全力提升中国医药产业创新能力

2012年

Building an innovation-driven pharmaceutical industry in China

2012

RDPAC

中国外商投资企业协会药品研制和开发行业委员会
China Association of Enterprises with Foreign Investment
R&D-Based pharmaceutical Association Committee

CAEFI

关于RDPAC

R&D-based Pharmaceutical Association Committee，**中国外商投资企业协会药品研制和开发行业委员会**

RDPAC**是一个由39家具备研究开发能力的跨国制药企业组成的非赢利性组织，隶属于“ 中国外商投资企业协会 ”。目前，RDPAC成员已在中国设立了49家生产工厂， 30个研发中心，在十一五期间总投资达200亿人民币，为中国引进了543种新化学实体和生物产品，制造并销售了2,817个品规的药物[1]。**

RDPAC的目标：以创新引领健康中国

RDPAC**致力于成为中国实现“ 健康中国2020 ”目标、不断提高居民和患者生活质量的重要合作伙伴：**

- **兼顾社会责任与行业发展，为中国提供高质量的、创新的医疗健康产品和服务；**
- **为确保患者及时获得优质的创新药品而努力；**
- **在研究和商业运营中保持诚信，遵循高标准道德规范；**
- **为中国生物制药产业的发展作出积极贡献；**
- **支持中国建立可持续发展的医疗卫生体系。**

内容摘要

❶ 中国政府正在全力提高医药产业的创新能力，并且已经取得了一系列的卓越成绩。

❷ 长期以来，RDPAC成员一直是中国医药产业的创新合作伙伴，在提升用药安全、药物质量以及治疗标准等方面作出了持续的贡献。

❸ 在全球性合作引领医药产业研发创新的今天，RDPAC成员有力地推动了中国融入全球医药创新体系的步伐。

❹ RDPAC成员在中国的研发创新投入正在大幅度提高，目前总投入水平已达到每年80亿元，超过中国所有大中型医药企业一年研发支出总投入的一半，并直接创造了约3,000个高端研发岗位。

❺ RDPAC成员与中国本土研究机构结成了超过210对合作伙伴关系，在中国致力于投资中国政府重点关注的疾病领域。

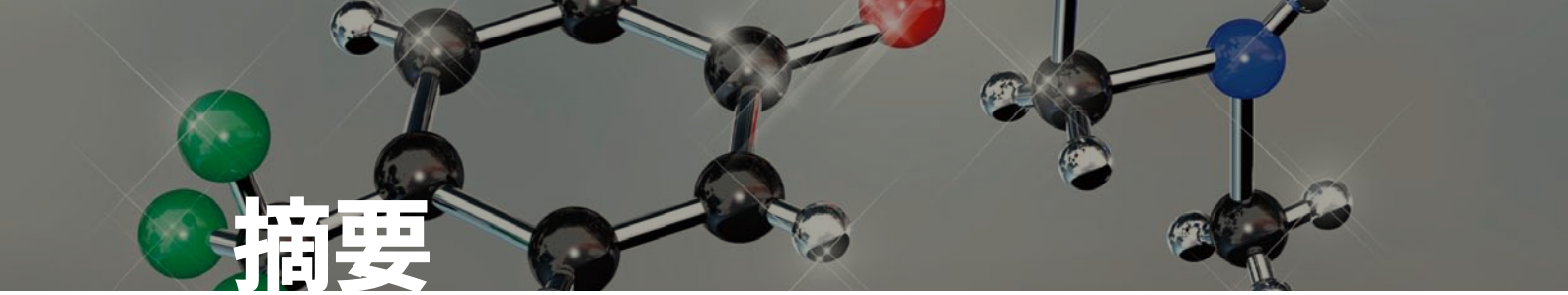
❻ RDPAC成员通过提升科研技术水平、培育高级管理人才以及协助拓展国际市场，有力推进了中国创新型本土企业的发展。

❼ RDPAC成员推动中国创建了一个总规模达60亿元、具有自主特色的研发外包产业。

❽ 展望将来，中国要成为真正的全球创新者，不仅需要提供不断完善的基础研发配套设施，更要注重建立支持创新的监管环境，制定合理的创新激励机制以及加大对知识产权的保护力度。

❾ 中国政府、本土企业以及RDPAC成员抱有一个共同的愿望，即希望中国成为全球医药创新的领军者。RDPAC期待有机会和中国政府共同努力、协同发展，实现这一愿望，惠及更多中国患者。

目录



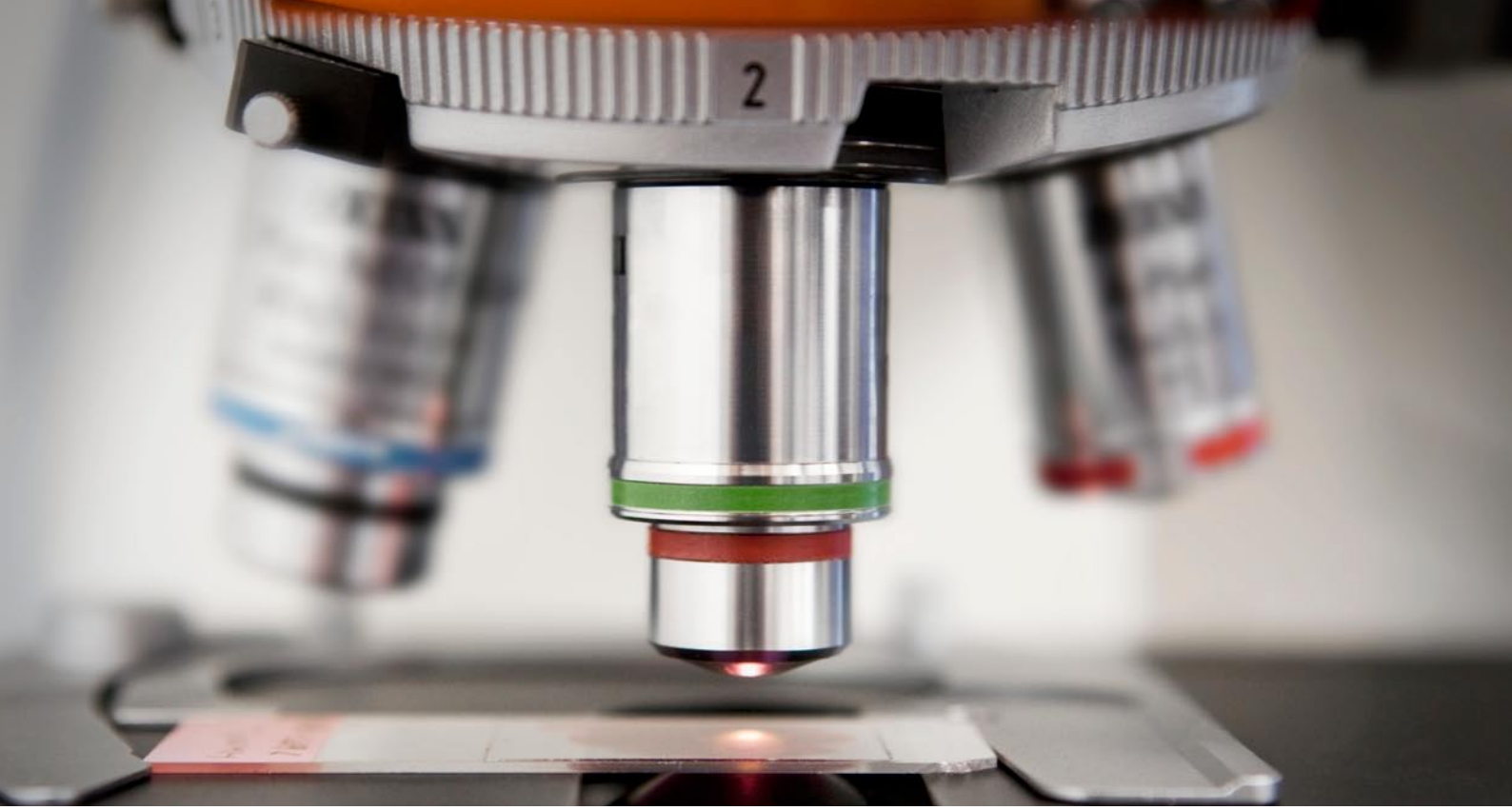
摘要

中国政府致力于建立一个创新型的医药产业，改变中国当前以低成本加工为主导的局面，注重创新驱动，转型发展，使中国成为全球医药创新的重要引擎。为了成功转型为知识型经济发展模式，并满足国内13亿人口日益增长的医疗服务需求，中国政府在过去数年中制定了目标远大而切实可行的产业发展方向。在国家“重大新药创制专项”计划中，政府明确产业发展目标为：到2015年，开发出30种原创新药；到2020年，使中国的研发能力达到世界一流国家水平。该目标的研发核心在于满足中国患者的医疗需求，如着重研究在中国多发且死亡率高的疾病。

为实现这一发展目标，中国政府做出了不懈努力：1）在每年有4.9万名博士毕业生的基础上，国家进一步推出了“千人计划”等项目吸引海外人才[2]；2）国家在基础设施建设上投入巨资，建成了至少22个生物医药产业园区[3]；3）产业标准日益受到重视，在过去五年间，获药物临床实验质量管理规范（GCP，Good Clinical Practice）认证的临床机构数量增加了约70%；4）药物创新取得初步进展，在2007至2010年间，5个原创新药申请获得了国家食品药品监督管理局（SFDA）的批准，有24种处于临床试验阶段的原创新药在美国或欧盟取得了专利[4]。

RDPAC成员在促进医药产业创新发展上，有着与中国政府共同的美好愿景。RDPAC成员来自于引领全球的研发创新企业，他们多年来不断为中国患者带来先进的药物和治疗手段，帮助提升了中国医药行业的整体素质和质量。RDPAC成员引进的创新药品奠定了中国仿制药行业发展的基础，他们的研发努力正在帮助中国不断融入到全球研发创新网络中去。RDPAC成员致力于中国医药产业创新的长期发展，在华计划年度研发投入规模超过2010年中国所有大中型制药企业研发开支的50%[5]。同时，他们积极地与公立医院、大学以及研究所开展了200多项合作，聚焦于中国政府密切关注的重点疾病领域，在这个过程中传递技术、知识以及行业标准。RDPAC成员培养的高级人才创立了诸如泰格医药、百济神州和华医药等新一代创新型医药公司，他们也积极与本土企业合作，帮助他们打开进军国际市场的大门。RDPAC成员在中国研发外包产业的形成和发展过程中发挥了重要的作用，不但促使研发外包产业发展到今天约60亿元的规模[6]，而且也帮助中国医药企业极大降低了研发创新的门槛。

当前中国医药产业正处于发展的关键阶段，产业发展前景良好，政府高度重视，基础设施不断完善，人才储备不断加强，产业投资持续增长。但是，要避免对产业的技术创新的束缚，相关政策环境还有待进一步改善。当下的决策，将会影响到医药产业明日的格局，中国政府除了要稳步改善研发基础设施外，更需要提供支持创新的监管体系，制定合理的创新激励机制，包括公平定价、及时的市场准入及强有力的知识产权保护创新。RDPAC 成员很荣幸有机会加入到中国这一具有历史意义的产业发展大潮中，并为之贡献力量。



中国政府致力于医药产业创新

在经历了20年的高速增长后，中国已经成为全球第二大经济实体，下一步国家将通过结构调整、产业转型来保持经济的持续、快速发展，转变旧有的以制造业为核心的发展模式，构建产业创新体系，以“创新驱动”，促“转型发展”。与此同时，伴随中国13亿人口的收入增加，人们对医疗卫生服务的需求也日益显著。

内容摘要1：

中国政府正在全力提高医药产业的创新能力，并且已经取得了一系列的卓越成绩。

（一）中国创新前景

考虑到上述转型发展和需求提升的双重挑战，国家明确今后医药产业的发展方向在于全力提升产业价值体系的创新能力，这也将成为中国医药行业可持续发展的驱动力。为实现这一前景，政府制定了远大而可行的发展目标：

- 到2015年，在“重大新药创制专项”的支持下，获得30个以上原创药物新药证书，开发30个以上通用名药物新品种，完成200个以上医药大品种的改造升级。
- 到“十二五”期末，在生物技术全球专利与论文发表领域跻身全球前三，年度出口增长率达到20%，重点骨干企业研发

投入从现今销售收入的1%左右增长到销售收入的5%以上。

- 到2020年，力争实现产业研发能力接近世界一流水平。

为实现发展目标，政府在产业“十二五”规划中明确了五大关键措施[7]：

- 加大对创新活动的财税激励，加强落实针对研发活动的税收优惠制度，鼓励民间资本投资创新型医药企业。
- 完善药品评估和审批流程，提高质量标准和监管规范。
- 加强对人才的吸引和培养，加强引进海外人才的力度，鼓励开展产业专业培训。
- 加强工业、大学和科研机构之间的合作，加快产业化步伐，提高研发实力。
- 拓宽国际合作渠道，推进本土企业与跨国企业建立战略合作伙伴关系，共同开发新产品，进入全球市场。

（二）迄今取得的可喜进展

中国政府在积极改善研发基础设施、人才资源和行业标准等方面进展迅速，过去10年间成绩斐然。目前在全国范围内已建成旨在提升产业创新能力的至少22个生物医药产业园区。政府通过税收激励、土地补贴和其它优惠政策（如试剂进口快速通道），为园区营造了良好的产业发展环境，帮助它们集聚了大量自主创新型医药企业。

国家同时致力于构建满足创新需求的人才储备库。中国目前每年毕业的博士人数位居全球第二，国家的“千人计划”以及地方上的各种人才引进项目，吸引了大量海外高端人才，他们同时拥有深厚的技术资源和管理经验，是推动中国创新型医药产业的中坚力量。

中国政府稳步提升了产品质量和安全标准，在过去两年中分别发布了新版药品生产质量管理规范（GMP，Good Manufacturing Practice）和质量控制标准，获药品临床试验管理规范（GCP，Good Clinical Practice）认证的机构数量在过去五年间增加了约70%。

上述一系列政策已取得了初步成果。在2007 - 2010年，有5个原创新药通过了国家食品药品监督管理局的批准，有24个在中国开发的处于临床试验阶段的创新型候选药品，在美国或欧盟取得了专利[4]。

RDPAC成员是产业创新的长期合作伙伴

内容摘要2：

长期以来，RDPAC成员一直是中国医药产业的创新合作伙伴，在提升用药安全、药物质量以及治疗标准等方面作出了持续的贡献。

RDPAC与中国政府有着共同的愿望，希望中国成为引领全球医药创新的领军者。RDPAC的39个成员公司长期以来一直是中国的创新合作伙伴，在提升中国患者用药安全、药物质量以及治疗标准等方面作出了持续的贡献。

（一）提升产品质量和安全标准

RDPAC成员通过在药品制造上的积极创新，大力提升了中国医药的质量和安全标准，各成员的生产基地都贯彻落实了新版药品生产质量管理规范，以确保他们所生产产品的质量。RDPAC成员还积极帮助中国本土合作伙伴提高医药质量和安全标准，如在与研发外包机构（CRO，Contract Research Organization）的合作中实行原料药（API，Active Pharmaceutical Ingredient）国际标准，并为研发外包机构员工提供培训，这一系列措施有效地提升了研发外包机构原料药的总体标准，同时使得与这些研发外包机构合作的本土企业也大大受益。

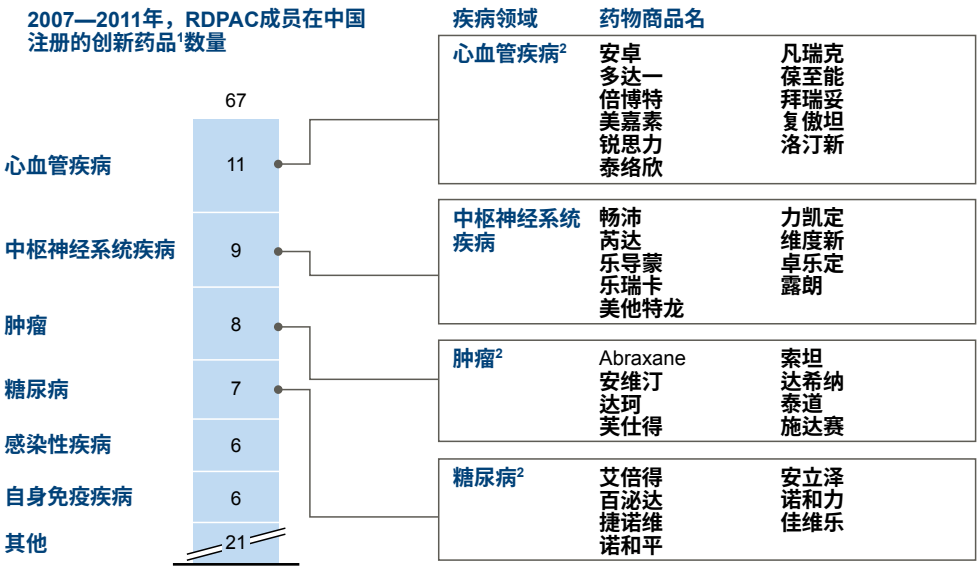
（二）提供创新药物，提高治疗标准

自从进入中国市场以来，RDPAC成员积极向市场提供原创产品，在新的治疗领域中不断投资，开展医师教育，帮助中国提高了治疗水平。例如，RDPAC成员帮助发展了非典型抗精神病药物的新疗法，这一市场在1999年时的规模仅为5800万元，而如今已经发展到23亿元[8]，本土企业也在这个市场发展的过程中获益匪浅。事实上，今天这个市场上的25个产品中有17个来自于非RDPAC成员。

在过去五年中，RDPAC成员已累计向中国市场引进了至少67种创新药物，占到了同期中国市场所有上市创新药物的80%[8]。这些创新药中包括用于治疗乳腺癌等威胁生命的疾病，以及缓解如老年黄斑变性等恶性疾病的有效药物，每年有成千上万名患者从中受益，大大延长了生命，并显著提高了生活质量。

RDPAC成员自上世纪80年代起就开始不断将诸多创新药品引入中国市场，除了造福于病患之外，还为国内仿制药行业的蓬勃发展奠定了基础。在目前总值达4000亿元的处方药市场中，国产仿制药已经占到了70%以上的份额，这些产品大多是由国有企业仿制RDPAC成员引入的创新药发展而来。通过这一途径，RDPAC成员公司不断为本土医药企业的在研产品线提供产品，对国内仿制药企业的持续发展发挥着极其重要的作用。

图表1：RDPAC成员将创新的果实带给中国患者



1 包括新分子结构或新复合处方，不包括剂型改变和疫苗
2 中国政府在慢性非传染病上的重点

资料来源: 国家食品药品监督局数据

RDPAC成员推动中国融入全球医药产业研发创新体系

内容摘要3：

在全球性合作引领医药产业研发创新的今天，RDPAC成员有力地推动了中国融入全球医药创新体系的步伐。

在医药研发已经越来越要求全球性合作的今天，医药研发的价值链跨越了国家和区域，依赖于不同地区在人才、资金、专业技术等多方面的合作。临床试验往往在多个国家的多个试验中心进行，创新药品的研发代表着不同地区参与者的共同努力。

任何一个要实现医药产业创新的国家都必须充分融入全球医药创新体系，做到研发无国界，充分利用全球人才和资源进行创新，并通过在全世界范围内获得收益来实现创新回报。中国政府已经在新的一个五年计划中明确指出要力争实现国内医药企业进入全球市场，要实现这一目标，中国就必须融入全球医药创新体系，成为其中的一个重要组成部分。

RDPAC成员对中国融入全球创新体系已经发挥了良好的协调作用，他们积极提供研发设施，整合各方资源，并搭建交流平台供各合作单位在创新过程中充分沟通。例如，一家RDPAC成员公司为促进中枢神经系统药物的发展，在亚洲、欧洲和美国分别成立了研发中心；另一家RDPAC成员公司则在美国和中国分别设立了糖尿病药物研发中心。这些RDPAC成员以在华设立的研发中心为平台，通过与中国本土医药企业和研发外包机构合作，整合中国人才资源， 并与中国研究机构和医院建立广泛的合作伙伴关系，快速推动中国融入全球医药创新体系。

RDPAC是由以创新和研发为导向的跨国制药企业所组成的创新领导者，代表国际一流研发水准，在研发投入和专业经验方面都是产业的领头羊。他们非常愿意与中国政府和本土企业分享资源，从而实现共同的发展目标， 为患者提供更好的医疗手段。正如一位本土制药企业的创始人所说：“医药行业有别与其它行业，属于知识密集型产业，药品研发的成功离不开多年的经验积累。跨国企业起步早，有很多资源和经验可以和我们分享。”RDPAC成员深刻了解自己的责任所在，并愿意竭诚合作，与中国政府共同应对国内医疗健康发展所面临的挑战。

RDPAC成员大力促进中国研发发展

（一）大力投资，聚焦创新

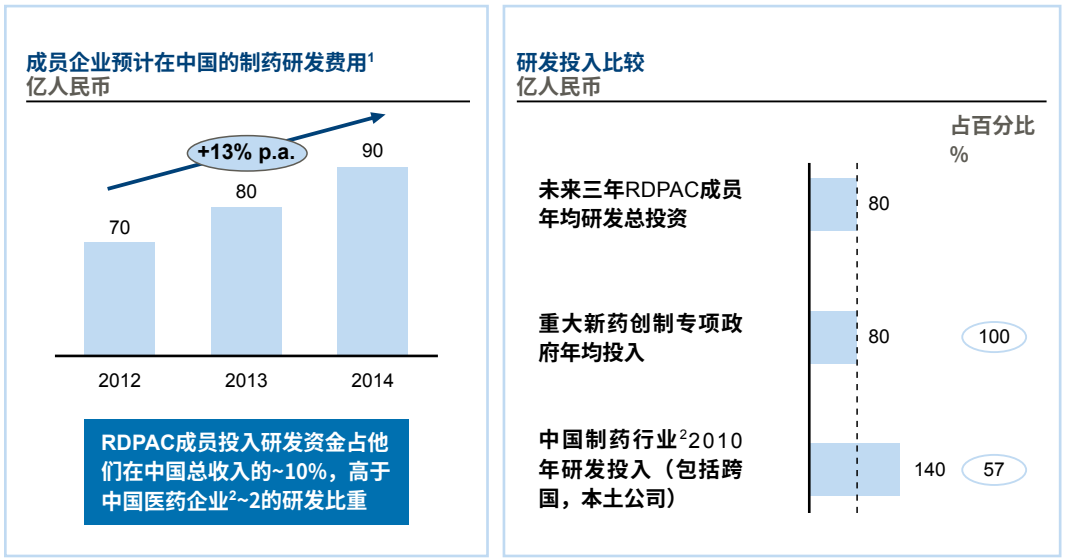
内容摘要4：

RDPAC成员在中国的研发创新投入正在大幅度提高，目前总投入水平已达到每年80亿元，超过中国所有大中型医药企业一年研发支出总投入的一半，并直接创造了约3,000个高端研发岗位。

RDPAC成员全力促进中国医药产业创新的决心体现在他们在中国长期对创新研发的投入上。在过去10年间，RDPAC成员在中国的研发中心已从7个激增到如今的30个，其中80%的雇员拥有硕士以上学位。这些研发中心为近3000名科学家和临床医师提供了具有高附加值的就业机会。目前这些研发中心仍在大规模拓展，预计未来几年内上述数字还将显著增加。

未来三年，RDPAC成员的研发总支出预计将超过240亿人民币，年均超过80亿人民币，这样的投入水平接近于：

图表2：RDPAC成员致力于在中国投资医药研发



1 从2011年和2014年研发费用以及2012-2014年累计资本支出推测
2 中国大中型制药企业
资料来源：RDPAC调研；中国科技统计年鉴

- 中国政府用于“重大新药创制专项”的年投入（80亿元人民币）[9]。

- 2010年，中国所有大中型医药企业（包括本土和跨国企业）研发总支出（140亿元人民币）的一半[5]。

- RDPAC成员在中国销售收入的10%，是中国政府为本土骨干企业制定的“十二五”期间研发投入目标（5%）的两倍[1]。

内容摘要5：

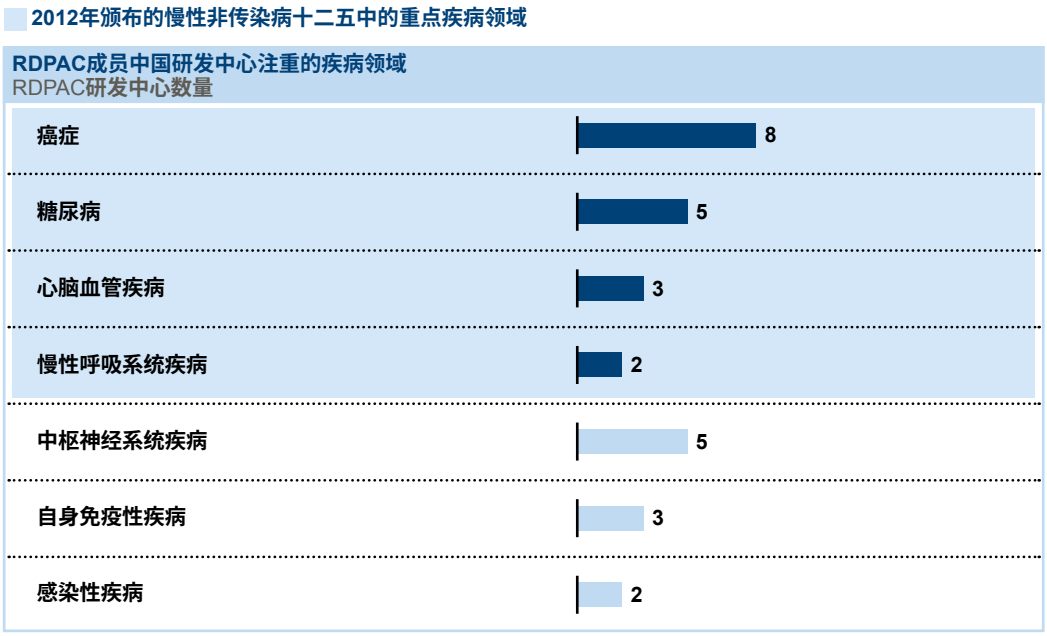
RDPAC成员与中国本土研究机构结成了超过210对合作伙伴关系，在中国致力于投资政府重点关注的疾病领域。

（二）积极组织研发，攻克重点疾病

国家要求中国医药产业将研发重点放在满足中国患者突出的医疗需求上。2012年，《中国慢性病防治工作规划》的工作重点指向四大高死亡率疾病：心脑血管疾病、肿瘤、糖尿病和慢性呼吸道疾病。“重大新药创制专项”除重点突出对上述疾病的研究外，还特别关注传染病、中枢神经系统疾病和自身免疫性疾病。

中国患者的需求是RDPAC成员在华的首要努力方向，其研发焦点与上述中国政府提出的重点领域完全吻合。目前，至少有12家RDPAC成员的研发中心将研发目标锁定在《中国慢性病防治工作规划》或“重大新药创制专项”列出的重点疾病领域上。此外，至少有4个研发中心致力于攻克胃癌、肝癌和肺癌这三类在中国发病率显著高于其他国家的医学难题。

图表3：RDPAC成员长期以来的研发聚焦中国的重点疾病领域



资料来源：RDPAC调研

（三）聚焦重点疾病，广泛开展合作

RDPAC 成员与本土研究机构开展了广泛合作，以增强后者在重点疾病领域的科研能力。2011年，RDPAC成员公司与大学、医院及科研机构共建立了210对合作伙伴关系。这些合作覆盖范围广泛，从联合研发到向本土合作伙伴转让关键知识产权（如小分子化合物库）等。一位中国知名学术机构领导曾说到：“我们关注的焦点始终是患者的需求，而不仅仅是创新本身。我们与包括跨国公司在内的合作伙伴的合作都是基于这一目标。”

这些多方面、深层次的合作成功营造了一个充满活力的科研创新环境，并在互利共赢的基础上，同时提高了RDPAC公司和本土研究机构双方在科研创新上的影响力。跨国公司和本地大学构建了很多这样的合作伙伴关系，引用一位中国知名学者的话：“我们已经不再仅仅是把资产交到跨国合作伙伴手里，今天我们的合作方向是共同开发，共同拥有知识产权成果，来成就更深入的伙伴关系和更长期的可持续性合作。”

（四）助力技能和人才培养，创建创新型本土企业

内容摘要6：

RDPAC成员通过提升科研技术水平、培育高级管理人才以及协助拓展国际市场，有力推进了中国创新型企业公司的发展。

随着近年来中国研发生态系统的不断改善，拥有自主创新能力的中国本土医药企业不断涌现，日益繁荣。RDPAC公司始终致力于帮助推动这一趋势的发展，不仅在培养人才上积极贡献力量，同时也大力帮助本土企业走出国门、走向世界。

RDPAC成员的研发中心为数以千计的中国科研人员提供了一流的工作环境，帮助这些科研人员成为中国下一代创新力量的源泉。作为全球协同研发团队的成员，本土科

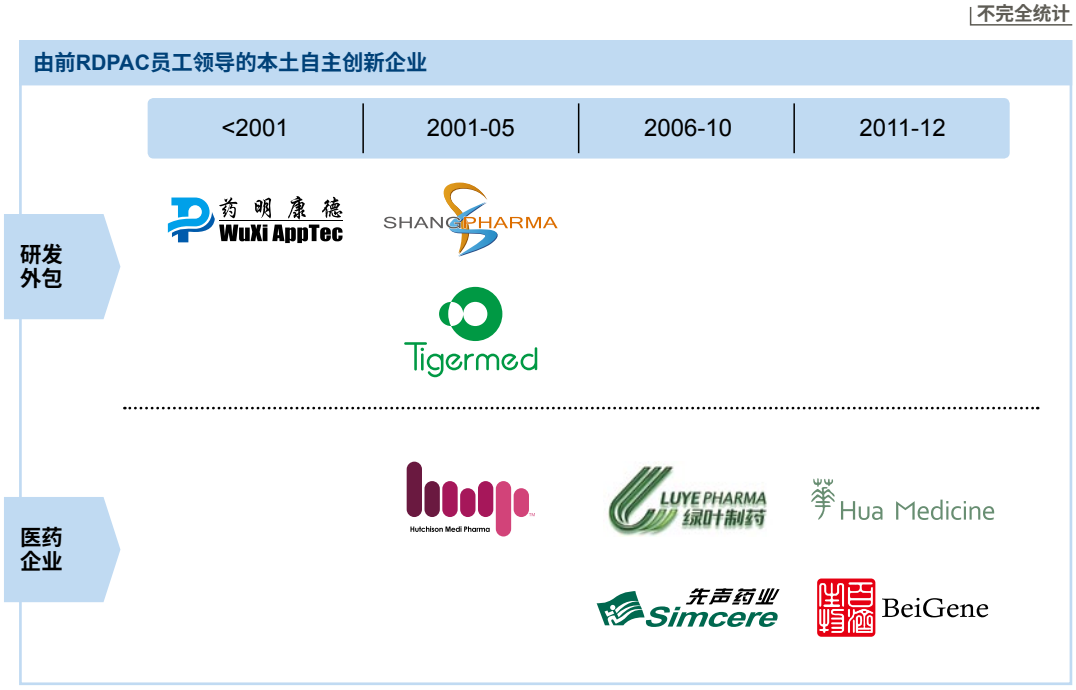
学家与来自世界各地的科学家们形成良好互动，共同解决最尖端的科技和医疗难题，并且获得在顶级生物医学研究机构如哈佛医学院的深造机会。这些经历极大提升了本土人才的专业技术水平，帮助他们成长为成熟的科学家。如一位国内学术专家所言：“中国每年有许多高校毕业生，但拥有全方位的创新经验，并且有能力领导研发团队、实现创新的人才却不多，跨国公司为我们的人才提供了一个很好的锻炼平台。”

这些研发中心还吸引了大量的海外归国人才。RDPAC成员在中国的研发人员中，归国人才的比例占到约20%，他们中的许多人拥有广泛、深厚的行业经验，从而进一步提升了中国医药产业的创新能力，加快了中国融入全球创新体系的步伐。

RDPAC成员还为处于研发价值链各环节的人才提供培训机会，特别是在提升中国医生水平方面发挥了重要作用，包括让中国医生参与创新药物试验，将中国临床实验机构融入国际临床实验中，及提供定期的药品临床试验管理规范（GCP，Good Clinical Practice）和实用临床培训等。据统计，他们已经为中国373个GCP机构的首席研究员（principle investigator）提供了600多场培训，并为其中的150多位提供了高强度的训练课程。这些课程显著提升了国内医生的科研能力，帮助他们达到国际标准，同时也通过提高临床能力保障了中国患者的安全。除培训医学工作者外，RDPAC成员还在价值链的各个环节上开展广泛合作，分享经验，帮助提高合作伙伴（如临床化验供应商）的行业标准。

RDPAC成员还起到了本土企业的人才孵化器的作用。不少前RDPAC员工通过成立自己的公司或者在本土企业中担任领导者，为推动本土医药产业的创新作出了积极贡献。如，致力于抗肿瘤药物研发的百济神州，致力于糖尿病药物研发的华医药，以及致力于外包研发的泰格医药。一位政府官员曾指出：“健康、双向的人才流动将是未来几年中国研发事业走向更大成功的一个关键因素。”

图表4：RDPAC成员与本土企业间的人才流动促进本土企业创新的发展



（五）帮助本土企业进军国际市场

中国本土制药公司一直希望能成功进入国际市场，RDPAC成员的国际视角和丰富经验使它们成为中国本土企业实现上述目标的宝贵合作伙伴。例如，和记黄埔医药近期与一家RDPAC成员企业联合签署了一项合作协议，就一个癌症候选药物在全球开发、审批、和销售等方面进行广泛合作。按协议规定，和黄医药将继续主导该项目在中国的研发活动，同时其合作伙伴将利用其在海外市场强大的研发、注册及商业化能力为和黄医药迈入国际市场铺平道路。另外一个案例是华医药签约得到一家RDPAC成员公司的一个糖尿病候选药物的全球开发许可。

随着越来越多的中国企业期望走向国际舞台，我们预期这种合作必将进一步增加。按一位中国本土企业高管所说：“我们对于将一流产品推向国际市场的前景热切期待并充满信心，并且欢迎与跨国公司的合作来加快这一进程。虽然我们可以靠自己的力量走出去，但可能需要花费多得多的时间。”

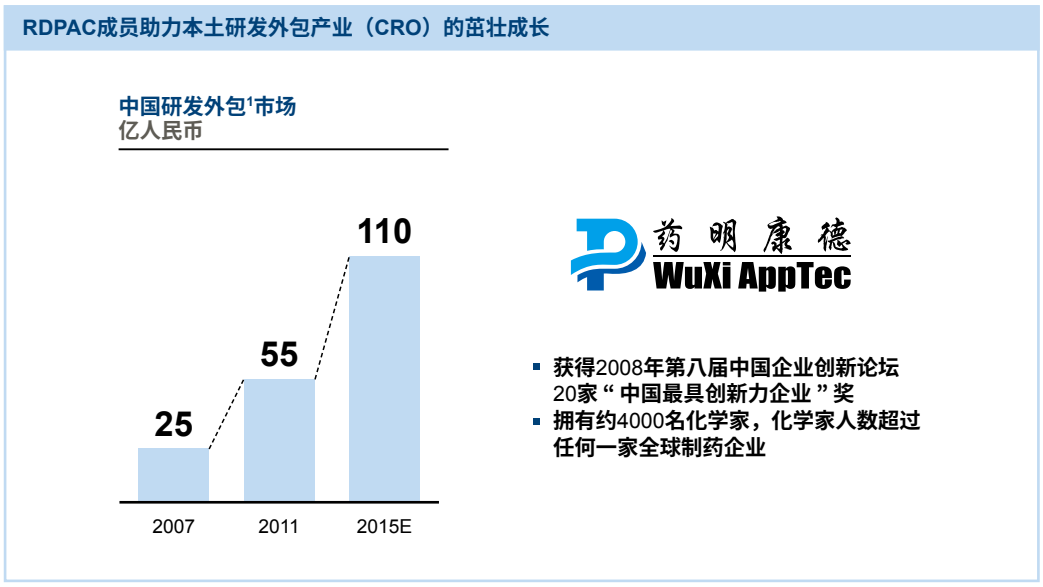
（六）助推中国创新型研发外包产业的起步和发展

内容摘要7：

RDPAC成员帮助中国创建了一个总规模达60亿元、有自主特色的研发外包产业。

在过去不到10年间，中国本地研发外包企业——无论是专注于早期研究还是专注于临床开发的企业——均呈现了指数级的增长，目前这一产业规模已经高达60亿元人民币，并且预计在未来5年内可能还会翻番，其迅猛的发展势头不亚于任何其它创新领域。在本土研发外包企业中首屈一指的药明康德曾荣获“20家中国最具创新力企业”的殊荣，其旗下拥有4000多名化学家，这一数字甚至超过了全球任何一家制药公司。

图表5：RDPAC成员通过合作助推本土研发外包产业的成长



1 包括早期研发和临床服务

资料来源：RDPAC调研；花旗银行投资分析报告

活跃的研发外包产业的存在，对于那些致力于谋求创新的中国本土企业来说大有裨益。因为常年与RDPAC成员合作，中国研发外包企业各项运作能力均已达到国际标准，使得那些尚未拥有全面研究开发能力的本土企业，可以充分利用外包企业所提供的世界一流的研发能力开展药物创新活动。同时，本土领先的外包研发企业正在开拓集成服务模式，以提供一个开放式的研发平台，使得任何公司，无论规模大小，都有机会借助这一平台参与创新。这个平台的建立，将成为中国本土制药企业创新的催化剂和助推器，帮助医药企业大幅降低创新的技术门槛。正如一家领先的研发外包企业创始人所说，“我们的集成服务将为任何有好点子的公司提供一个参与研发与创新的开放平台，这是我们做为一个公司的最终目标。”

RDPAC成员为研发外包公司提供了稳定的市场需求，他们所贡献的收入占一些领先的研发外包企业收入的90%以上。RDPAC成员还为国内研发外包公司提供必要的技术转让以助其更好发展。一位研发外包企业高管在回顾其公司创建初期时表示：“在技术方面，我们所学的每一件事都得益于跨国公司与我们的合作。”

帮助中国成为全球医药产业创新的领军者

融入全球研发体系是当今取得创新成功的关键。政府很早以来就鼓励国内企业通过与国际领先企业之间的合作来推动创新。华为的成功就是开展国际合作的典型代表。作为创新领导者，华为的获批专利数目前排名世界第四位。华为的第一个拳头产品，即1994年问世的C&C08电话交换器，就得益于1989年与上海贝尔建立的合作关系。此后，华为与其它十几家全球领先企业建立了合作关系，包括在2001年与NEC和松下成立合资公司，共同研发3G技术，以及在2005年与英特尔合作开发WiMAX无线网络[10]。RDPAC成员十分乐于与本土医药公司建立起类似的全球合作关系，帮助中国成为世界创新的领军者。

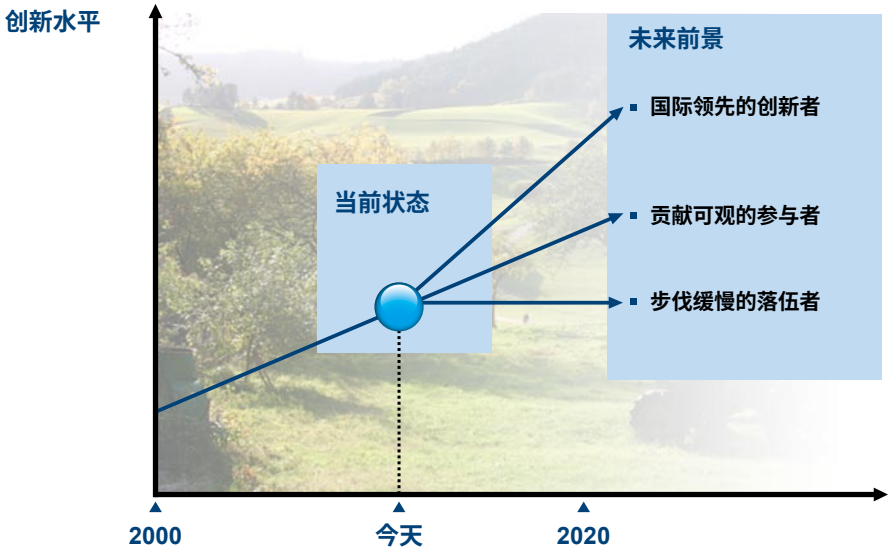
（一）中国正处于创新征程的十字路口

中国的医药产业正处于发展的关键阶段，今天的决策必将影响明日的产业格局。在创新征程的十字路口上，本土制药企业可以选择仅仅开发面向中国市场的药品，或将“立足中国，服务全球”这一宏伟蓝图设定为自己未来的发展目标。

面对这一形势，中国政府需要立足于现实，制定长远可行的决策计划，既为中国13亿人民提供安全、有效、方便、价廉的医疗卫生服务，又为医药产业创新活动建立切实的激励机制。

从“封闭的本土市场”到“全球医药创新伙伴”，未来的中国可能面临如下三种非常不同的情况。

图表6：中国医药产业正处在发展的十字路口



在最理想的情况下，政府在经济、基础设施及监管等方面做出英明的决策，从而推动中国的创新达到崭新的高度。到2020年，充分融入全球创新体系。在未来的几十年中，中国将达到美国目前在全球创新体系中的地位，成为全球创新体系中一支举足轻重的力量。中国将持续而稳定地为全球市场提供创新药物，造福全世界人民。

在第二种情况下，中国在本土市场的研发势头保持活跃，但由于政策上的限制，不能充分参与到海外市场。中国企业为创新作出了可观贡献，但却不能充分发挥出其在全球市场上的潜能。

在最差的情况下，中国企业因政策限制而被隔绝于全球创新体系之外，仅限于在自己的本土市场发展。中国企业未能成功参与到全球研发的价值链上，同时也对顶级研发人才和投资者缺乏吸引力。如果这一情况成为现实，将意味着中国政府错失了通过创新来满足中国患者的需求以及拉动国内经济增长的良机。

（二）实现跨越式发展

中国正面临着打造全新的产业生态系统，赶超西方国家，实现跨越式发展的绝好机会。在上述第一种情况下，中国的现代医药研发历史相对较短并没有太多历史遗留体系的牵绊，因此可以避开西方国家曾经走过的弯路，借鉴全球的最佳做法，建立起一个有中国特色的产业体系。

要出现这样的机会，中国政府可以充分利用体制制度优势，发挥中央在政策制定和执行上的强大领导力，并借助于RDPAC成员丰富的研发经验和雄厚的实力，为中国创新作出贡献。例如，一个值得推荐的做法是构建起完整、开放式的患者数据库。这样的一个体系不仅有助于保证患者的安全，而且可以为医药企业提供丰富的患者数据来源，从而帮助医药企业通过数据分析来指导未来的研发方向。这一数据库的形成必将帮助中国在全球创新体系中建立起独特的优势。这样一个体系在任何国家仅依靠行业内的某个或几个企业努力是不可能的，必然需要政府的大力支持和引导。此外，国家也可以考虑将关注重点集中在少数几个需求尚未得到满足的医疗领域上，启动全国性项目，鼓励企业和研究机构在这些疾病领域开展合作，并且制定出鼓励合作的激励机制。RDPAC成员作为中国政府的长期合作伙伴，非常愿意提供创新设想，并开展交流，为中国的创新作出贡献。

（三）关于提升中国制药企业研发创新能力的建议

内容摘要8：

展望将来，中国要成为真正的全球创新者，不仅需要提供不断完善的基础研发配套设施，更要注重建立支持创新的监管环境、制定合理的创新激励机制以及加大对知识产权的保护力度。

中国政府已明确表达期望成为全球领先医药创新强国的决心。为实现这一宏伟目标，除了要进一步完善研发基础设施外，还必须建立支持创新的监管环境，制定合理的创新激励机制，并强化对知识产权的保护。RDPAC成员将全力支持中国政府实现这一目标，并期望能有机会与中国政府展开多方面的合作，分享在国际市场上推动创新的先进经验。这一思路与产业“十二五规划”中的重点任务高度吻合。

1、构建监管体系，鼓励创新活动

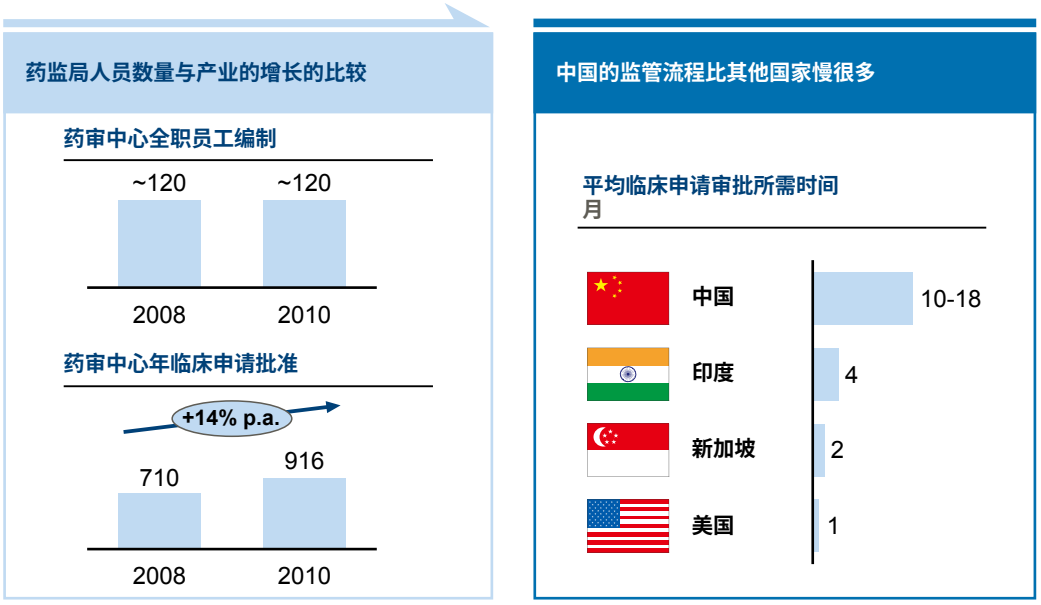
近年来，国家药监局在提高效率和增强透明度等方面取得了显著成效。药品评审中心实施了机构重组，加强了与医药企业间的沟通和对话，并向药品开发企业发布了数个技术指南。目前，评审中心正在采取进一步鼓励创新的举措，包括制定具体的审批流程、完善临床试验步骤等。中国在药品创新方面能否成功，将在很大程度上依赖于能否进一步成功构建鼓励创新的监管体系。如一位来自本土制药企业的高级管理人员所说：“改善中国研发环境，亟需解决的问题是改善药监局的监管体系，其它的举措皆可在此之后实施。”

中国可以考虑适当调整监管条例，加强与全球监管范例的一致性，强化提升临床配套设施，来为本土企业进入国际市场奠定良好基础。具体建议如下：

- **缩短临床试验申请（CTA）的审批时间。**目前，中国临床试验申请审批时间在10-18个月之间，比国际平均的时间要长很多，这已成为中国本土企业和在华跨国企业药品研发的一大瓶颈。若国内临床试验申请的审批时间能够与国际水平相当，将会极大地提升中国的创新能力，缩短药品开发、上市的时间，并能更快、更早地惠及患者。

审批时间过长的根本原因在于，国内创新研发活动不断增加，国家药监局的处理能力却始终保持不变。2008年至2010年间，临床试验申请审批的案例数以每年14%的速度增长，然而在此期间，药审中心的人员编制却没有相应扩充[11,12]。随着政府加大对医药行业创新方面的投资，药审中心的人员编制也应得到相应的扩充。正如一位高级研发管理人员所指出的：“中国的研发活动正以前所未有的

图表7：中国监管机构人员数量与产业的快速增长不相符，可能会为创新制造瓶颈



资料来源：药监局年度报告

速度发展，我们为什么不能把新增投资中的10%用于提升药监局的能力上？这项投资必然进一步提高研发和创新的总体环境。”

另一个缩短临床试验申请审批时间的建议是修改中国临床试验申请的修正流程。在其它国家，政府在企业首次递交了申请之后都可以受理临床试验的修正申请，但是在国内，若临床试验方案出现调整，企业就必须递交新的临床试验申请，从而导致了公司和监管方的大量重复劳动。

- **放开进口新药在中国开展一期临床试验的管制。**目前，国内一期临床试验的基础设施尚不健全，很大程度是由于对临床试验的监管过于严格，可以说国内关于开展首次人体试验（FIH）研究的严格限制政策已经成为药品创新从“实验室到病房”的一大障碍。在确保患者安全的前提下，帮助中国建立起更成熟的早期临床基础设施，对支持本土企业研发工作意义重大。正如一位研发高管所言：“我愿意做更多的专门针对中国患者的药物研发工作，但现在我需要在中国完成‘发现’阶段的工作，然后去韩国或日本完成一期临床，再回到中国完成后期临床试验。这样浪费的时间太多。”放开针对进口新药的首次人体试验政策限制，将有助于中国医药企业更好的开展一期临床试验，大规模开发药物。

中国可以借鉴其它国家的成功经验，通过严格监控实验过程来提高一期临床的安全性。比如，韩国成立了政府运营的临床中心，在严格受控环境下进行一期临床，以确保患者安全。

- **参照人用药品注册技术要求国际协调会（ICH）的严格标准，统一监督流程和要求。**中国政府已申明自愿参加亚太经济合作组织（APEC）医学监管的统一行动，以确保组织内区域在2020年之前实现统一的制药和医疗仪器产品的监管流程。遵循国际标准可以帮助国内的企业提高能力，成功进入全球市场。因为实施统一的标准就意味着任何一家制药企业若能达到所在国的标准，也就达到了国际标准，从而帮助企业更快进入国际市场。

- **建立起一个药物审批的上市许可人制度。**目前在中国，药品上市许可与生产许可证相互捆绑在一起。开发出创新药品的企业必须建立起自有的生产能力或者是通过收取一次性费用将产品转让给另一家生产商，产品才能上市。并且在产品上市后开发企业就不能再获得任何收入，也无需对患者的安全承担任何责任。这种规定与鼓励在国内专注研发、但不具备生产能力的创新企业开展研发活动的政策不符。同时，因为药品转让后企业不再需要对它们所研发的产品负责，并且就只能收取一次性的转让费用，他们在研发上所能获得的回报也就极为有限。目前上市许可体系在美国、欧盟和日本市场上被广泛推广，这一体系允许创新药企业委托另一家企业生产产品，但是仍然保留市场销售的权利，并要求其承担患者安全的责任，值得中国借鉴。

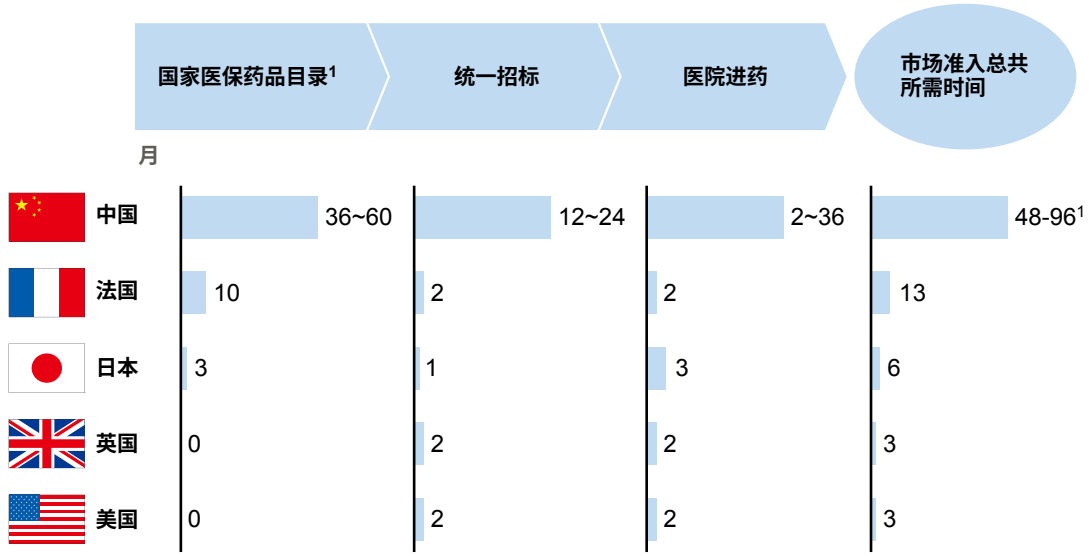
2、制定激励机制，合理奖励创新行为

医药创新是一个复杂、昂贵而且风险很高的过程，每个新药在成功问世之前，其研发过程平均耗时10至15年，成本超过80亿元[13]。改善患者治疗效果是这些研发活动的终极目标，但同时也需要如定价、市场准入和税收优惠等有效措施来保证研发活动的可持续性。在上述这些方面，我们的具体建议如下：

- **通过合理定价奖励创新，确保为患者提供优质安全的药品。**由于只有20%的新药能够收回研发成本，国家需要制定一些面向医药企业的激励措施，使它们愿意承担新药研发的成本和风险[14]。公平的定价有助于培育一个强大的、以创新为驱动力的医药行业。当前“成本加成法”的定价模式无法准确反映研发的费用以及药品创新企业在药品研发过程中所承担的风险，不利于激励企业创新，并有可能将中国隔绝于全球创新体系之外，减少了中国患者获得优质药品的机会。日本等国在强制降价环境下对专利药品实施价格保护政策，使创新型企业有足够时间收回他们的研发投入，这是一项非常重要的保护机制。在中国药品的市场准入慢于其他国家的现实情况下（见下一段），这一政策的实施显得尤为重要。我们需要认真考虑在专利期后设立几年的价格保护延续期的可行性。质量不同，价格有差异，是另一个鼓励企业创新的重要机制，也是保障患者安全的基础。建立和维护综合性的质量管理体系，保障医药产品质量提升的可持续发展空间，需要大量的资金投入，但这个体系的建立正是因质定价的前提，因此为了提升患者安全，需要政府坚持不懈地开展下去。一名政府高级官员曾经这样说过：“医药产品必须遵循市场经济的规则，充分考虑研发、制造和销售等各个环节的费用和成本，确保医药产品获得合理的利润。只有这样，医药产业才会越做越强。”

- **通过快速市场准入鼓励创新，帮助患者尽早得益于新药。**医药研发企业需要新药能快速获得市场准入，从而确保其后续的创新产品能够获得持续的资金支持。在中国，创新药品在到达渠道终端之前，必须首先被列入国家药品报销目录（NRDL），然后完成以省为单位的药品统一招标和以医院为单位的进药的流程。目前中国的国家药品报销目录每4到5年才更新一次，而德国、英国和新加

图表8：创新药在中国上市惠及患者的时间要比其他国家慢4—8年



1 医保目录遴选和医院进药在中国可以平行开展

资料来源：RDPAC; FDA; EMA; 访谈

坡等国则是滚动更新其报销目录，其它如西班牙、意大利和韩国等国也至少每年更新一次。中国的药品招投标流程也十分漫长，一般需耗时1到2年不等，而在其它国家，仅需半年就可以完成药品招投标工作。再加上后续医院进药流程所需耗费的时间，在中国获得市场准入时间要比其它国家晚4-8年不等。这种漫长的市场准入流程大大减少了创新类化合物的有效专利时间，同时也会影响企业投资创新的动力。

- **为研发创新提供税收优惠。**这一激励机制在全球得到广泛应用，具体如美国、新加坡等国都有大力扶持政策。中国的税收政策已经规定了研发费用减免的相关制度，但企业在实施过程中会遇到一些现实挑战。比如，哪些费用应被视作“研发费用”模糊不清，导致创新型企业无法从该项政策中实际获益。简化研发税收减免的流程和步骤，使得这一政策具有更加实际的指导意义和操作可行性，会在鼓励创新方面大有收益。

3、完善知识产权环境（IPR），保护创新

知识产权保护是任何一种成功的研发模式都必不可少的部分。完善的知识产权保护机制是对研发企业所投入的时间、成本和所承担的风险给予的充分尊重和回报的保证。给予企业有力的知识产权保护，将大大激发企业对研发投入的热情。同时可以成为一个强有力的政策工具，帮助政府推动医药行业向价值链上游发展，并有效地鼓励本土医药骨干企业实现研发投入达到收入5%以上的目标。

自2001年加入世界贸易组织以来，中国稳步改善了医药产业的知识产权环境，保证化合物和制药产品可享受20年的专利保护期。进一步加强知识产权的保护，既符合中国自身的利益，也有利于鼓励产业进一步创新。中国政府可以考虑以下数个方面进一步推进知识产权环境的完善：

- 减少新药定义的模糊性，如澄清新化学实体（NCE，New Chemical Entity）等概念，并强化对创新药物监管数据的充分保护，以实现《中国药品管理法》的相关规定。

- 更好地将创新药品的监管审批流程和专利管理体系相结合，强化专利联网系统，避免或减少耗时耗力的法律争端。

- 遵循国际知识产权保护惯例，维护和强化医药知识产权保护机制，确保生物医药产品的知识产权得到充分保障。对于那些侵犯知识产权的行为，应追究其责任并给予相应的惩罚。

总结

内容摘要9：

中国政府、本土公司以及RDPAC成员有一个共同的愿望，希望中国成为引领全球医药创新的领军者。RDPAC期待有机会和中国政府共同努力、协同发展，实现这一愿望，惠及更多中国患者。

中国政府、本土企业以及RDPAC成员有着共同的愿望，即将中国建设成为全球医药创新的领军者。政府、本土企业和跨国公司共同开展的一系列创新举措已呈现出良好的发展势头，中国正朝着这一目标大步迈进。随着创新研发投入持续增加，中国的外包研发行业不断拓展服务，大量本土人才及海外归国人才为创新提供强有力的人才资源支撑，中国市场的巨大潜力不断推动中国融入全球创新体系，中国医药企业的创新必将吸引到更多资源，加快中国实现创新目标的步伐。

RDPAC 很高兴能有机会与中国政府合作，培育一个强大的全球创新医药产业，造福中国患者。我们将携手前行，为实现中国医药产业的创新愿景不懈努力！

参考文献

1. RDPAC内部数据
2. 中国教育部2010年统计数据，
3. 经济日报，2011年12月13日
4. J. Qi, et. al., "Innovative drug R&D in China", Nature Review Drug Discovery, 2011, 10, 333-334
5. 中国科技统计年鉴（2011年）
6. 花旗银行投资和分析报告
7. 医药工业“十二五”发展规划，“十二五”生物技术发展规划
8. GBI Source
9. 中国证券报，2012年6月29日
10. Ying Zhang, "Alliance-based Network View on Chinese Firms' Catching-up: Case Study of Huawei Technologies Co. Ltd.", United Nations University Working Paper Series
11. 药品注册审批年报（2009/2010年）
12. 医药经济报，2011年4月1日
13. Improving Global Health through Pharmaceutical Innovation 2012, IFPMA
14. Pharmaceutical Industry Profile 2012, PhRMA

缩写

APEC	亚太经济合作组织
API	原料药
CAEFI	中国外商投资企业协会
CDE	药品评审中心
CNS	中枢神经系统
CRO	研发外包机构
CTA	临床试验申请
CV	心血管
FIH	首次人体试验
GCP	药品临床试验管理规范
GLP	药物非临床研究质量管理规范
GMP	药品生产质量管理规范
ICH	人用药品注册技术国际协调会议
IPR	知识产权
NCE	新化学实体
NDA	新药申请
NRDL	国家药品报销目录
R&D	研究与发展
RDPAC	中国外商投资企业协会药品研制和开发行业委员会
SFDA	食品药品监督管理局
WTO	世界贸易组织

RDPAC成员公司名录

雅培
艾尔建
安斯泰来
阿斯利康
百特
拜耳医药保健
百健艾迪
勃林格殷格翰
百时美施贵宝
新基医药
中外制药
杰特生物医疗
第一三共制药
卫材
礼来
费森尤斯卡比
GE医疗
健赞
葛兰素史克
匈牙利吉瑞大药厂
益普生
利奥制药
灵北
默克雪兰诺
默沙东
萌蒂
诺华
诺和诺德
辉瑞
罗氏
赛诺菲
参天
施维雅
住友
武田
优时比
西安杨森

ABOUT RDPAC

The R&D-based Pharmaceutical Association Committee (RDPAC) is a committee of the China Association of Enterprises with Foreign Investment (CAEFI). It is a non-profit organisation made up of 39 member companies with pharmaceutical R&D capabilities.

Between them, RDPAC members have 49 plants and 30 R&D centres, they have invested 20 billion (RMB) during the 11th Five Year Plan and introduced 543 New Molecular Entities, Altogether, they manufacture and sell 2817 different medicines.[1]

RDPAC VISION- HEALTHIER CHINA THROUGH INNOVATION

RPDAC's vision is to be a valued partner in delivering the "Healthy China 2020" goal to improve the health and quality of life of the people in China.

- Provide our high-quality/innovative healthcare products and services in a socially responsible and commercially viable manner;
- Commit to securing patients timely access to innovative and high quality drugs;
- Achieve highest standard of integrity for ethical research and business practice;
- Contribute to the growth of the biopharmaceutical sector in China;
- Support the development of a sustainable healthcare system in China.

KEY MESSAGES

1. The Chinese government has boldly committed to moving the pharmaceutical industry up the value chain towards innovation and has made good progress towards this ambitious goal.

2. RDPAC members have been long-term innovation partners with China through continuous contributions to patient safety, drug quality and treatment standards for Chinese patients.

3. Pharmaceutical R&D innovation today is conducted through global networks, and RDPAC members are integrating China into the global R&D innovation system.

4. RDPAC members have rapidly increased their investments in China R&D to 8 billion RMB per year, accounting for >50% of China's large and mid-size pharmaceutical industry R&D spending and creating ~3000 direct high value-added R&D positions.

5. These investments are primarily in disease areas identified by government and we have been ongoing partners to local research institutions in these areas with more than 210 partnerships.

6. RDPAC members are helping to build innovative local Chinese companies by developing expertise, seeding talent and taking them global.

7. RDPAC members have helped create a distinctive RMB 6 billion local Chinese CRO industry.

8. To become a truly global innovator, in addition to making steady progress towards a thriving scientific infrastructure, China needs to provide a supportive regulatory environment, reward innovation and continue to protect IPR.

9. The Chinese government, local companies and RDPAC members share a similar vision to see China become a leading global innovation partner. RDPAC welcomes the opportunity to continue to partner with the government to reach our joint aspiration for the benefit of Chinese patients.

Table of Contents

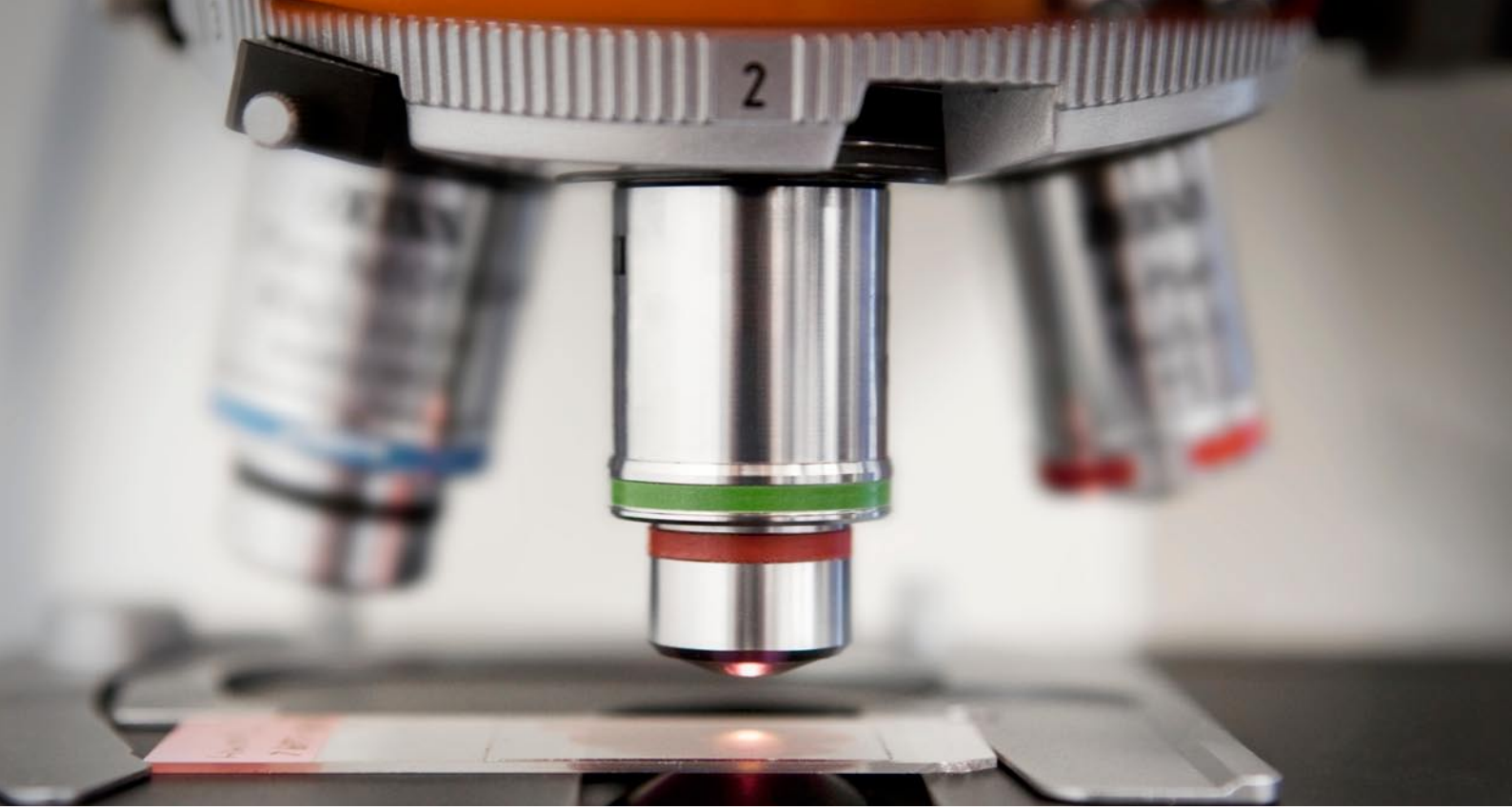
Executive Summary

The Chinese government has a vision: to move the pharmaceutical industry from one based on low-cost manufacturing to one that is a dynamic source of global innovation. To meet the dual challenges of building a knowledge-based economy and the rising healthcare needs of its 1.3 billion population, China has articulated ambitious and tangible objectives towards an innovation-based pharmaceutical industry. The Major New Drug Development project aims to deliver 30 new drugs by 2015 and government officials have expressed a desire for R&D capabilities to reach those of first-tier countries by 2020. At the heart of this R&D effort is a commitment to address the needs of Chinese patients: the country's leading mortality causes are also the priorities for R&D innovation.

China's government has made strenuous efforts towards its innovation goals. China produces 49,000 PhDs a year and initiatives like the "Thousand Talent Plan" help attract overseas talent to China.[2] Large investments in infrastructure have also been made with the establishment of at least 22 biomedical high-tech parks.[3] Standards have been steadily rising as shown by the number of Good Clinical Practice (GCP) certified sites increasing by ~70% in the last five years. Early successes include 5 New Drug Applications (NDAs) approved by SFDA from 2007 to 2010, and 24 novel drugs discovered in China with both China and global US/EU patents which are currently in clinical trials.[4]

RDPAC members share and are partners in the Chinese government's vision for the industry. RDPAC members are leading global companies in R&D innovation and for many years have brought innovation to China in the form of advanced medications to meet Chinese patients' needs, and innovation in standards to improve the quality of care and raise quality across the industry. The innovative drugs that RDPAC members introduced help set the foundation for China's generics industry. Today, RDPAC members are integrating China into the global R&D innovation network. They are committed to China for the long-term, with planned R&D annual investment accounting for >50% of 2010 China's large and mid-size pharmaceutical industry R&D spend.[5] They are embracing the government's emphasis on priority disease areas, and transferring knowledge, capabilities and standards through over 200 active public-private relationships. RDPAC members have developed talent that has seeded local companies such as Beigene, Hua Medicine and Tigermed, and partnered with local companies to enter global markets. They have been instrumental in building a distinctive RMB 6 billion local Chinese contract research organisation (CRO) industry that lowers the barrier for Chinese companies to pursue R&D innovation.[6]

China's pharmaceutical industry is at a crossroads. Industry ambition is rising, driven by many converging forces that include government focus, infrastructure growth, availability of talent and increasing investment. However, some elements of the policy environment are misaligned with this ambition and risk limiting future innovation. Decisions taken today will determine the industry outlook tomorrow. In addition to making steady progress towards a thriving scientific infrastructure, China will need to provide a supportive regulatory framework to foster innovation, proper incentives and rewards for innovation including fair pricing and timely market access, and stronger protection for intellectual property rights (IPR). RDPAC members are honoured to be part of China's historical movement towards innovation and hope to continue to contribute to the innovation dialogue.



CHINA HAS MADE A BOLD COMMITMENT TO INNOVATION

After two decades of extraordinary growth, China has become the world's second largest economy. The Chinese government now wishes to take growth to even higher levels by making the transition from a manufacturing-based economy to a dynamic innovation-driven economy across many industries. At the same time, China faces the formidable task of providing quality healthcare to 1.3 billion people with rising incomes and expectations.

Message 1

The Chinese government has boldly committed to moving the pharmaceutical industry up the value chain towards innovation and has made good progress towards this ambitious goal.

China's vision for innovation

Given this dual challenge, the government has boldly committed to moving the pharmaceutical industry up the value chain towards innovation. This is the driving force behind the sustainable development of the pharmaceutical industry. China has articulated ambitious and specific goals in support of this vision:

- By 2015, the Major New Drug Development project seeks to deliver 30 innovative drugs, 30 generic drugs that

address major unmet health needs, and over 200 improvements to frequently-used drugs.

- By the same date, the 12th Five Year Plan envisions China being in the global top three for global patents and biomedical publications, with export growth of 20% per year and key local players increasing investment to at least 5% of revenues in R&D from ~1% today.

- By 2020, China aims to upgrade pharmaceutical R&D capabilities to approach those of first-tier countries.

To achieve these goals, the 12th Five Year Plan outlines five key levers for implementation[7]:

- Increasing financial incentives for innovation, strengthening implementation of R&D tax benefits and encouraging private capital investment in innovative pharmaceutical companies.

- Enhancing processes for drug review and approval, improving quality standards and regulatory compliance.

- Strengthening talent attraction and cultivation, attracting overseas talent and encouraging healthcare professional training.

- Encouraging collaboration between industry, universities and research institutes, accelerating commercialisation and increasing R&D capabilities.

- Broadening international collaboration, promoting strategic partnerships with multinationals to develop new products and enter global markets.

Good and steady progress to date

China has swiftly begun to implement this innovation vision, improving its innovation infrastructure, talent base and standards. The last decade has seen a surge of development, with at least 22 biomedical hi-tech parks established across the country to promote pharmaceutical innovation. Through tax incentives, subsidised land and policy incentives such as the fast-track channel for reagent imports, the parks are working to co-locate a critical mass of innovative pharmaceutical companies and build an environment for collaboration.

China is also building a vibrant pool of talent to fuel innovative R&D. It already produces the second largest numbers of PhD graduates globally. Initiatives such as the "Thousand Talent Plan" and local variations have attracted many high profile returnees with deep scientific and management experience to help build an innovative industry in China.

The Chinese government is also steadily raising quality and safety standards. New Good Manufacturing Practice (GMP) and Quality Control standards have been released in the last two years, and the number of Good Clinical Practice (GCP) certified sites has increased by ~70% in the last five years.

While still at an early stage, these policies to stimulate local innovation are already bearing fruit. Early successes include 5 New Drug Applications (NDAs) approved by SFDA from 2007 to 2010, and 24 novel drugs discovered in China with both China and global US/EU patents which are currently in clinical trials[4].

RDPAC MEMBERS HAVE BEEN LONG-TERM PARTNERS IN INNOVATION

Message 2

RDPAC members have been long-term innovation partners with China through continuous contributions to patient safety, drug quality and treatment standards for Chinese patients.

RDPAC shares the government's desire to see China become a leading partner for pharmaceutical innovation. The 39 RDPAC members have long been China's partners in innovation, contributing to improving patient safety, drug quality and treatment standards.

Introducing best practices to raise quality and safety standards in China

RDPAC members have played an active role in consistently driving drug manufacturing innovation that raises the quality and safety standards in China. They have introduced Good Manufacturing Practice (GMP) to their own sites. These significant innovations have resulted in quality differentiation for these products. RDPAC members are also actively assisting local partners to help raise product quality for Chinese patients. As one example, by applying global Active Pharmaceutical Ingredient (API) standards to Clinical Research Organisation (CRO) partners and offering training to their employees, they have raised API standards across CRO partners. This in turn benefits local companies who use these same CROs for their work in China.

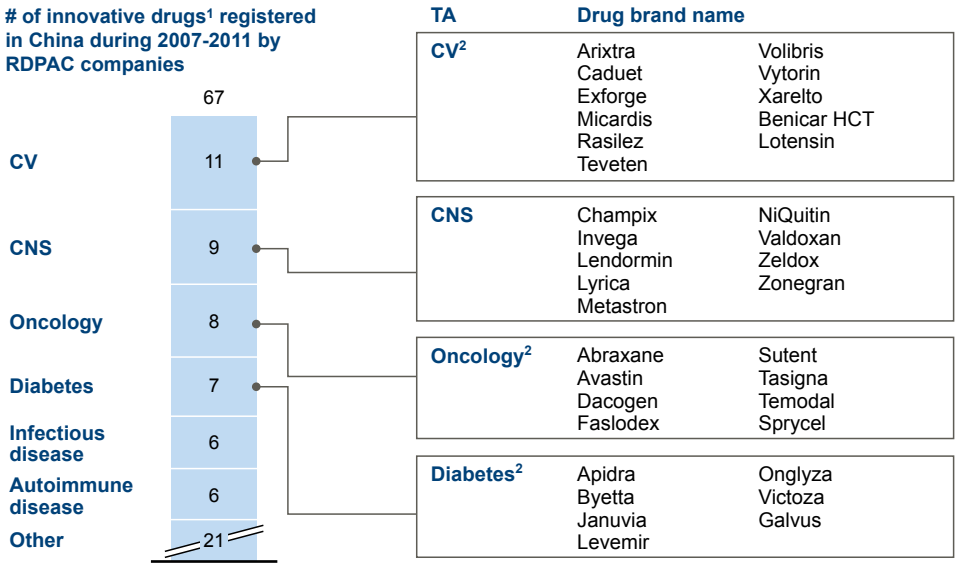
Raising treatment standards and bringing innovative new drugs to Chinese patients

Since entering the Chinese market, RDPAC members have raised patient treatment standards by bringing original products to market and investing in new therapeutic classes with physician education even when these markets had small commercial value. For example, RDPAC members helped develop new treatments for atypical anti-psychosis in China. Patients have benefited from these treatments with the value of treatments growing from RMB ~58 million in 1999 to RMB 2.3 billion today.[8] The local industry has also benefited by participating in these treatment classes and 17 of 25 products on the market come from non-RDPAC companies.

In the last five years, RDPAC members have introduced at least 67 innovative drugs for the benefit of Chinese patients, representing over 80% of all innovative drugs introduced to China during this period.[8] Innovative drug examples include effective therapies for life-threatening diseases such as breast cancer and devastating conditions such as age-related macular degeneration, improving life for tens of thousands of patients each year.

Besides addressing patients' needs, the numerous innovative drugs introduced by RDPAC companies since the 1980s have also formed the basis for the development of the vibrant local pharmaceutical generics industry, which today is dominated by local companies. More than 70% of the thriving ethical pharmaceuticals market of more than RMB 400 billion is comprised of local generic products which are created from off-patent innovative drugs introduced by RDPAC companies9. RDPAC companies thus play a significant role in continuing to nurture the growth of local generic manufacturers by providing them with a constant pipeline of innovative products that go off-patent.

Exhibit 1: RDPAC members have been bringing the fruit of innovation to Chinese patients



1 Rx drug that are new molecules or new combinations, excluding formulation changes, excluding vaccines
2 Chinese government's priority on non-communicable chronic diseases

SOURCE: SFDA

RDPAC MEMBERS ARE INTEGRATING CHINA INTO THE GLOBAL R&D INNOVATION SYSTEM

Message 3

Pharmaceutical R&D innovation today is conducted through global networks and RDPAC members are integrating China into the global R&D innovation system.

Pharmaceutical R&D today is a global effort. The R&D value chain extends across countries and continents, driven by the availability of talent, investment, scientific expertise and the private-public relationships that power innovation. Clinical trials are often conducted across multiple sites in multiple countries. Innovative drugs are discovered and developed through the collective efforts of different, geographically dispersed sites, with IPR shared by contributing partners.

Integration into the global innovation network is a must for any country with ambition in pharmaceutical innovation. Pharmaceutical R&D does not have borders. Talent and resources are distributed globally and success in innovation is rewarded by revenue from around the world. China has already emphasized in the five year plans its aim for its local industry to enter into the global market. For success in Pharmaceutical R&D innovation, it is important for China to become part of the global Pharmaceutical innovation network.

RDPAC member companies are facilitators in this effort, providing the infrastructure and coordination that integrates innovation across partners. For example, one RDPAC company has established R&D centers in Asia, Europe and the US for Central Nervous System drug development. Another company is developing diabetes products with R&D sites in China and the US. By establishing R&D centers that tap into China's talent pool, building partnerships with China's research institutes and hospitals, and working with China's local pharmaceutical companies and CROs, RDPAC members are increasingly integrating China into the global innovation network.

As leading global innovators composed of innovation-driven companies with strong R&D engines, RDPAC members lead the pharmaceutical industry in R&D investment and cumulative expertise, and are excited to share with the local industry and the Chinese government its resources to support the joint goal of innovation for better patient care. As the founder of one Chinese local company remarked, 'The pharmaceutical industry is distinctive from other business in that it is knowledge based and success takes years of cumulative experience. The multinationals have had an early start and have much to share." To meet China's healthcare challenges today all hands will be needed to help achieve success. RDPAC members recognize these responsibilities and embrace this partnership.

RDPAC MEMBERS ARE CONTRIBUTING TO CHINA R&D

Committed to investing in innovation

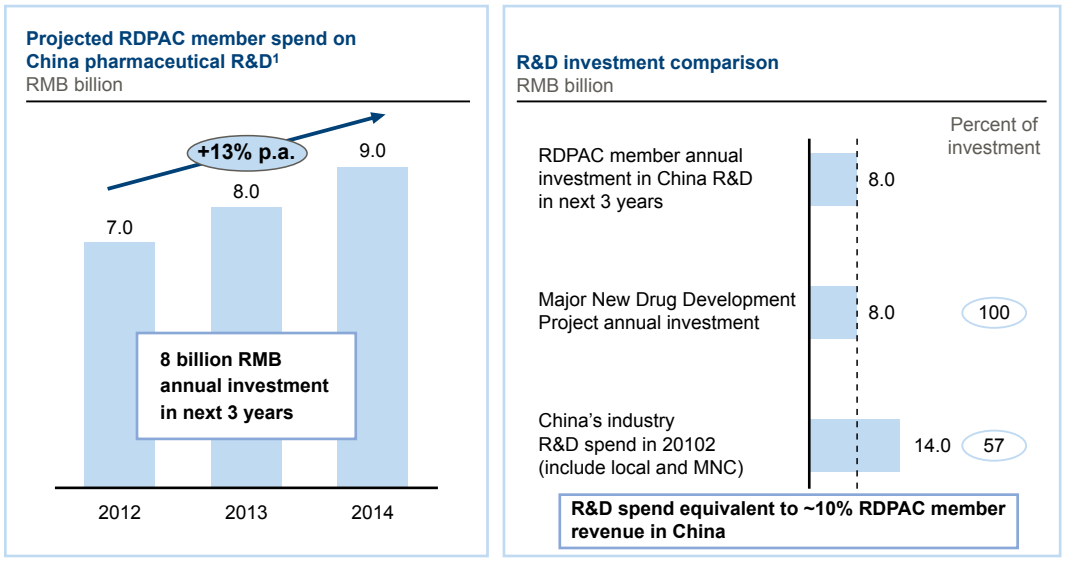
Message 4

RDPAC members have rapidly increased their investments in China R&D to 8 billion RMB per year, accounting for >50% of China's large and mid-size pharmaceutical industry R&D spending and creating ~ 3000 direct high value-added R&D positions.

RDPAC members have demonstrated their commitment to China by investing in China's long-term innovation. The number of RDPAC member R&D centres in China has quadrupled over the last decade from 7 to 30, providing high quality employment opportunities for some 3,000 scientists and clinicians, 80% of whom hold advanced degrees at Master's level or higher. This number is expected to rise substantially in the next few years as these R&D centres are increasing recruitment levels still further to support future expansion in China.

The combined annual R&D spend of RDPAC members is expected to exceed

Exhibit 2: RDPAC members are committed to make significant investments in China pharmaceutical R&D



1 Extrapolated from R&D spend in 2011 and 2014, and cumulative capital expense from 2012-2014

SOURCE: RDPAC survey

RMB 24 billion over the next three years, equivalent to at least RMB 8 billion annually. To put the scale of this investment in perspective, it is close to:

- Chinese government's investment in the Major New Drug Development project of ~RMB 8 billion a year[10] or
- >50% of China's total large and mid-size pharmaceutical industry R&D spend (including both locals and multinationals) in 2010 of RMB 14 billion[5] or
- ~10% of RDPAC members' total revenue in China, which is twice the government's goal of 5% by 2015 for key local players[1]

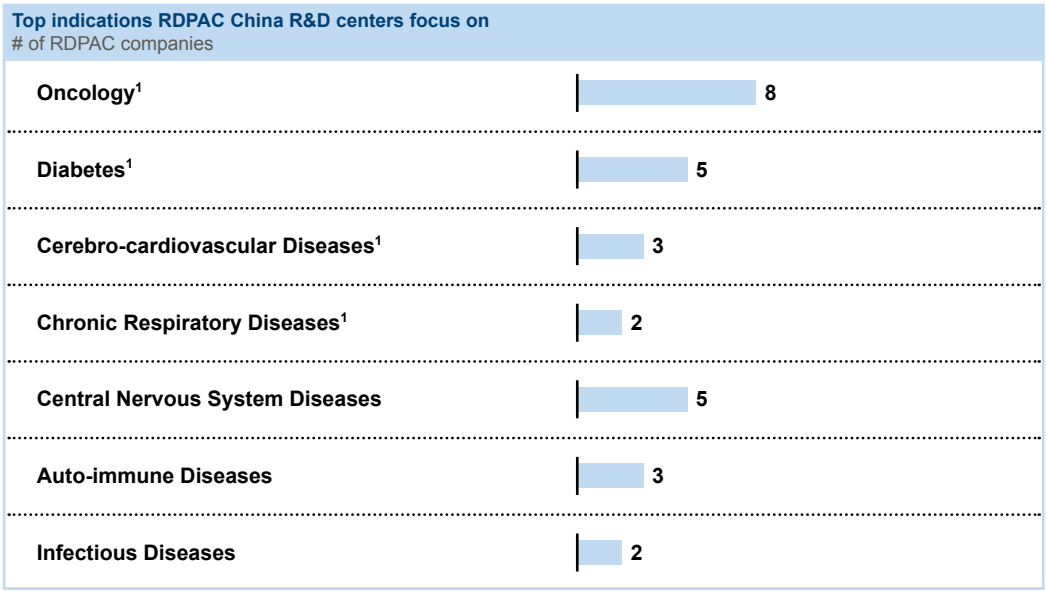
Tackling China's priority disease areas

The Chinese government focuses its pharmaceutical R&D efforts on the priority needs of Chinese patients. The 2012 National Plan for Non-communicable Chronic Diseases emphasises four leading mortality causes: cardiovascular and cerebrovascular diseases, oncology, diabetes, and chronic respiratory diseases. The Major

Message 5

These investments are primarily in disease areas identified by government and we have been ongoing partners to local research institutions in these areas with more than 210 partnerships.

Exhibit 3: RDPAC members' ongoing R&D efforts focus on China's unmet health needs



1 Disease focus for the 2012 National Plan for Non-communicable Chronic Diseases

SOURCE: RDPAC survey

New Drug Development project highlights the above diseases and in addition infectious diseases, central nervous system diseases and autoimmune diseases.

Chinese patients' needs are at the forefront of RDPAC members' R&D activities in China, in full alignment with China's priorities. At least 12 RDPAC member R&D centres are focused on the priority disease areas identified in the 2012 National Plan for Non-communicable Chronic diseases or the Major New Drug Development project. At least four centres focus on gastric, liver or lung cancers, diseases which have higher prevalence in China than other parts of the world.

Public-private partnerships also focus on priority disease areas

RDPAC members also partner extensively with local research institutions to further their scientific activities in priority disease areas. In 2011 there were 210 active partnerships with universities, hospitals and research institutes. These partnerships cover a wide range of activities from joint development projects to the transfer of key assets (such as a small molecule library) to local partners. As one leading Chinese academic describes it, "Our focus has always been on patient needs, not just innovation alone, and we worked towards such goals with our partners including the multinationals."

These proliferating and deepening relationships promote a vibrant and innovative R&D environment. Collectively they act as a multiplying factor to synergistically increase the impact of research from both RDPAC companies and local institutions. Multinational companies and local universities are increasingly building mutually beneficial partnerships. In the words of a leading Chinese academic, "We have moved on from the days of handing over an asset to our multinational partners. These days we co-develop the asset and co-own the resulting IP; these are deeper, longer-term relationships."

Building innovative Chinese companies by developing expertise and incubating talent

Message 6

RDPAC members are helping to build innovative local Chinese companies by developing expertise, seeding talent and taking them global.

The improving R&D ecosystem in China has enabled innovative local pharmaceutical companies with R&D capabilities to emerge and prosper. RDPAC companies are helping to accelerate this phenomenon by both acting as talent incubators and helping these Chinese companies to globalise.

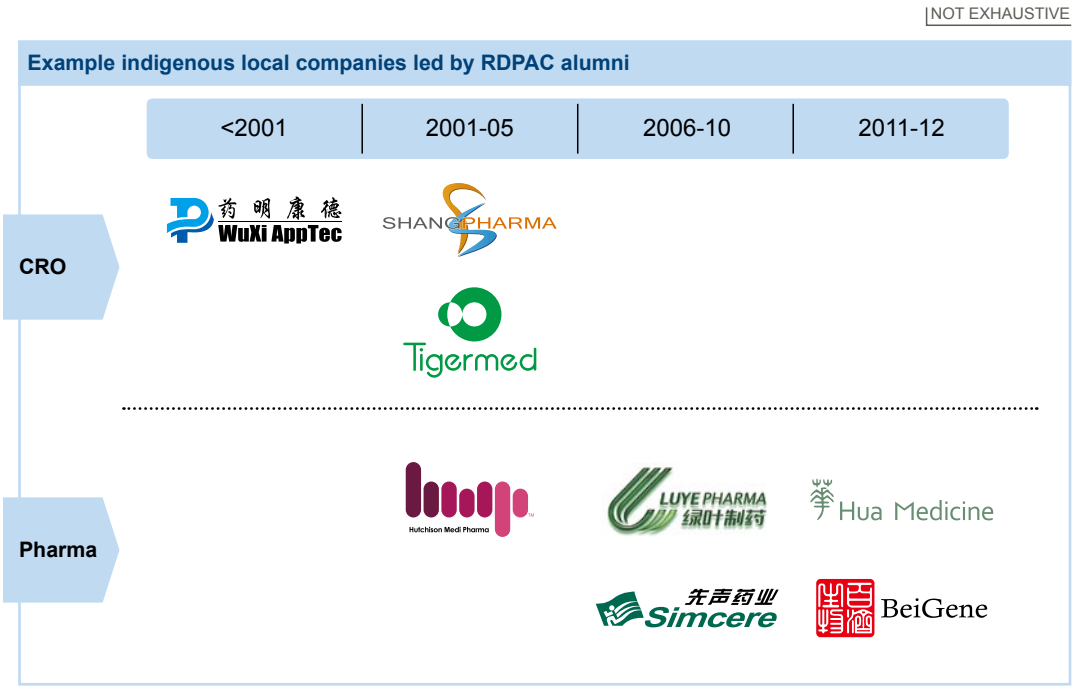
RDPAC member R&D centres provide a leading-edge work environment for thousands of employees who will be the next generation of local innovators. As members of globally integrated R&D teams, local scientists interact with global scientists and colleagues around the world to tackle the latest scientific and medical problems, and often receive overseas training opportunities at top biomedical research institutes such as Harvard Medical School. Such experiences greatly enhance the expertise of local talent and help to develop them into mature scientists. As one local academic observed, "China has many graduates with advanced degrees, but not that many people with end-to-end innovation experience and capable of leading innovation. The multinationals provide a training ground for our people."

The R&D centres are also a magnet for overseas returnees, many with extensive industry experience. These returnees form about 20% of the employee base, further enhancing the capabilities and global integration of China's innovative pharmaceutical industry.

RDPAC members also contribute to external talent cultivation across the R&D value chain. RDPAC members have played a major role in improving the capabilities of China's clinicians by engaging them in trials for innovative medicine, integrating Chinese clinical sites into global trials, and providing routine Good Clinical Practice (GCP) and practical clinical training,. Collectively, they have provided ~600 training sessions for primary investigators across 373 GCP sites in China, including intensive training for ~150 primary investigators. These training sessions substantially increase the scientific ability of local clinicians to perform to global standards and safeguard patient safety. In addition to training healthcare professionals, RDPAC members also partner widely along the R&D value chain to share know-how and improve standards, for example with laboratory test suppliers.

RDPAC members are also talent incubators for local organisations. RDPAC alumni have led local innovation efforts by founding local Chinese companies of their own, or by taking leadership positions in existing local companies. Examples include local gems such as BeiGene, an oncology asset specialist; Hua Medicine, a new entrant with a diabetes pipeline; and CROs such as Tigermed. As one government official put it, "A healthy, bi-directional flow of talent will be a major success factor for China's R&D in the years to come."

Exhibit 4: Talent flow from RDPAC members to local companies have seeded local innovation efforts



Helping local companies enter global markets

China's local pharmaceutical companies are ambitious and aim to succeed in global markets. The global reach and know-how of RDPAC members makes them valuable partners for such endeavours. For example, Hutchinson Medi Pharma recently entered a global licensing, co-development, and commercialisation agreement for a Phase I cancer molecule with an RDPAC member. Hutchison Medi Pharma will continue to lead development in China, with their partner leading development, registration and commercialisation for the rest of the world, providing Hutchison Medi Pharma with opportunities to expand beyond China. In another example, Hua Medicine in-licensed the global sales rights of an innovative diabetes candidate from an RDPAC member.

We expect these collaborations to rise over time as more Chinese companies prepare for global entry. As one local company executive explained, "We are very excited about the potential of our best-in-class drug in the global market and we welcome multinational collaboration; we can do it on our own, but it will take much more time to do so."

Building a robust and innovative Chinese CRO industry

Message 7

RDPAC members have helped create a distinctive RMB 6 billion local Chinese CRO industry.

China's local contract research organisations (CROs), both research-focused and development-focused, have grown exponentially to become a RMB 6 billion industry sector in less than 10 years. The sector is on track to double again within five years, a phenomenon that rivals any innovative industry. One local CRO champion, Wuxi Apptec, has been recognised as one of China's top 20 innovative companies and boasts 4,000 chemists, more than any global pharmaceutical company.

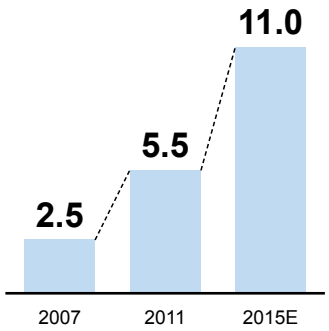
The existence of this vibrant CRO industry, which operates to global standards due to years of partnership with RDPAC members, is hugely beneficial to local Chinese companies looking to innovate. Those that do not yet have the full range of research or development functions can tap into the world-class capabilities these CROs provide. Furthermore, local CRO champions are expanding into integrated services with the goal of providing open platforms that allow any company – however small – to participate in innovation. This makes them an important catalyst for the R&D efforts of local pharmaceutical companies, greatly lowering barriers to entry for innovation. As one leading CRO executive explains, "Our integrated services provide an open platform for anyone with a good idea to participate in R&D and innovation – that is our ultimate goal."

RDPAC members provide a steady revenue stream, accounting for over 90% of the revenue of some leading CROs. They have also provided the necessary technology transfer to enable Chinese CROs to succeed. One CRO executive, reflecting on the early days of the company, stated, "Multinationals partnered with us and taught us everything we know from a technology perspective."

Exhibit 5: RDPAC members fostered the local CRO industry through outsourcing services

RDPAC members have enabled the stellar rise of the CRO sector in China

China CRO[1] market size
RMB billion



药明康德 WuXi AppTec

- Awarded "Top 20 innovative company in China" at China Enterprise Innovation Forum
- ~4,000 chemists, more than any global pharmaceutical company

1 Include both discovery and development services

SOURCE: RDPAC survey, City Bank investment and analysis report

HELPING CHINA BECOME A LEADING GLOBAL INNOVATION PARTNER

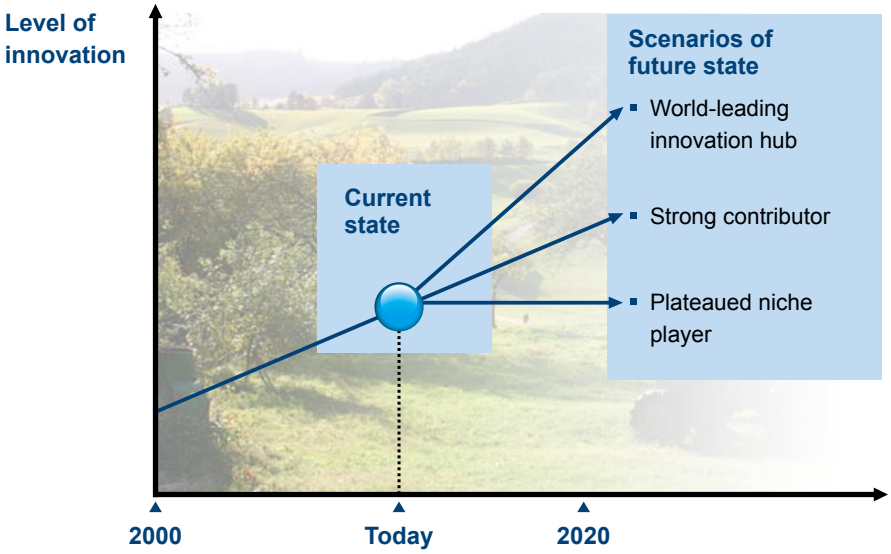
Integration into the global R&D network is critical to innovation today. China has long had the foresight to encourage innovation through partnerships with global leaders. The success of Huawei, a national innovation champion now ranked fourth globally for patent approvals, illustrates the benefits of this approach. In its early years, Huawei formed partnerships with several multinationals to share R&D efforts. Their first key product, the C&C08 telephone switch in 1994 benefited from technology spillover from a partnership established in 1989 with Shanghai Bell. Huawei later collaborated with over a dozen leading companies, including a joint venture with NEC and Panasonic in 2001 to work on 3G technology, and partnered with Intel to develop the WiMAX wireless network in 2005.[11] RDPAC members are excited to help China's local companies build similarly strong global partnerships in the pharmaceutical industry, so China can become a leading global innovation partner.

China is at a crossroads on the journey to innovation

China's pharmaceutical industry is at a crossroads. Decisions taken today will determine China's outlook tomorrow. China can develop products in China purely for China or take a more ambitious view and develop products for the world.

Thoughtful and pragmatic choices will be required to fulfill China's responsibilities both to provide affordable healthcare to 1.3 billion population and to ensure adequate rewards for innovation.

Exhibit 6: China pharmaceutical industry is at crossroads



Three very different scenarios are possible, ranging from becoming a leading global pharmaceutical innovation partner to being relegated to a local niche player.

In the most visionary scenario, skillful economic, infrastructural and regulatory choices power China's innovation momentum to the next level. By 2020, China is well on track towards integration into the global innovation network. Over the following few decades, it becomes a vital member of the network, much like the United States today. The result is a steady stream of innovative drugs that benefit patients globally.

In the second scenario, China sustains active local R&D, but lingering policy challenges limit participation in other markets. Chinese companies make meaningful contributions to innovation, but do not reach their full global potential.

In the final, least attractive scenario, China becomes a niche player locked out of the global innovation network due to policy constraints. Chinese companies do not actively participate in the global R&D value chain, and are unattractive destinations for top R&D talent and investment. This scenario represents a missed opportunity to meet the needs of Chinese patients and drive economic growth through innovation.

Leapfrogging into the Future

China has a unique opportunity to build a pharmaceutical R&D ecosystem that leapfrogs that of Western countries and helps move it into the first scenario. Unencumbered by historical legacy systems, it can build a uniquely Chinese system that incorporates best practices globally and avoids the pitfalls of more mature systems.

The Chinese government can leverage its unique strength and expertise in developing and implementing centralized strategic initiatives as well as harnessing the presence of the many RDPAC member R&D centers and commitment to innovation in China to do this. One potential idea is to establish a comprehensive, open-platform patient data repository. Such a system will not only improve patient safety, it will also provide a rich source of patient data that can be analyzed to deliver insights for directing future R&D efforts. Establishing such a system, beyond the capability of any individual industry player to create and difficult to replicate, will provide China with a distinctive advantage in the global innovation network. Another potential idea is for China to consolidate its innovation efforts and concentrate them more selectively into fewer disease areas of greatest unmet needs with national programs that create pre-competitive platforms for companies and institutes to work together on diseases or biological targets with tangible incentives that encourage collaboration. For these ideas, and other innovation opportunities, there is much that RDPAC members can do here to support China's innovation vision as long-term partners with the Chinese government.

Suggestions to improve China pharmaceutical R&D innovation

Message 8

To become a truly global innovator, in addition to making steady progress towards a thriving scientific infrastructure, China needs to provide a supportive regulatory environment, reward innovation and continue to protect IPR.

China clearly aspires to become a global innovation leader. Towards this goal, in addition to making steady progress towards thriving scientific infrastructure, China needs to develop a supportive regulatory environment, commit to rewarding innovation and protect intellectual property rights. RDPAC members share China's vision and welcome the opportunity to partner with government to share their experience of facilitating innovation around the world. This is also in line with the implementation plan outlined in the 12th Five Year plans.

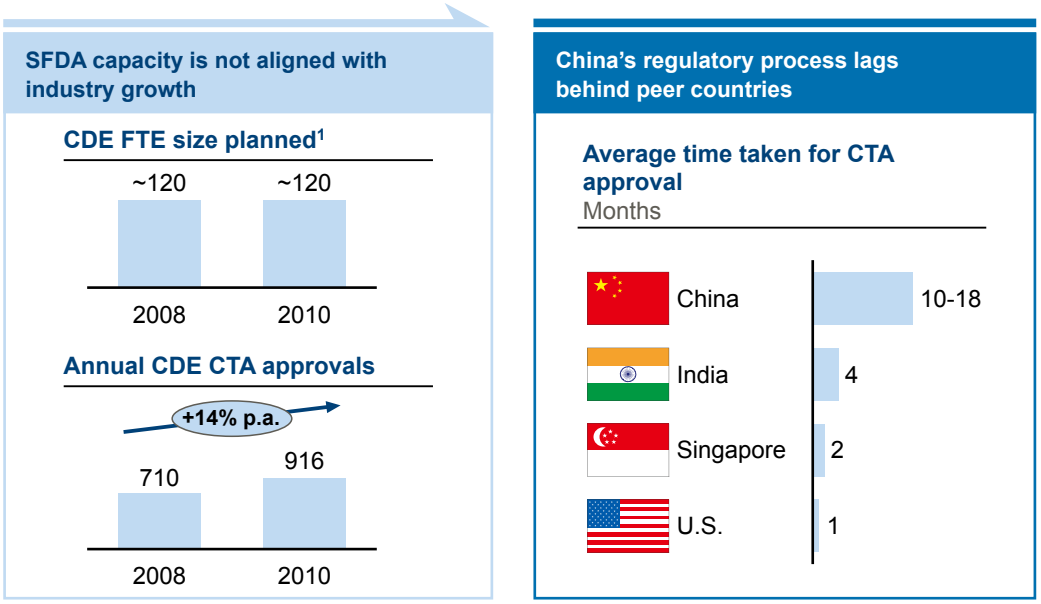
1. Develop a supportive regulatory framework that fosters innovation

Over the last few years, the SFDA has made significant strides to increase efficiency and transparency. It has re-organised the Centre for Drug Evaluation (CDE), engaged in frequent industry dialogue and issued multiple technical guidelines for drug developers. The CDE is now undertaking a series of further initiatives to encourage innovation, including developing detailed approval pathways and enhancing clinical trial conduct. These are steps to celebrate since China's future success in pharmaceutical innovation will depend on its ability to create a regulatory framework that supports and fosters innovation. As a local pharmaceutical executive explains, "Improving the SFDA regulatory framework is the first and foremost concern for China's R&D environment, everything else can come afterwards."

China can harmonise with international regulatory norms to help it further integrate into global innovation network, strengthen clinical infrastructure and ready local companies for the global market. Specific suggestions include:

- **Shorten the Clinical Trial Application (CTA) review process timeline.** It would greatly assist Chinese innovation if the CTA

Exhibit 7: China's regulatory agency capacity is not aligned with rapid industry growth, and risks bottlenecking future innovation



1 By the Organization Department of Central Committee of Communist Party of China

SOURCE: SFDA annual report

review process timeline was more in line with other countries. At present, CTA approval in China takes 10 to 18 months, which is much longer than international practice. This is a significant barrier to drug development in China for domestic and international innovators alike. Accelerating the CTA review timeline will speed up drug development and reduce the time it takes for innovative drugs to reach the patient. This will help Chinese companies be competitive in the global race to develop new drugs for patients. In addition, it will also enable a significant increase in China's participation in global registration trials, allowing Chinese clinicians opportunities to be leaders in highest quality trials where they can work with global colleagues and engage on cutting edge medical problems.

Underlying the CTA delay is a misalignment between steady SFDA capacity and rising industry innovation activities. CTA review rose from 2008 to 2010 at 14% annually, while the size of the CDE staff planned by the Organisation Department of Central Committee of Communist Party of China remained unchanged.[12,13] As the government increasingly directs industry spend towards innovation, resources at SFDA will also need to expand to keep pace. As one executive suggests, "As China is expanding R&D at an unprecedented speed, why not spend ten percent of the newly added resources to building up SFDA capability? This will significantly strengthen the overall R&D and innovation environment."

Another way to reduce the average CTA timeline would be to modify China's CTA amendment process. While many countries accept CTA amendments after initial submission, changes in clinical trial protocol in China often require new CTA submissions, leading to repeat work for companies and regulators alike.

- **Open up policies on Phase I trials in China for new drugs manufactured outside of China.** China's clinical infrastructure for Phase I trials is currently under-developed, largely due to very restrictive regulations on their conduct. For example, China's policies on FIH studies are an impediment to the full spectrum of "bench to bedside" drug innovation. Patient safety should always be the first consideration but a more nuanced approach would allow for the development of a more mature early stage clinical development infrastructure that will benefit local companies who would also be able to make use of it in their R&D efforts. As one R&D executive describes it, "I would like to do more work developing drugs specifically for Chinese patients, but now I need to do my Discovery work in China, go to Korea or Japan for Phase I, and then get back to China for late phase clinical trials. It takes too long and does not make much sense." Opening up FIH opportunities for new drugs manufactured outside of China would promote efforts to develop drugs at scale.

  China can look to other countries for lessons on how to increase FIH safety though tight controls and monitoring of the process. Korea, for example, has established government-run clinical centres to conduct FIH trials in a controlled environment to ensure patient safety.

- **Harmonise process and requirements to International Conference of Harmonisation (ICH) standards.** We applaud China's voluntary participation in the Asia-Pacific Economic Cooperation (APEC) Medical Regulatory Convergence initiative that has set targets for regional alignment of regulatory processes for medical devices and pharmaceutical products by 2020. Harmonization to international standards are a way to help local companies build capabilities and get ready for global market entry. With single harmonized standards, a local Chinese company meeting the local standards will also immediately meet international standards, accelerating their penetration of overseas markets. RDPAC looks forward to partnering with SFDA on implementing this initiative.

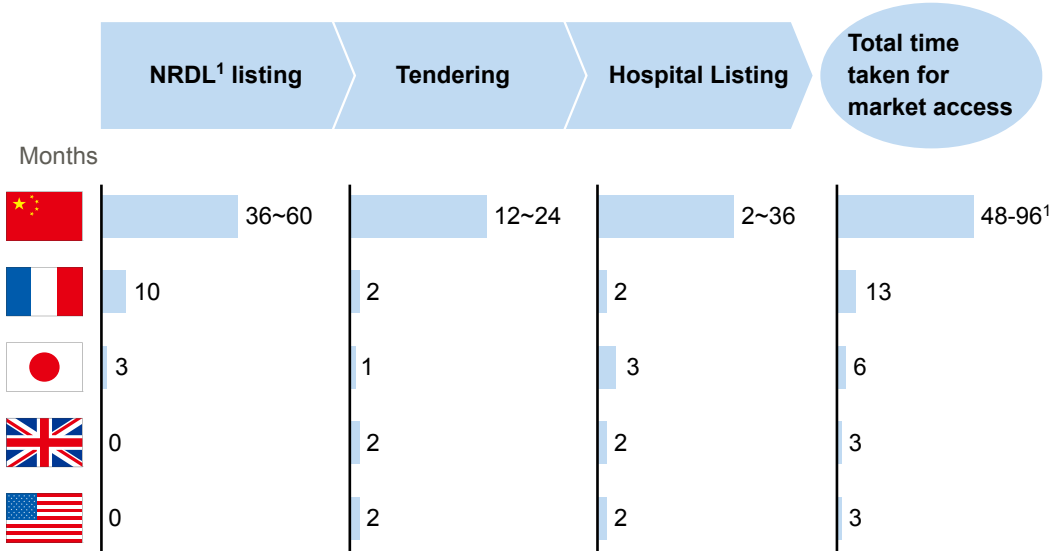
- **Establish a Marketing Authorization Holder system for regulatory approval.** Today China's innovative drug approvals are bundled together with manufacturing approval. Companies that develop innovative medicines need to either establish their own manufacturing capability or transfer their products to a manufacturer for a one-time fee with no further revenues or responsibility for patient safety once the product is on market. This creates a mis-alignment of incentives for innovators without local manufacturing as they are freed from the responsibility of patient safety for their product and their return from R&D is diminished by the one-time transfer payment. The Market Authorization Holder system adopted widely in US, EU and Japan seeks to address these issues by allowing companies with innovative products to commission a different company to manufacture the product, but allows the innovator to retain marketing rights as well maintains their responsibility for patient safety.

2. Structure incentives to properly reward innovation

Pharmaceutical innovation is a complex, costly, and risky undertaking. On average, the process takes between 10-15 years and costs at least RMB 8 billion per successful new drug.[14] The ultimate goal is improved patient outcomes, but several critical factors help to make R&D activities sustainable, including pricing, market access and tax incentives that reward innovation. Specific suggestions include:

- **Reasonable pricing that rewards innovation and ensures drug quality and safety for patients.** Only 20% of new medicines launched recover their R&D costs, so companies need an incentive to take on the risk and expense of researching and discovering new drugs.[15] Fair pricing encourages a strong and innovative pharmaceutical industry, whereas a 'cost plus' pricing approach that does not properly reflect the R&D expense and risk incurred by drug innovators will severely diminish incentives for innovation, isolate China from the global innovation network and reduce opportunity for Chinese patient to access new medicines. In particular, providing price protection from mandatory price cuts for pharmaceutical products under patent (e.g. Japan) are an important mechanism to allow innovative companies sufficient time to to recoup their R&D investment. This is especially important in China where market access lags other markets (see next paragraph)

Exhibit 8: Chinese patients' access to innovative drugs is 4 – 8 years behind other countries



1 National reimbursement drug list; NRDL and hospital listing can occur in parallel in China

SOURCE: RDPAC; FDA; EMA

and extension of price protection for a few years beyond patent expiry should also be considered. Quality-based differential pricing is another element that encourages innovation and is fundamental to enhancing patient safety. Establishing and maintaining comprehensive quality control systems to ensure consistently high quality pharmaceutical products is an expensive endeavor but to improve patient safety, this is something the government could continue to encourage through quality-based differential pricing.As one senior government official remarked, "Medical products must follow the rules of market economy, follow the rules of R&D, manufacturing, sales and fair profit. Only through this can the pharmaceutical industry become bigger and stronger."

- **Timely broad market access that enables patients to benefit from new drug therapies and further encourages innovation.** Companies developing a new drug need prompt access to the market to fund a continuing pipeline of innovative products for patients. To gain full market access, China's innovative drugs need to first access the National Reimbursement Drug List (NRDL) and go through procurement and hospital formulary listing processes. While China's National Reimbursement Drug List has historically been updated every four to five years, countries like Germany, the UK and Singapore update their equivalent lists on a rolling basis, while other countries including Spain, Italy and Korea update annually. Tenders take one to two years in China, but typically less than a year in other countries. When taken together with the time required for hospital listings, the total time required for full market access in China is four to seven years behind other countries. This lengthy market access process greatly reduces the patent life of innovative compounds and is a serious disincentive for companies to invest in innovation.

- **Tax credits for R&D encourage innovation.** This tool is widely used by governments around the world, including the US and Singapore. China's tax policy permits deductions for R&D expenses, but companies encounter practical challenges with implementation. For example, the definition of what constitutes an R&D expense is often ambiguous, so innovators do not benefit fully from this policy. Simplifying procedures would also make this tool more practical and attractive to encourage innovation.

3. Secure a strong intellectual property rights (IPR) environment to protect innovation

Robust IPR protection is vital to any successful R&D model. A strong IPR environment rewards innovators for the time, cost and risk taken, and provide the necessary incentives to encourage long-term investment commitments. For China's innovators, locals and multinationals alike, a strong IPR policy will provide the safeguards needed for companies to make meaningful and significant investments in R&D. As such, it is a powerful policy tool to deliver the government objectives of moving the pharmaceutical industry upstream into an innovation-driven industry and will be essential for the government to achieve its goal of encouraging leading local companies to invest greater than 5% of their revenues into R&D.

China has made improvements to its pharmaceutical IPR environment since its accession to the WTO in 2001 by starting to grant 20-year patent protection to chemical compounds and pharmaceutical products. Continuing to improve IPR is in China's best interests in order to stimulate innovation and further progress can be made in the following areas:

- **Reducing ambiguity of product definitions** e.g. NCE, and enforcing meaningful and adequate protection for the regulatory data packages of innovative biopharmaceutical products in line with the Chinese Drug Administration Law.

- **Better integrating the drug regulatory approval process** with patent enforcement for innovative biopharmaceutical products by strengthening the patent linkage system so that costly legal disputes can be reduced or avoided.

- **Continuing to maintain a biopharmaceutical IP protection regime** in line with and enforced the same way as international Intellectual Property norms to ensure that biopharmaceutical intellectual property rights are safeguarded with adequate penalties for infringement

CONCLUSION

Message 9

The Chinese government, local companies and RDPAC members share a similar vision to see China become a leading global innovation partner. RDPAC welcomes the opportunity to continue to partner with the government to reach our joint aspiration for the benefit of Chinese patients.

The Chinese government, local companies and RDPAC members share a common vision to see China become a leading global partner for pharmaceutical innovation. Fortunately China is well-placed to achieve this vision. Initiatives by government, local companies and multinationals to stimulate innovation have created strong momentum. Innovative R&D investment continues to rise, China's CRO sector is expanding in reach, and a flood of local talent and returning overseas Chinese are contributing intellectual muscle. The huge Chinese market also offers a strong incentive to establish China as a vital part of the global innovation network. This will encourage further investments in innovation and accelerate China's progress on this front.

RDPAC welcomes the opportunity to work collaboratively with government and other key stakeholders to foster a strong, globally innovative pharmaceutical industry in China to the benefit of Chinese patients. Together we will achieve China's vision for pharmaceutical innovation in China.

REFERENCES

1. RDPAC internal data
2. 2010 Education Statistics Data, Ministry of Education, China
3. Economic Daily, Dec. 13, 2011
4. J. Qi, et. al., "Innovative drug R&D in China", Nature Review Drug Discovery, 2011, 10, 333-334
5. China Science and Technology Statistics Yearbook 2011
6. Citi Bank Investment and Analysis report
7. Pharmaceutical Industry 12-FYP, Biotechnology 12-FYP
8. GBI Source
9. IMS
10. China Securities News, Jun. 29, 2012
11. Ying Zhang, "Alliance-based Network View on Chinese Firms' Catching-up: Case Study of Huawei Technologies Co. Ltd.", United Nations University Working Paper Series
12. New Drug Registration Approval Annual Report (2009/2010)
13. Pharmaceutical Economics News (Menet), Apr. 1, 2011
14. Improving Global Health through Pharmaceutical Innovation 2012, IFPMA
15. Pharmaceutical Industry Profile 2012, PhRMA

ACRONYMS

APEC	Asia-Pacific Economic Cooperation
API	Active Pharmaceutical Ingredient
CAEFI	China Association of Enterprises with Foreign Investment
CDE	Centre for Drug Evaluation
CNS	Central Nervous System
CRO	Contract Research Organization
CTA	Clinical Trial Application
CV	Cardiovascular
FIH	First In Human
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
ICH	International Conference of Harmonisation
IPR	Intellectual Property Rights
NCE	New Chemical Entity
NDA	New Drug Application
NRDL	National Reimbursement Drug List
R&D	Research and Development
RDPAC	R&D based Pharmaceutical Association Committee
SFDA	State Food and Drug Administration
WTO	World Trade Organization

LIST OF RDPAC COMPANIES

Abbott
Allergan
Astellas
AstraZeneca
Baxter
Bayer HealthCare
Biogen Idec
Boehringer Ingelheim
Bristol Myers Squibb
Celgene
Chugai
CSL Biotherapies
Daiichi-Sankyo
Eisai
Eli Lilly
Fresenius Kabi
GE Healthcare
Genzyme
GlaxoSmithKline
Gedeon Richter
Ipsen
LEO Pharma
Lundbeck
Merck Serono
Merck Sharp & Dohme
Mundipharma
Novartis
Novo Nordisk
Pfizer
Roche
Sanofi
Santen
Servier
Sumitomo
Takeda
UCB
Xian-Janssen

中国外商投资企业协会药品研制和开发行业委员会

地址：中国北京市朝阳区东三环北路8号
北京亮马河大厦1座506室

邮编：100004

电话：8610-6590 7696

传真：8610-6590 7697

网址：www.rdpac.org

China Association of Enterprises with Foreign Investment
R&D-based Pharmaceutical Association Committee

ADD: Room 506, Office Building1, Landmark Tower,
No.8 Dongsanhuanbei Rd.Chaoyang District, Beijing 100004, China

TEL: 8610-6590 7696

FAX: 8610-6590 7697

WEBSITE: www.rdpac.org