adequate measures in place to ensure that the overall healthcare system is able to benefit from global innovation. Timely access to the latest innovative therapies will reduce the cost-burden of chronic diseases overall and improve patients' quality of life.

3.2.1 Accelerate approval and improve market access for innovative drugs

While Novartis applauds China for taking important steps in reforming the evaluation and approval system of medicinal products, the processes for clinical trials approval and drug approval in China still takes much longer than international practice. Streamlining the review and approval systems will accelerate drug approval, will improve the efficiency of global drug development and will reduce the time it takes for innovative new medicines to reach Chinese patients

China could enhance the development of innovative drugs through facilitating global clinical trials in China and the fast implementation of fast-track approval procedures to expedite access to innovative drugs for treating serious conditions, similar to the procedures applied by the US FDA[16]. In particular, patients suffering serious and high-prevalence chronic diseases (e.g. those identified through data analysis) could benefit from earlier assess to these drugs. More specifically, cancer patients would immediately benefit from greater access to innovative oncology drugs. While cancer is now the leading cause of death in China, only limited drug therapies are presently available to Chinese patients.

16 US FDA Guideline on Expedited Programs for serious conditions, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf

3.2.2 Update national reimbursement list and reimbursement rates based on clinical evidence

To further promote the availability of innovative drugs in the market, Novartis also recommends facilitating their timely inclusion on reimbursement lists and include more high-value innovative drugs into the local critical disease insurance schemes. Since its implementation in 2009 China's essential drug system and reimbursement model has significantly improved patient access to drugs; however, continued efforts including regular updating of reimbursement lists are needed. Novartis believes that it would be particularly beneficial to allow the inclusion of innovative chronic disease drugs on the provincial DRLs shortly after CFDA approval. This would allow Chinese patients more timely access to cost-efficient innovative drug therapies and incentivize tailored innovation aimed at treating high-prevalence chronic diseases.

The analysis of clinical data (refer to 3.1.2) can inform policy decisions on medical insurance schemes, including drugs that should be included on the NDRL and their insurance coverage rates. Based on the results of comparative studies on cost-efficiency of competing drugs, policy makers could adapt reimbursement rates accordingly. In addition, Novartis suggests that also the price setting of innovative drugs adequately considers the value of the medicine for the healthcare system and the expected health outcome for patients and follows free market principles. Studies that demonstrate the value of innovative medicines relative to the cost provide the foundation for a fact-based pricing.

Novartis is willing to support the national and provincial governments in China to set up clear and transparent processes that result in improved and accelerated pricing and reimbursement decisions. The collaboration with the pharmaceutical industry and international organizations, such as Health Technology Assessment international (HTAi)[17] and HTAsiaLink[18], could prove beneficial to leverage international experience relevant for developing an appropriate approach in China.

3.2.3 Encourage integration between international and domestic innovators

17 http://www.htai.org/
18 http://www.htasialink.org/

Many multinational pharmaceutical companies, including Novartis, have localized R&D and manufacturing operations in China. To best utilize these resources for the benefit of the healthcare system, Novartis suggests further integration of R&D capabilities of multinational innovators into China's healthcare reform efforts. Successful integration requires equal treatment of both domestic and multinational entities, i.e. drugs of multinational companies with large R&D presence in China should have equal access to reimbursement lists as domestic company products.

The CFDA has unveiled implementation policies to streamline and expedite approval of innovative and high quality drugs, notably facilitating R&D-based companies to commercialize their assets through piloting a Marketing Authorization Holder (MAH) system.

Novartis recognizes the marketing authorization holder (MAH) pilot as a positive development that will further boost R&D efforts in China, since it will, in addition to drug manufacturers, enable research and development organizations and Chinese scientific research personnel to seek drug approval as a MAH. We encourage the CFDA to further develop similar policies as well as enhance IPR protection to incentivize innovation stemming from both domestic and multinational companies.

3.3 Improve disease management via patient-oriented services

Both the 13th FYP and the Healthy China 2020 plan call for the establishment of patient-oriented healthcare services across all levels of the tiered healthcare system as an important step in the reform efforts to achieve optimal healthcare outcomes. In line with these goals, improved disease management should include a rational drug use policy system to ensure its comprehensive implementation.

3.3.1 Allocate greater healthcare resources for chronic disease treatment

In addition to the private sector's engagement in the research and development of medicines, more public funding is needed to support the availability of life-changing new medicines and an efficient healthcare system.

To address the shift in disease burden from infectious to chronic conditions, funding could be reallocated to prioritize data collection and analysis (refer to sections 3.1.1 and 3.1.2), as well as enhancing the capability building of healthcare

personnel and increasing the efficiency of hospital management, particularly regarding the treatment of chronic diseases.

3.3.2 Improve process control in drug use

Process control has proven instrumental to improve health outcomes and reduce costs by decreasing hospitalization and avoiding premature deaths [19]. Process control involves the disease management system following the diagnosis and drug prescription by a physician. It also involves understanding patient adherence to a medication regimen, checking for any additional conditions or adverse reactions and, consequently, making any necessary treatment adjustments. However, especially in the often overcrowded Tier III hospitals, effective process control is difficult to apply as patients after hospital discharge only have limited interaction with the physician who treated them[20].

To optimize chronic disease management, Novartis suggests establishing mechanisms to facilitate an efficient collaboration among healthcare organizations within the tiered service system, from Tier III hospitals to Community Health Centers (CHC), with a clear allocation of roles and responsibilities to each party. Integrated healthcare action among these organizations could help strengthen medical treatment capabilities at the primary level. More importantly, it would ensure that healthcare professionals are appointed to supervise patients' adherence to prescribed medication regimens and to immediately address potential complications. This could be realized, for instance, by including process control measures in the drug use protocol and patient's treatment outcomes as criteria to evaluate physician performance.

Similar initiatives aimed at strengthening process control capabilities at the primary level have proven successful in other countries, e.g., in the US. According to the US Medicare Modernization Act of 2003 prescription drug plans are required to be included in medication therapy management services delivered by a qualified healthcare professional. This medication therapy management model particularly benefits patients with multiple chronic conditions (such as diabetes, asthma,

[19] Pharmaceutical Innovations to Address Chronic Diseases: http://www.ifpma.org/fileadmin/content/Global%20Health/NCDs/PDF143.pdf
[20] "Chronic disease management in China": http://social.eyeforpharma.com/column/chronic-disease-management-china

hypertension, hyperlipidemia, and congestive heart failure) who take several medications or who are likely to incur annual costs above a predetermined level[21].

3.3.3 Optimize hospital management

A core goal of the Healthy China 2020 plan is to establish a modernized hospital management system that can support a healthier population. Good hospital management can save lives and increase much needed productivity at a time of budget constraints. However, current hospital management systems in China put disproportionate emphasis on low-priced treatments with sometimes questionable effectiveness over the use of innovative drugs that can deliver better outcomes and thus reduce costs in the medium to long-term.

To overcome these challenges, we welcome the government's commitment to set up a modern hospital management system that can drive a shift to a value-based healthcare system. Important elements of efficient hospital management systems include capability training of skilled healthcare personnel in hospital management; chronic disease management and surveillance of patients' drug use and safety; clear definitions of processes, roles and responsibilities; and regular assessments of such processes and compliance. In addition, hospital accreditation and clinical certification programs supported by the government could help to further raise the quality of healthcare services.

3.3.4 Encourage Public-Private Partnerships on physician training and patient education

Enhance capabilities at the primary healthcare level is crucial to advancing the policy goal of accelerating the tiered healthcare system. Novartis has partnered with local governments in Beijing and Xinjiang to address key healthcare needs in chronic respiratory disease and hypertension, respectively. Based on these experiences, we would like to share key challenges identified at the primary level for implementing a rational drug use policy system and provide recommendations regarding the use of public-private partnership models to address them.

Physicians at primary healthcare services often lack appropriate devices to make accurate diagnosis. Additionally, they lack sufficient knowledge or access to

[21] https://www.medicare.gov/part-d/coverage/medication-therapy-management/medication-therapy-programs.html

resources to use the most appropriate medicines for treating chronic diseases. This issue seems to greatly affect the quality of healthcare provision both in urban and rural areas, as has been shown by the mentioned programs in Beijing and Xinjiang.

Integrated public-private efforts involving capacity building trainings provided to physicians at Community Health Centers (CHCs) by doctors from high-level hospitals have proven particularly successful to enhancing physicians' capabilities, leading to improved health outcomes. In Xinjiang, Novartis supported a total of 14 trainings targeting physicians at primary healthcare centers, enhancing knowledge about most efficient drugs and developing sound disease management processes. At the onset of the three-year pilot in 2012, only 27% of patients could control hypertension at normal levels. By the end of the project, in December 2015, this figure had increased to 57.3%.

The pilot also raised patient awareness of the healthcare benefits of a rational drug use and the need to pursue healthier lifestyles to enhance prevention.

3.4 Enhance quality supervision of generics to ensure safety and efficacy

Generic drugs of appropriate quality are a vital cornerstone of safe, effective and cost-efficient treatment of chronic diseases. Therefore, Novartis applauds and supports the Chinese government's recent policy developments to establish guidelines on quality control that intend to narrow and close the quality gap between generics and originators via the so-called "drug consistency evaluation".

3.4.1 Release implementing consistency evaluation guidelines

Novartis looks forward to the CFDA releasing the implementing guidelines for the drug consistency evaluation, including procedural guidelines and details on the supervision mechanism to allow timely action by China's pharmaceutical companies.

The current draft guidelines foresee that manufacturers self-certify the consistency of their products. Measures should be put in place to ensure that data are not compromised due to a potential conflict of interest. Novartis fully supports that approval and supervision of the drug consistency evaluation is overseen by the CFDA to ensure a consistent nationwide standard.

Further, to increase efficiency and availability of high-quality generics, both domestic and multinational pharmaceutical companies with manufacturing facilities in China should have the option to refer to international bioequivalence data and waive local bioequivalence study requirements.

Generic drugs that have proven to be bioequivalent to the off-patent originator medicine (the reference product) in line with international standards are affordable treatment options with the same efficacy and safety as the original, and therefore, take some burden from the healthcare system.

3.4.2 Reward high-quality generics

Novartis recommends that high-quality generics should be recognized through a tiered quality system during the bidding process. Categories should be based on scientific criteria and internationally accepted standards and include a category for originators/reference drugs with the highest price premium.

Quality tiers should be set at the national level, and consistent implementation at the provincial level should be ensured to achieve same high standards for patients in all Chinese provinces.

3.4.3 Enhance quality control and supervision

For the sake of patient safety, CFDA should enhance and centralize the quality supervision and management system to monitor all generics manufacturers. Novartis also recommends that the CFDA or provincial FDAs conduct sampling and inspections to continually compare the quality between originators and generics. Sampling will ensure quality is maintained after a product has passed the consistency evaluation. Further, CFDA may also consider establishing a system to remove those products from the market which have failed to meet said consistency sampling inspections.

Novartis applauds the CFDA’s first successes in elevating the quality of generic drugs. Novartis recommends to continue building on these successes by aligning the current Chinese requirements of Good Manufacturing Practices (GMP) with international standards and upgrading the enforcement mechanisms to ensure their implementation. As GMP standards do not only target final products, but also the

entire production process, they provide a useful mechanism to upgrade quality across the entire pharmaceutic development and production chain.

IV. CONCLUSION

Novartis feels honored and thankful to have been able to provide recommendations for deepening the healthcare and pharmaceutical sector reform in the 13th FYP period. China is well placed to lead the development of a rational drug use policy system that can facilitate patients' access to better treatments and support the sustainability of the healthcare system based on greater efficiencies.

Epidemiological and clinical data are key enablers for pharmaceutical innovation that effectively addresses the most pressing healthcare needs. Moreover, developing an evidence-based disease landscape is a crucial step in shaping China's rational drug use policy system, with the aim of enhancing the quality of life of patients and establishing a modernized hospital management model that will improve the wellbeing and prosperity of all Chinese citizens.

Novartis is ready and eager to support the government's efforts to optimize China's drug policy system. China faces unique healthcare challenges given the size of its population and inequalities among the rural and urban regions. Building a rational drug use policy system in the face of such challenges would not only help to realize the core goals of the Healthy China 2020 strategy but, on a global scale, could set a successful model to improve the efficiency and sustainability of healthcare systems as countries around the world deal with what the World Health Organization has termed 'the tsunami of chronic diseases'[22].

[22] Reuters. "WHO says chronic diseases kill 3 million annually in China". Jan 29, 2015: http://www.reuters.com/article/us-china-health-idUSKBN0KS0YL20150119