行稳致远：推动放射性药物产业创新与高质量发展

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摘要

放射性药物作为融合核技术与现代医学的重要创新治疗领域，近年来在中国生物医药产业发展中受到越来越多关注。其中，放射配体疗法（Radioligand Therapy, RLT）正成为中国生物医药产业快速发展中的重要创新方向之一。近年来，随着产业投资持续加速、研发管线不断丰富，放射配体疗法在中国生物医药创新版图中的战略地位日益凸显。同时，放射配体疗法兼具核技术与精准医疗属性，在安全管理、环境监管及临床应用等方面具有特殊性，需要在鼓励创新与强化安全治理之间实现更高水平的协调。

为推动产业高质量发展，建议在行业加速发展的同时，重点完善以下两方面基础制度：

1. 构建清晰、稳定且可预期的监管框架。在严守安全性与有效性底线的基础上，提供明确且具有包容性的政策指引，畅通高质量放射配体疗法产品的上市路径。
2. 优化医疗机构准入及临床应用机制，完善从准入到临床实施的全链条制度体系，在确保安全规范的前提下，加速创新放射配体疗法向临床实践的转化，切实提升患者的治疗可及性。

政策建议

建议一：进一步完善全生命周期监管治理体系，统筹安全底线与创新活力，推动产业高质量本土化发展。

[①] 本报告仅代表企业相关研究观点，不代表论坛主办单位和承办单位立场和观点。

重点举措：

1. 完善法规体系：清晰界定放射性药物及其关键组分的监管属性。明确注册分类、审评路径及技术标准，提升监管规则的透明度、清晰度与可执行性，为产业创新提供稳定的制度预期。

2. 规范医疗机构制备治疗性放射性药物管理：建立全国统一、基于风险分级的质量与安全管理体系，并由省级或国家药品监管部门审批，在保障安全的同时统筹考虑监管复杂性及知识产权保护等因素。

3. 完善仿制及“me-too”产品技术审评标准：针对“me-too”放射性药物探索建立更加清晰的技术审评标准，并推动监管数据保护原则在审评实践中的一致适用。可进一步明确数据保护原则的适用边界，为未来审评实践提供更加清晰的制度预期，避免未经授权直接依赖原研企业专有数据。同时，进一步明确放射性仿制药的技术要求及生物等效性评价标准，以提升产品质量和监管可预期性。

4. 优化本地化生产政策衔接：在推进创新药本地化生产过程中，可探索在符合监管要求的前提下继续沿用原有品牌名称的做法，以增强企业长期投资预期，并提升产品全生命周期政策环境的连续性与稳定性。

建议二：优化医疗机构准入及临床应用体系，推动放射配体疗法规范化、规模化发展，切实提升患者可及性。

重点举措：

1. 建立创新应用绿色通道：鼓励具备相应资质能力的医疗机构优先开展创新治疗性放射配体疗法的临床应用，建立临床研究与应用转化的联动机制，确保参与临床研究的医疗机构能够根据临床需要开展相关治疗，加速创新成果惠及患者。

2. 探索差异化医院准入机制：针对半衰期短、临床价值高的放射配体疗法，探索实施“预评估 + 动态备案”等灵活准入模式，优化医院药事准入及临时采购流程。

3. 优化医院绩效与费用管理政策：对高价值放射配体疗法实行差异化管理，在药占比考核中予以合理调整。深化 DRG/DIP 支付方式改革，建立反映放射性药物临床价值与运营特殊性的特例单议或除外支付机制，消除医院引进新技术的经济顾虑。

4. 加强核医学能力建设与多学科协作（MDT）：支持更多符合条件的医疗机构获取放射配体疗法执业资质。大力推广以患者为中心的多学科诊疗模式，并加强核医学专业人才梯队建设与培训体系，夯实临床应用的人才基础。

5. 构建“准入—支付—管理”协同生态：推动将符合条件的放射配体疗法纳入标准化疾病诊疗路径。积极探索基本医保、城市普惠型商业保险（惠民保）及商业健康险的多层次支付衔接机制，形成覆盖临床规范应用、多元支付保障与患者全周期管理的协同闭环。

结语

全球生物医药产业发展经验表明，唯有构建协调统一的制度体系与有序清晰的发展路径，方能充分释放技术创新的长期价值。持续完善政策体系、加强制度衔接，将是推动放射配体疗法创新成果转化为长期临床价值与产业价值的关键。

诺华愿与中国政府、监管机构及各界合作伙伴携手，共同推动放射配体疗法在中国实现安全、可持续的发展。

第一部分：中国放射配体疗法产业发展格局——迈向全球领先的重要窗口期

放射性药物是指以放射性同位素为标记，用于疾病精准诊断或治疗的特殊药品[1]。依据临床用途，主要分为分子影像诊断类与治疗性放射性药物[2]。本文主要聚焦治疗性应用领域，重点讨论其中发展迅速、技术前沿的放射配体疗法（Radioligand Therapy, RLT）。

放射配体疗法是一种靶向精准医疗技术，目前在肿瘤治疗领域应用最为广泛。其基本机制是将具有疾病靶向能力的配体与治疗性放射性同位素相结合。该疗法能精准识别并结合表达特定分子靶点的肿瘤细胞，在细胞内部或周围释放电离辐射，实现对肿瘤细胞的精准杀伤，同时减少对周围正常组织的损伤[3,4]。

放射配体疗法的显著特征在于其“诊疗一体化”模式，即基于同一分子靶点，同步实现影像学诊断与治疗干预[5]。通过这一模式，医生可以在治疗前利用影像学手段精准评估患者靶点表达情况，从而筛选适合接受治疗的患者。临床研究表明，放射配体疗法在转移性去势抵抗性前列腺癌和神经内分泌肿瘤等领域展现出突破性疗效[6,7]，尤其为缺乏有效治疗手段的患者提供了新的治疗路径。

1.1 中国放射配体疗法产业生态：现状综述与政策支撑

近年来，得益于国家政策的持续引导、生物医药原始创新能力的跃升、产业资本的深度布局以及临床需求的爆发式增长，中国放射配体疗法产业生态正加速成型。

当前，从上游同位素供应，到中游放射性药物研发与产业化，再到下游临床应用能力建设，放射配体疗法产业发展的关键要素正日趋完善，为未来产业规模化发展奠定了重要基础。

表 1：中国放射配体疗法产业生态发展概览

环节	发展现状综述	核心驱动因素
上游：医用同位素	供应能力持续提升：关键诊断用同位素自给率突破 80%；治疗用同位素产能逐步建设。	政策引导：《医用同位素中长期发展规划（2021—2035年）》[9]； 基础设施升级：反应堆技术升级改造。
中游：研发、生产与流通	创新活跃度持续提升：中国在全球新增治疗性放射性药物研发管线中的占比不断提高；GMP 生产能力与核药房网络持续扩展。	生物医药创新能力提升；产业资本持续投入；跨国企业本地化布局。
下游：临床应用	需求潜力大但处于爬坡期：核医学基础设施与服务能力不断完善，但整体应用水平与发达国家相比仍有提升空间。	癌症疾病负担较重；人口老龄化加速；临床需求持续增长。

1.2 上游：医用同位素供应能力持续提升

长期以来，医用同位素供应不足一直是制约放射配体疗法产业发展的关键结构性瓶颈。近年来，随着国家《医用同位素中长期发展规划（2021～2035年）》的深入实施，这一局面正逐步得到缓解。该规划由国家原子能机构牵头，多部门协同推进，通过加快反应堆升级改造、布局关键同位素国产化生产线等战略性举措，持续提升中国医用同位素保障能力。

截至 2023 年，中国在钼-99/锝-99m 等关键诊断用同位素方面的自给率已超过 80%；与此同时，镥-177、锕-225 等治疗用同位素的国内生产能力也在持续提升。政策驱动下的本土化供应体系建设，正在有效降低对外部供应波动的依赖，并逐步缓解长期制约放射配体疗法产业规模化发展的上游瓶颈。

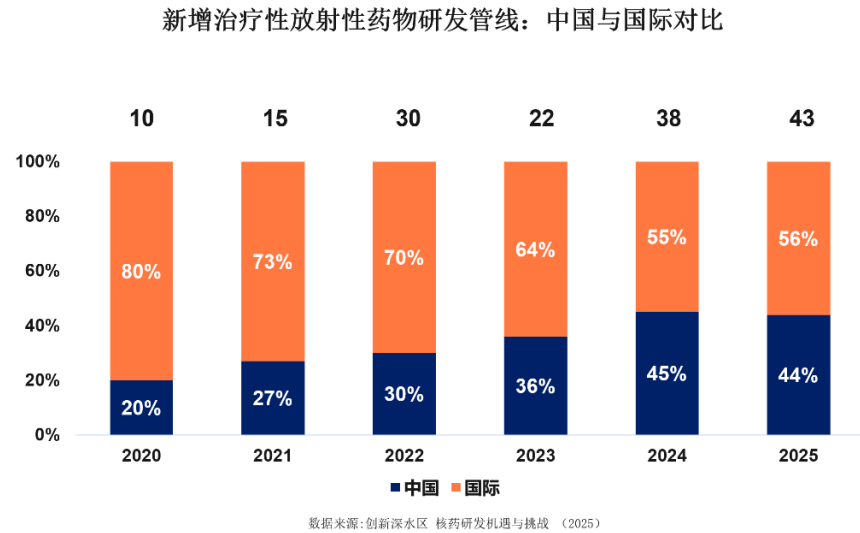

图 1：2020—2025 年中国在全球治疗性放射性药物研发管线中的快速崛起 [10]

1.3 中游：研发与生产能力持续提升

中国放射性药物领域的研发创新活动正保持稳步增长。根据 Insight 数据库统计 [10]，2020 年中国在全球新增治疗性放射性药物研发管线中的占比约为 20%；到 2024～2025 年，这一比例已提升至约 44%～45%，显示中国在该领域的创新活跃度显著提升，与国际领先市场之间的差距正逐步缩小。

在研发创新持续推进的同时，中国放射性药物的生产制造能力也在不断增强。随着符合 GMP 标准的放射性药物生产设施持续建设，以及跨国企业加快推进本地化生产布局，中国放射性药物的整体产能规模与供应稳定性显著提升，产业链韧性进一步增强 [11]。

在流通环节，第三方核药房网络正逐渐成为短半衰期放射性药物配送的重要基础设施。数据显示，中国核药房数量已由 2020 年的 63 家增加至 2024 年的 89 家，反映出中国在“即时生产—即时配送”模式下的供应保障能力正在稳步提升 [8]。

1.4 下游：临床需求基础雄厚，发展空间广阔

临床需求是推动放射配体疗法长期发展的根本动力。从疾病负担看，中国是全球癌症防控形势最严峻的国家之一。国际癌症研究机构（IARC）数据显示，2022 年中国新发癌症病例约 480 万例、癌症死亡约 260 万例，占全球总量的约四分之一 [12]。与此同时，随着人口老龄化加速，到 2035 年中国 60 岁及以上人口预计将达到约 4 亿人 [13]，肿瘤诊疗需求将持续呈刚性增长态势。

尽管近年来中国核医学基础设施与服务能力显著提升，但与美国等成熟市场相比，核医学和放射性药物治疗的整体应用仍处于发展阶段。巨大的临床需求叠加尚未完全释放的应用潜力，意味着随着医疗体系能力与临床应用条件的进一步完善，放射配体疗法未来仍具备广阔的发展空间。

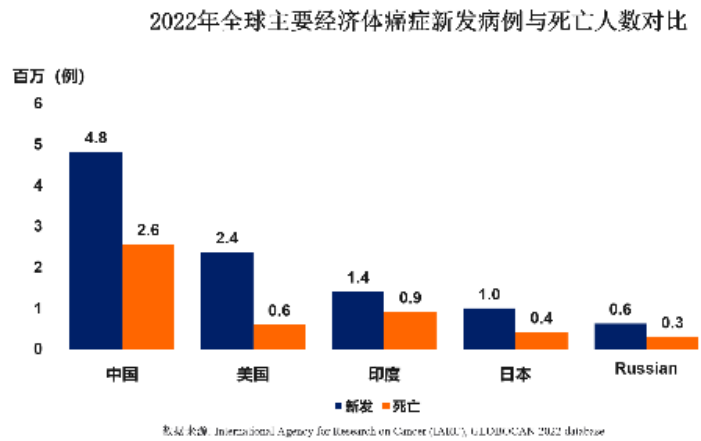

图 2：2022 年中国癌症疾病负担的全球对比

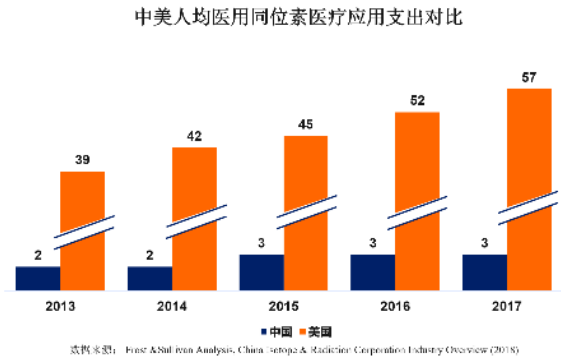

图 3：中美医用同位素利用水平差距对比 [14]

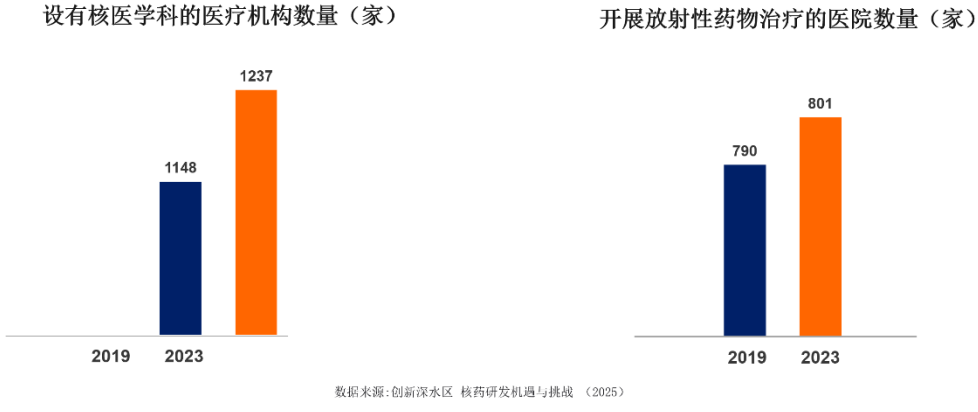

图 4：中国核医学与放射性药物治疗服务能力持续提升

第二部分：迈向可持续发展——推动放射配体疗法长期发展的关键因素

当前，中国正加快推进生物医药产业高质量发展，放射性药物等前沿治疗技术正逐步成为生物医药创新体系的重要组成部分。随着中国放射配体疗法产业生态进入加速成长期，行业发展的核心议题正从早期的“基础能力建设”逐步转向“构建支撑长期可持续发展的制度体系”。

国际经验表明，在政策支持、资本投入和技术突破共同推动下，新兴技术产业的长期发展质量，很大程度上取决于监管治理体系、制度执行能力与临床应用机制能否实现同步演进[15][16][17]。如果制度建设滞后于产业扩张，往往容易出现投资分散、资源配置效率不高等问题，从而影响产业整体发展质量。

对于放射配体疗法而言，协同发展的重要性尤为突出。由于其涉及放射性物质应用，该技术在辐射安全、环境管理以及产品全生命周期质量控制等方面均提出了更高要求[18]。因此，确保产业发展在安全、规范和有序的轨道上推进，不仅是维护公众信任与社会安全的底线要求，更是提升中国放射配体疗法产业全球核心竞争力、实现行稳致远的根本保障。

展望未来，放射配体疗法实现可持续高质量发展，关键在于持续推动以下两个重点领域的制度创新与体系完善：

1. 构建清晰、稳定且可预期的监管框架。在严守安全性与有效性底线的基础上，提供明确且具有包容性的政策指引，畅通高质量放射配体疗法产品的上市路径。

2. 优化医疗机构准入及临床应用机制，完善从准入到临床实施的全链条制度体系，在确保安全规范的前提下，加速创新放射配体疗法向临床实践的转化，切实提升患者的治疗可及性。

审视当前实践，上述两个关键领域仍存在较大的制度优化空间。通过精准的政策供给与系统的制度衔接，有望充分释放放射配体疗法的长期价值，推动创新成果加快转化为稳定的临床价值与持续的产业活力。

2.1 监管体系：持续完善中亟待深化适配

近年来，中国在放射性药物监管与技术规范体系建设方面取得了积极进展。国家药品监督管理局（NMPA）已建立专门的审评通道，并陆续发布多项技术指导原则，体现出国家层面对这一新兴领域的高度重视[19]。

但随着放射配体疗法技术的快速发展，现有监管体系在部分关键环节仍面临“制度供给滞后于产业创新”的挑战。为充分释放产业潜力，亟需在产品界定、风险管理及产业链协同等方面，构建更具适应性、前瞻性与可预期性的监管生态。

表 2：放射配体疗法产业发展的主要监管制度挑战

领域	缺口	相关政策/措施
关键组成部分的监管界定	放射配体疗法关键组成部分的定义及监管路径仍有待明确	《放射性药品管理办法》（1989 年发布，2024 年修订）
医疗机构制备放射性药物监管	全国统一的医疗机构制备放射性药物管理路径及监管边界仍有待明确	《医疗机构制备正电子类放射性药物管理办法》（2006 年）；《药品管理法》
me-too 与仿制药注册路径	复杂放射性药物在数据保护及生物等效评价标准方面的适用边界仍需进一步明确	《放射性治疗药物非临床研究技术指导原则》 《放射性体内诊断药物非临床研究技术指导原则》

本地化政策激励与实施衔接	相关支持政策已出台，但在实施细则与协同衔接仍有进一步完善空间	国务院发布文件（国办发〔2024〕53 号） 国家药监局《关于改革完善放射性药品审评审批管理体系的意见》

2.1.1 关键放射配体疗法组成部分监管界定仍需进一步明确

现行《放射性药品管理办法》发布于 1989 年，并于 2024 年进行了修订，奠定了监管基础 [20]。但在放射配体疗法产业发展背景下，部分关键组成部分的监管界定仍缺乏统一和明确的制度安排，例如放射性核素、化学前体、冷试剂盒以及发生器等，在定义、监管属性、注册路径及技术要求等方面仍有进一步明确的空间。同时，针对放射配体疗法的特定技术指导原则仍相对有限。

上述情况在一定程度上可能带来监管理解上的不确定性，从而对创新产品的研发推进、注册审评及临床应用节奏产生一定影响。

2.1.2 医疗机构制备治疗性放射性药物的监管机制仍需进一步明确

医疗机构制备治疗性放射性药物是指在具备条件的医疗机构内部制备并用于满足特定临床需求的放射性药物 [21]。中国虽已出台《医疗机构制备正电子类放射性药物管理办法（2006）》涵盖 12 种 PET 药物 [22]，但对于该范围之外的产品，目前尚缺乏明确的管理路径。

在实践中，仍存在若干需要进一步明确的问题，例如：

1. 各省级药品监管部门是否具备开展放射性药物制备审评、检验和监管的专业能力；

2. 医疗机构制备相关技术要求（如作用机制、制剂工艺及非临床安全性评价等）是否具有统一明确的标准；

3. 医疗机构制备条件是否能够全面满足现行 GMP 和药物警戒要求。

考虑到许多院内制备的放射性药物通过静脉给药，其安全管理要求通常高于一般院内制剂。

在现行法律框架下，虽然《药品管理法》确立了“市场无供应方可使用院内制剂”的原则[23]，与国际惯例一致[24,25]。但在执行层面，相关边界在部分情况下仍不够清晰。院内制备产品和已上市产品仍可能并存使用，从而在监管界定和知识产权保护方面带来一定的不确定性。

2.1.3 “me-too”及仿制产品路径：监管可预期性仍有提升空间

在现行制度下，若“me-too”放射性药物（即在已有同类创新药作用机制基础上开发的后续创新产品）以创新药路径申报，通常需要开展独立的临床研究[23]，这在一定程度上避免了对原研临床数据的不当依赖。

与此同时，随着监管体系不断完善，仍有一些前瞻性问题有待在实践中进一步观察。例如，国家药监局药品审评中心（CDE）已发布治疗性和诊断性放射性药物的非临床研究技术指导原则[26][27]，为研发活动提供了更清晰的技术预期，但相关技术规范在具体审评实践中的适用方式仍需进一步积累经验。未来，随着实践经验不断积累，还需要持续关注这些技术规范在独立申报中的具体适用方式，以及监管数据保护原则在实际审评中的落实情况。

对于放射性仿制药，目前在部分常用诊断性放射性药物领域，在特定条件下可豁免临床试验或生物等效性（BE）研究。未来此类做法是否会扩展至放射配体疗法或放射配体影像仿制药，以及针对这类复杂产品应如何科学界

定 BE 评价标准，仍有待进一步明确。相关技术标准的进一步细化，有助于在保障安全的同时提升监管可预期性。

2.1.4 本地化政策方向明确，但实施仍有提升空间

近年来，中国出台了一系列支持创新药本地化生产的政策措施，包括优先配置审评审批资源、优化境外已上市产品转入国内生产的审批流程等[28][29]。但针对放射性药物的具体实施细则仍有待进一步明确，影响了政策红利的充分释放。

对于放射配体疗法而言，本地化不仅涉及生产设施转移，还需要与同位素供应、热室放行系统、专业运输体系、医疗机构准入及支付机制等多个环节协同推进。若在这些关键环节形成更具连续性和稳定性的政策支持，将有助于提升产业长期投资的确定性，推动高质量、可规模化的产业生态体系建设。

2.2 临床应用体系：基础设施持续完善，但“软能力”仍需进一步提升

近年来，中国核医学基础设施（“硬能力”）建设成效显著。如本文第一部分所述，在设备配置、医疗设施建设以及服务覆盖范围等方面均取得了明显进展，为放射配体疗法的发展奠定了更加坚实的基础。

然而，相较于硬件设施的快速发展，支撑临床高效运行的管理体系、人才生态和支付机制（“软能力”）仍处于逐步完善阶段。未来产业的可持续发展，不仅需要持续推进基础设施建设，更需要在管理机制创新、临床协同深化以及支付能力提升等方面同步加强，从而实现从“有得用”到“用得好”的跨越。

表 3：放射配体疗法临床准入与应用面临的主要挑战

问题	缺口
医疗机构准入机制	现行路径沿用传统药品管理流程，缺乏针对放射性药物“短半衰期、即时性”特征的差异化评价与绿色通道机制。
专业能力与多学科协作	核医学专业人才储备与多学科诊疗（MDT）协同机制不健全，区域间能力发展不均衡。
支付与保障机制	多数创新产品未纳入国家医保药品目录，商业保险覆盖有限，影响医院引入及临床使用。

2.2.1 医疗机构准入与运行机制仍存在一定约束

目前，放射配体疗法在医疗机构的准入流程总体仍沿用传统药品管理路径，尚未充分体现放射性药物的特殊属性。在三级医院中，药品通常需经过药事管理与药物治疗学委员会评审等常规程序。对于半衰期较短、需要按患者需求即时生产和配送的放射性药物而言，现有流程在部分情况下难以及时匹配其临床使用特点，从而在一定程度上影响治疗的可及性。

此外，由于放射配体疗法治疗费用相对较高，其临床应用还可能受到医院绩效考核指标的影响，在 DRG/DIP 支付方式改革及“药占比”严控的背景下，高值放射配体疗法可能被视为成本负担，从而抑制了临床科室的引进意愿。

以浙江省前列腺癌为例，该省每年新增患者超过 1.5 万例，但放射配体疗法实际治疗病例目前仍不足 200 例[30]。相关治疗所使用的同位素镥-177 半衰期仅约 5 天，需要根据处方需求进行生产。然而，复杂的医院准入与采购流程往往导致供应响应速度滞后于临床需求窗口，造成“人等药”而非“药等人”的被动局面，直接影响了患者的及时救治。

2.2.2 专业能力与多学科协作仍存在不均衡

放射配体疗法相关专业知识和临床能力在不同医疗机构之间仍存在较大差异，这在一定程度上反映出相关专业人才储备仍有不足。在实际临床实践中，部分机构仍存在“不会用（缺乏技术能力）、不敢用（担忧辐射安全）、用不上（缺乏药物可及）”等情况。

以浙江省为例，在 76 家三级医院中，仅有 39 家开展核医学诊疗服务，而真正具备先进放射性药物治疗能力的医院仅 9 家[30]。核医学专业人才队伍仍处于发展阶段，具备“诊疗一体化”综合决策能力的复合型医师队伍规模有限，难以满足庞大的患者需求。

更深层次的问题在于学科定位偏差。在许多医疗机构中，核医学科仍被边缘化为单纯的“辅助检查部门”，在肿瘤多学科诊疗决策体系中的话语权不足，导致放射配体疗法未能作为一线或优选方案进入主流治疗路径。加之临床医生、患者及公众对核医学治疗的认知尚待普及，进一步限制了创新疗法的合理推广。

2.2.3 支付与保障机制仍处于探索阶段

目前，多数创新放射配体疗法产品尚未纳入国家医保药品目录，只有部分城市层面的商业健康保险开始提供有限保障。治疗费用问题导致大量潜在受益患者无法接受治疗。

这一情况延缓了真实世界卫生经济学证据的积累，使得未来进医保价值评估与谈判缺乏有力依据，形成“低使用—无数据—难准入”的负向循环。

此外，现行鼓励医院创新药使用的政策红利（如国谈药“双通道”、单独支付等）主要惠及医保目录内品种。由于多数放射配体疗法目前尚未纳入该体系，难以享受相关政策支持，进一步削弱了医疗机构的引进动力。

第三部分：政策建议

针对上述制度与实践中的关键问题，进一步完善相关政策体系，对于推动中国放射配体疗法产业生态实现可持续发展具有重要意义。

建议一：进一步完善全生命周期监管治理体系，统筹安全底线与创新活力，推动产业高质量本土化发展。

重点举措：

1. 完善法规体系：清晰界定放射性药物及其关键组分的监管属性。明确注册分类、审评路径及技术标准，提升监管规则的透明度、清晰度与可执行性，为产业创新提供稳定的制度预期。

2. 规范医疗机构制备治疗性放射性药物管理：建立全国统一、基于风险分级的质量与安全管理体系，并由省级或国家药品监管部门审批，在保障安全的同时统筹考虑监管复杂性及知识产权保护等因素。

3. 完善仿制及“me-too”产品技术审评标准：针对“me-too”放射性药物探索建立更加清晰的技术审评标准，并推动监管数据保护原则在审评实践中的一致适用。可进一步明确数据保护原则的适用边界，为未来审评实践提供更加清晰的制度预期，避免未经授权直接依赖原研企业专有数据。同时，进一步明确放射性仿制药的技术要求及生物等效性评价标准，以提升产品质量和监管可预期性。

4. 优化本地化生产政策衔接：在推进创新药本地化生产过程中，可探索在符合监管要求的前提下继续沿用原有品牌名称的做法，以增强企业长期投资预期，并提升产品全生命周期政策环境的连续性与稳定性。

建议二：优化医疗机构准入及临床应用体系，推动放射配体疗法规范化、规模化发展，切实提升患者可及性。

重点举措：

1. 建立创新应用绿色通道：鼓励具备相应资质能力的医疗机构优先开展创新治疗性放射配体疗法的临床应用，建立临床研究与应用转化的联动机制，确保参与临床研究的医疗机构能够根据临床需要开展相关治疗，加速创新成果惠及患者。

2. 探索差异化医院准入机制：针对半衰期短、临床价值高的放射配体疗法，探索实施“预评估 + 动态备案”等灵活准入模式，优化医院药事准入及临时采购流程。

3. 优化医院绩效与费用管理政策：对高价值放射配体疗法实行差异化管理，在药占比考核中予以合理调整。深化 DRG/DIP 支付方式改革，建立反映放射性药物临床价值与运营特殊性的特例单议或除外支付机制，消除医院引进新技术的经济顾虑。

4. 加强核医学能力建设与多学科协作（MDT）：支持更多符合条件的医疗机构获取放射配体疗法执业资质。大力推广以患者为中心的多学科诊疗模式，并加强核医学专业人才梯队建设与培训体系，夯实临床应用的人才基础。

5. 构建“准入—支付—管理”协同生态：推动将符合条件的放射配体疗法纳入标准化疾病诊疗路径。积极探索基本医保、城市普惠型商业保险（惠民保）及商业健康险的多层次支付衔接机制，形成覆盖临床规范应用、多元支付保障与患者全周期管理的协同闭环。

结语

当前，放射配体疗法在中国正进入重要发展窗口期。在供应链自主可控能力显著提升的支撑下，在本土创新活力迸发的驱动下，中国放射配体疗法产业已积蓄起雄厚的发展势能，前景广阔，未来可期。

然而，行稳方能致远。在这一关键转折阶段，产业发展的核心逻辑正从单纯的“规模扩张”转向“质量优先、可持续增长”。面对放射配体疗法技术高度复杂、产业链条长、跨界融合深的特点，唯有构建稳定、透明、协同的制度生态，才能为技术创新提供肥沃土壤。国际经验证明，新兴技术的长远生命力，不仅取决于技术突破的速度，更取决于制度环境的厚度与产业协同的精度。

持续完善相关制度体系、加强产业链协同，不仅有助于推动放射配体疗法产业健康发展，也会进一步促进创新药物更高效地转化为临床价值。以放射配体疗法为代表的创新放射性药物，也将为更多患者带来新的治疗选择，并为推进“健康中国”战略提供有益支撑。

诺华愿与中国政府、监管机构及各界合作伙伴携手，共同推动放射配体疗法在中国实现安全、可持续的发展。

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Steady Progress, Long-Term Success: Advancing the High-Quality and Sustainable Development of the Radioligand Therapy Industry

Novartis [1]

Executive Summary

Radioligand Therapy (RLT) has emerged as one of the most dynamic segments in China's booming biotech industry, evidenced by accelerated investment and a robust pipeline of drug candidates. At the same time, RLT involves distinctive safety and environmental considerations, requiring careful alignment between rapid innovation and robust safety governance as the sector develops.

To achieve this balance, two foundational systems should be strengthened in parallel with industry growth:

- A clear and predictable regulatory framework that robustly safeguards safety and efficacy while providing reliable, innovation-friendly guidance to bring high-quality RLT candidates to market.
- An optimized hospital access and clinical implementation pathway that enables innovative RLT therapies to be delivered safely, efficiently, and in a timely manner, translating scientific progress into real-world patient benefit.

[1] The views expressed in this report are those of the enterprise research and do not represent the official stance or opinions of the forum host and organiser.

Recommendations

Recommendation 1: Further refine and align the regulatory governance framework for radiopharmaceuticals to reflect the full lifecycle of RLT products, supporting safe innovation, orderly competition, and localization.

Key actions include:

- Update Regulations: Revise the Administrative Regulation on Radioactive Pharmaceutical Products to clarify the definitions, regulatory attributes, registration pathways, and technical requirements for radiopharmaceuticals and their components.
- Standardize Management of Locally Manufactured Therapies: Establish nationally consistent, risk-based quality and safety control systems, approved by provincial or national medical products regulatory authorities, taking into account safety, regulatory complexity, and intellectual property considerations.
- Strengthen Technical Review Standards for Me-too and Generics: Establish reasonable technical review criteria for "me-too" radiopharmaceuticals and reinforce consistent application of Regulatory Data Protection (RDP) principles, ensuring that proprietary originator data are not relied upon in stand-alone regulatory assessments without authorization. Further clarify technical and bioequivalence requirements for generic radiopharmaceuticals to enhance product quality, safety assurance, and regulatory predictability.
- Optimize Localization Rights: Allow originator products to continue using their original brand names after localization, so as to protect originator rights and ensure policy continuity across the full product lifecycle.

Recommendation 2: Further optimize the hospital access and clinical implementation framework for radiopharmaceutical therapies, enabling safe, timely, and scalable clinical use of RLT while improving patient affordability.

Key actions include:

- Establish Green Channels for Qualified Institutions: Encourage priority clinical

use of innovative therapeutic radiopharmaceuticals in medical institutions with appropriate qualifications and capabilities, and ensure that hospitals participating in clinical research are able to provide RLT therapies on an as-needed basis.

- Implement Differentiated Hospital Access Mechanisms: For short half-life, high-clinical-benefit radiopharmaceuticals, explore tailored evaluation approaches such as pre-assessment plus dynamic filing to streamline formulary entry and temporary procurement processes.
- Optimize Hospital Performance Assessment Policies: Exclude eligible high-value radiopharmaceutical therapies from drug expenditure ratio evaluations and refine DRG management models to better reflect the clinical and operational characteristics of RLT.
- Strengthen Nuclear Medicine Capacity and MDT Integration: Support more hospitals in obtaining RLT treatment qualifications, expand multidisciplinary team participation, and enhance the training pipeline for specialized nuclear medicine professionals.
- Advance Coordinated Access and Payment Pathways: Incorporate eligible radiopharmaceuticals into standardized disease treatment pathways and explore alignment with city-level inclusive insurance and commercial insurance programs to form an integrated access, payment, and clinical management framework.

Conclusion

Experience across emerging technologies shows that only well-coordinated and orderly development delivers lasting impact. Continued policy refinement and system alignment will be key to translating RLT innovation into sustainable clinical and industrial value.

Novartis stands ready to work with all stakeholders to support the safe and sustainable development of radioligand therapy in China.

Section 1: China's RLT Landscape – On Track to Global Leadership

Radiopharmaceuticals are specialized medicinal products labeled with radioactive isotopes for targeted diagnosis and therapy[1]. They are broadly categorized into agents used for molecular imaging and diagnosis and those used for therapeutic treatment[2]. This paper focuses on therapeutic applications, with particular emphasis on radioligand therapy (RLT), an advanced and rapidly evolving segment of therapeutic radiopharmaceuticals.

Radioligand therapy is a form of targeted precision medicine that has been most widely applied in oncology. By linking a disease-specific targeting ligand with a therapeutic radioisotope, RLT delivers ionizing radiation directly to tumor cells expressing defined molecular markers, enabling precise tumor cell destruction while minimizing exposure to surrounding healthy tissue[3,4].

A defining feature of RLT is its theranostic paradigm, in which the same molecular target can be used for both imaging and treatment[5]. This integrated approach allows physicians to identify appropriate patients and confirm target engagement prior to therapy. Clinically, RLT has demonstrated meaningful benefit in selected cancers such as metastatic castration-resistant prostate cancer and neuroendocrine tumors, particularly for patients with limited treatment options[6,7].

China RLT Ecosystem Development Status and Policy Support

China is rapidly strengthening its RLT ecosystem, driven by continued policy support, expanding biotechnology innovation capacity, growing industrial investment, and substantial clinical demand. Across isotope supply, radiopharmaceutical innovation, and clinical adoption, the enabling conditions for RLT scale-up are steadily improving.

Table 1. Overview of China's Radioligand Therapy Ecosystem Development

Segment	Current Status	Key Drivers
Upstream: Medical isotopes	Domestic supply capacity expanding; self-sufficiency in key diagnostic isotopes exceeds 80%; therapeutic isotope capability continuing to build	Policy support: *Medical Isotope Development Plan (2021–2035)* National investment on reactor upgrades
Midstream: R&D, manufacturing & logistics	Innovation activity rising; China's share of new therapeutic radiopharmaceutical pipelines increasing; GMP manufacturing and nuclear pharmacy networks steadily expanding	Strengthening biotech innovation capacity; Continued capital investment; Multinational localization
Downstream: Clinical utilization	Nuclear medicine infrastructure and service capacity improving; utilization still at an earlier stage compared with developed markets	Large cancer burden; Population aging; Expanding clinical demand

Upstream: isotope supply capacity improving

Medical isotope availability has historically been a key structural bottleneck for RLT development. This constraint is now gradually easing under the Medical Isotope Development Plan (2021–2035)[8], led by the China Atomic Energy Authority together with relevant ministries. China has accelerated reactor upgrades and expanded domestic production capacity for key medical isotopes.

By 2023, self-sufficiency in key diagnostic isotopes such as Mo-99/Tc-99m had exceeded 80%, while domestic capacity for therapeutic isotopes including Lu-177 and Ac-225 continues to expand[9]. This policy-driven localization is helping reduce exposure to supply volatility and alleviate a longstanding constraint on RLT scale-up.

Midstream: R&D and manufacturing capabilities scaling

China's radiopharmaceutical innovation activity is expanding steadily. According to Insight Data[10], China's share of newly added therapeutic radiopharmaceutical pipelines increased from around 20% in 2020 to approximately 44%-45% in 2024–2025, indicating a narrowing gap with leading international markets.

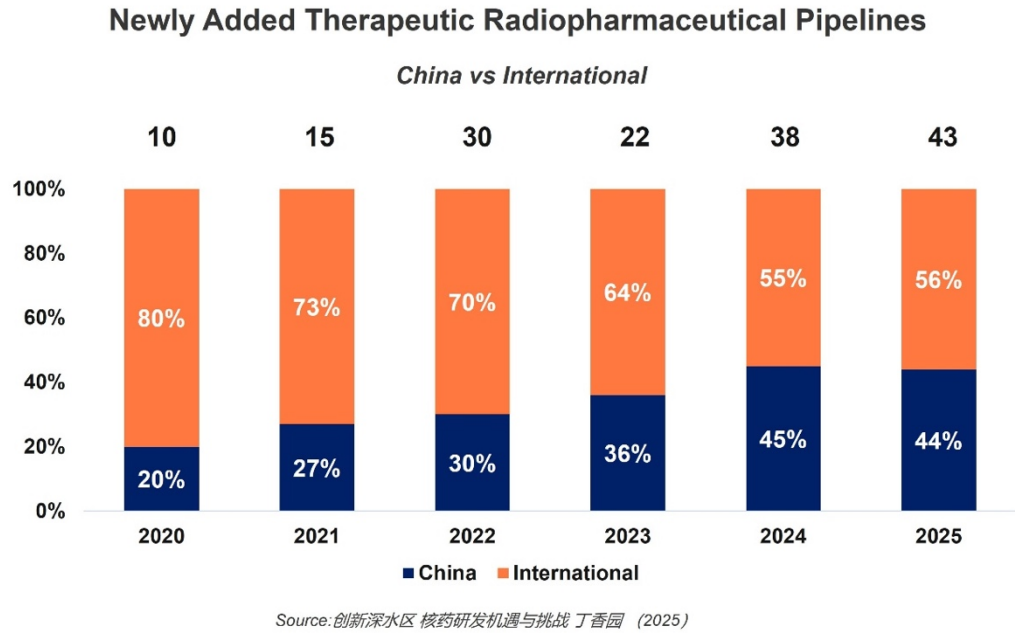

Chart 1. Rapid Rise of China in Global Therapeutic Radiopharmaceutical Pipelines (2020–2025)

Manufacturing capabilities are strengthening in parallel. Continued investment in GMP-compliant radiopharmaceutical facilities, together with ongoing localization efforts by multinational companies, is improving production reliability and supply resilience[11].

At the distribution level, third-party nuclear pharmacy networks are increasingly serving as core logistics infrastructure for short-half-life radiopharmaceuticals. China's nuclear pharmacy count increased from 63 in 2020 to 89 in 2024, indicating steadily improving just-in-time supply capability[8].

Downstream: strong clinical demand with significant room for growth

Clinical demand provides a fundamental foundation for the long-term development of radioligand therapy in China. In absolute terms, China bears the world's largest cancer burden. According to the International Agency for Research on Cancer (IARC), the country recorded approximately 4.8 million new cancer cases and 2.6 million cancer deaths in 2022[12], accounting for roughly one quarter of the global total. With the population aged 60 and above projected to reach 400 million by 2035[13], demand for oncology diagnosis and treatment is expected to continue expanding.

In recent years, China's nuclear medicine service capacity has improved steadily, supported by continued expansion in clinical infrastructure. At the same time, compared with developed markets such as the United States, overall utilization of nuclear medicine and radiopharmaceutical therapies in China remains at an earlier stage of development. The combination of substantial clinical need and still-maturing utilization suggests considerable headroom for future growth as system capacity and clinical readiness continue to advance.

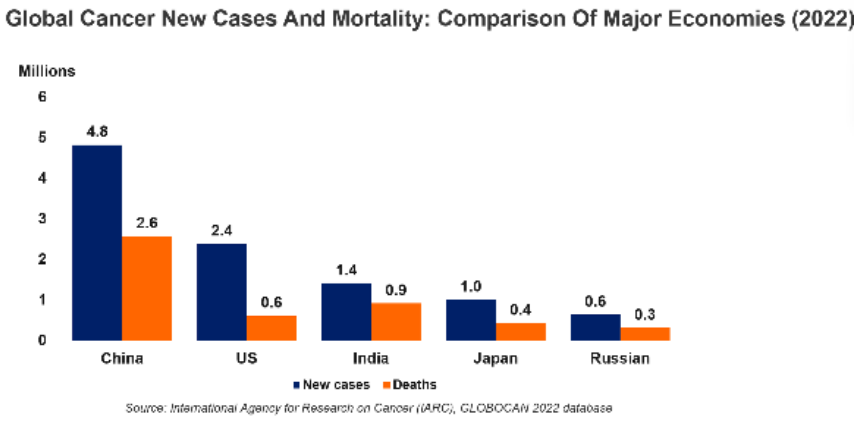

Chart 2. China's Cancer Burden in Global Context (2022)

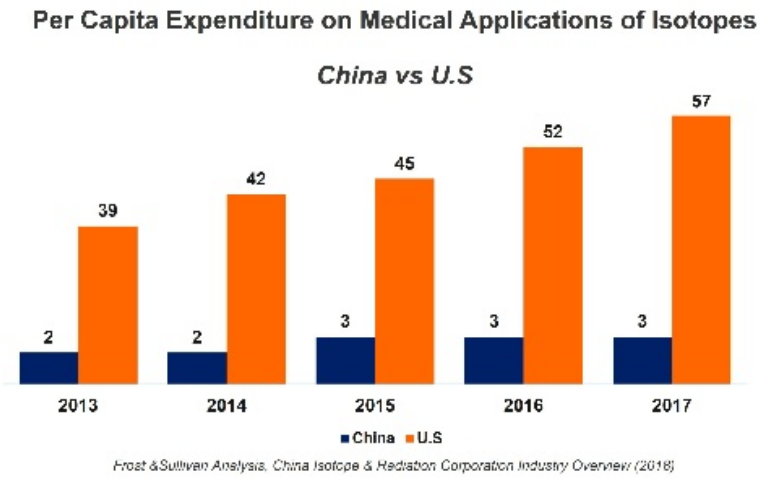

Chart 3 Gap in Medical Isotope Utilization Between China and the U.S[14]

Chart 4. Expansion of Nuclear Medicine and Radiopharmaceutical Therapy Capacity in China

Section 2: Into Sustainable Development — Addressing Key Factors for RLT's Long-Term Viability

As China's radioligand therapy ecosystem enters a phase of accelerated development, attention is increasingly shifting from early capacity build-up toward the conditions required for long-term, sustainable growth.

International experience[15,16,17] suggests that when emerging technology sectors expand rapidly, often supported by policy incentives, capital inflows, and technological breakthroughs, long-term outcomes depend on whether regulatory frameworks, institutional capacity, and clinical systems evolve in step. Where this alignment lags, sectors may face fragmented investment and implementation inefficiencies.

For RLT, the need for coordinated development is particularly important. Due to its radioactive nature, the modality places elevated requirements on radiation safety, environmental management, and full-lifecycle quality control[18]. Ensuring that industry expansion proceeds in a stable, orderly, and well-regulated manner is therefore essential to maintaining public confidence and supporting long-term competitiveness.

Looking ahead, sustainable RLT development will depend on continued progress in two priority areas:

- A clear and predictable regulatory framework that robustly safeguards safety and efficacy while providing innovation-friendly guidance for high-quality RLT products; and
- An optimized hospital access and clinical implementation pathway that enables RLT therapies to be delivered safely, efficiently, and in a timely manner, translating scientific progress into real-world patient benefit.

Current practice suggests that gaps remain in both dimensions.

2.1 Regulatory framework: progressing but not yet fully adapted to RLT

Table 2. Key Regulatory Gaps Affecting the Development of RLT

Issue Area	**Key Gap Identified**	**Relevant Policies / Measures**
Regulatory clarity for key RLT components	Lack of unified definitions and clear regulatory pathways for key RLT components	*Radioactive Pharmaceuticals Management Measures* (1989, rev. 2024)
Oversight of Locally Manufactured Therapies (LMT)	National LMT pathway and enforcement boundaries remain unclear	*Administrative Measures for Medical Institution Preparation of Positron Radiopharmaceuticals* (2006); *Drug Administration Law*
Me-too and generics pathways	Application boundaries for data protection and BE standards in complex radiopharmaceuticals remain to be further clarified.	*Technical Guidelines for Non-clinical Research on Therapeutic Radiopharmaceuticals* *Technical Guidelines for Non-clinical Research on Diagnostic Radiopharmaceuticals*
Localization incentives and implementation continuity	Supporting policies in place, but detailed implementation and cross-linkage across the RLT value chain can be further strengthened	General Office of the State Council Circular (Guo Ban Fa [2024] No. 53) NMPA Opinions on *Reforming and Improving the Review and Approval System for Radiopharmaceuticals*

In recent years, China has made notable progress in strengthening the regulatory and technical framework for radiopharmaceuticals. The National Medical Products Administration (NMPA) has established dedicated review pathways and issued a series of evaluation guidelines, reflecting growing national-level focus on this emerging field[19].

At the same time, as radioligand therapy technologies continue to evolve rapidly, certain elements of the current framework would benefit from further refinement to more fully reflect the modality's unique technical characteristics and risk profile.

2.1.1 Gaps in regulatory clarity for key RLT components

The Radioactive Pharmaceuticals Management Measures, administered by the National Medical Products Administration and originally issued in 1989 (latest revision in 2024)[20], still lack unified clarity on the definitions, regulatory attributes, registration pathways, and technical requirements for key RLT components, including radionuclides, chemical precursors, cold kits, and generators. Dedicated technical guidelines specific to radioligand therapies also remain limited.

This situation may create regulatory uncertainty and could slow the development, registration, and clinical adoption of RLT innovations.

2.1.2 Oversight for Locally Manufactured Therapies requires further clarification

Locally Manufactured Therapies (LMT) refer to radiopharmaceutical products prepared and used within qualified medical institutions to meet specific clinical needs[21]. China has established an initial regulatory foundation in this area. The Administrative Measures for Medical Institution Preparation of Positron Radiopharmaceuticals (2006) set requirements for 12 PET radiopharmaceuticals[22]. However, products outside this defined scope currently lack a clearly established LMT pathway.

In practice, several areas remain subject to interpretation, including:

- whether provincial drug administrations have sufficient capacity to conduct specialized review, testing, and inspection for radiopharmaceutical preparations;
- whether technical expectations for hospital preparation, including mechanism of action, formulation and manufacturing process, and nonclinical safety evaluation, are consistently defined; and
- whether production conditions at medical institutions fully align with current GMP and pharmacovigilance requirements.

Given that many hospital-prepared radiopharmaceuticals are administered intravenously, the associated safety considerations are inherently higher than those for conventional in-house preparations.

Under the current legal framework, Drug *Administration Law*[23] provides the general principle that LMT should apply only where no marketed product is available. This approach is broadly aligned with international regulatory practice[24,25]. In practice, however, enforcement boundaries are not always explicit. Hospital-prepared products may continue to coexist with NMPA-approved products in some settings, creating regulatory ambiguity and potential intellectual property risks.

2.1.3 "Me-too" and generic pathways: areas where predictability can be strengthened

Encouragingly, under the current framework, "me-too" radiopharmaceutical products applying as innovative drugs are generally expected to conduct their own clinical studies[23]. This helps mitigate the risk of inappropriate reliance on originator clinical data.

At the same time, some forward-looking questions remain as the system continues to mature. The Center for Drug Evaluation (CDE) has issued non-clinical technical guidelines for therapeutic and diagnostic radiopharmaceuticals[26,27], providing clearer development expectations. As implementation experience accumulates, continued observation will be important, particularly regarding how these guidelines are applied in stand-alone applications and how data protection principles are operationalized in practice.

For generic radiopharmaceuticals, current practice for certain widely used diagnostic products has allowed waivers of clinical or bioequivalence (BE) studies under defined conditions. Whether similar approaches may extend to future RLT or radioligand imaging generics, and what constitutes appropriate BE assessment for these more complex products, remains to be further clarified. Greater technical specificity in this area would enhance regulatory predictability while maintaining robust safety assurance.

2.1.4 Localization incentives: direction clear, implementation continuity can be enhanced

China has introduced supportive policies to prioritize review and approval resources for clinically urgent innovative drugs and to streamline the process for transferring overseas-approved products to domestic manufacturing[28,29].

However, implementation rules specific to radiopharmaceuticals have not yet been fully clarified, which may limit the effective realization of these incentives in practice.

For radioligand therapy, localization involves not only manufacturing site transfer but also coordination across isotope supply, hot cell release systems, specialized transport, hospital access, and reimbursement. Greater continuity and consistency of policy support across these interconnected elements would help strengthen long-term investment certainty and support the development of a high-quality, scalable industrial ecosystem.

2.2 Clinical implementation: hardware improving, but "soft capacity" still developing

Table 3. Clinical Access and Utilization Gaps for RLT

Issue Area	Key Gap Identified
Hospital access and operational readiness	Access pathways still follow conventional drug processes and do not fully match RLT's time-sensitive and operational characteristics
Workforce capability and multidisciplinary integration	Nuclear medicine talent pool and MDT integration remain uneven, limiting effective clinical use
Payment and reimbursement pathways	Most innovative RLT therapies remain outside NRDL, with limited commercial coverage and constrained hospital uptake

China's nuclear medicine infrastructure ("hard capacity") has expanded steadily in recent years, as outlined in Section 1, reflecting continued progress in equipment deployment, facility readiness, and service coverage. This provides an increasingly solid foundation for the development of radioligand therapy.

At the same time, the clinical management framework and professional capability ("soft capacity") for RLT remain in a phase of maturation. Looking ahead, further progress will depend not only on continued infrastructure build-out, but also on strengthening management mechanisms, clinical integration, and specialized talent development to support the sector's sustainable and efficient growth.

2.2.1 Hospital access and operational readiness remain constrained.

Hospital access for RLT largely continues to follow conventional pharmaceutical pathways, which do not fully reflect the unique characteristics of radiopharmaceuticals. In tertiary hospitals, formulary entry is typically advanced through standard processes such as Pharmacy and Therapeutics Committee review, centralized or hospital-level negotiations. These pathways often involve multiple approval steps, lengthy timelines, variable requirements for temporary procurement, and limited differentiated evaluation mechanisms tailored to nuclear medicine products.

In addition, the relatively high cost of RLT therapies means their clinical use may be further influenced by hospital performance metrics such as DRG management and drug expenditure controls, which can constrain routine adoption.

Taking prostate cancer as an illustrative example, Zhejiang Province reports more than 15,000 new patients annually, yet actual RLT treatment volumes remain below 200 cases per year[30]. The corresponding isotope Lu-177 has a short half-life of approximately five days and requires prescription-driven production. Under current complex hospital management procedures, supply responsiveness and clinical demand are not always well aligned, which may limit timely patient access.

2.2.2 Workforce capability and multidisciplinary integration remain uneven

Professional knowledge and clinical capability in RLT remain uneven across institutions, reflecting a broader talent and workforce gap. In practice, challenges such as “not knowing how to use,” “hesitating to use,” and “being unable to use” advanced radiopharmaceuticals are still observed in some clinical settings.

Taking Zhejiang Province as an illustrative example, among 76 tertiary hospitals, 39 currently provide nuclear medicine diagnostic and therapeutic services, yet only nine have the capability to deliver advanced radiopharmaceutical therapies[30]. The nuclear medicine workforce is still developing, with a relatively limited pool of physicians possessing integrated, system-level expertise in nuclear medicine and theranostics.

In many institutions, nuclear medicine departments continue to be positioned primarily as auxiliary services, with relatively limited participation in multidisciplinary team (MDT) decision-making. Awareness of nuclear medicine therapies among clinicians, patients, and the broader public also remains in a phase of gradual improvement. Together, these factors may constrain the appropriate and wider clinical utilization of innovative radiopharmaceutical therapies.

2.2.3 Payment and reimbursement pathways are still developing

Many innovative RLT products remain outside the National Reimbursement Drug List (NRDL), and to date only limited city-level commercial insurance programs have begun to provide partial coverage. As a result, patient affordability remains a key constraint on broader clinical uptake.

This situation not only creates barriers to patient access to innovative radiopharmaceutical therapies, but also slows the accumulation of real-world health economic evidence needed to support value assessment and reimbursement decision-making. In addition, many policy mechanisms designed to facilitate hospital access and clinical use are primarily applicable to NRDL-listed products. As RLT therapies are largely outside this framework, they are currently unable to fully benefit from these access-support policies, which may further constrain hospital adoption and utilization.

Section 3: Recommendations

In light of the gaps identified above, targeted policy refinement will be important to support the sustainable development of China's radioligand therapy ecosystem.

Recommendation 1: Further refine and align the regulatory governance framework for radiopharmaceuticals to reflect the full lifecycle of RLT products, supporting safe innovation, orderly competition, and localization.

Key actions include:

- Update Regulations: Revise the Administrative Regulation on Radioactive Pharmaceutical Products to clarify the definitions, regulatory attributes,

registration pathways, and technical requirements for radiopharmaceuticals and their components.

- Standardize Management of Locally Manufactured Therapies: Establish nationally consistent, risk-based quality and safety control systems, approved by provincial or national medical products regulatory authorities, taking into account safety, regulatory complexity, and intellectual property considerations.
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- Advance Coordinated Access and Payment Pathways: Incorporate eligible radiopharmaceuticals into standardized disease treatment pathways and explore alignment with city-level inclusive insurance and commercial insurance programs to form an integrated access, payment, and clinical management framework.

Conclusion

Radioligand therapy is entering an important window of development in China. Supported by strong clinical demand, improving supply capabilities, and growing innovation momentum, the sector is well positioned for continued expansion. At this stage, however, the focus should not be on speed alone. Sustainable impact will depend on steady, well-coordinated progress that matches the sector's growing complexity.

The experience of many emerging technologies shows that only development that advances in a stable and orderly manner can ultimately go far. For China's RLT ecosystem, continued policy refinement and system-level coordination will be important to ensure that innovation translates into durable clinical value and long-term industrial strength.

Novartis stands ready to work with all stakeholders to support the safe, high-quality, and sustainable development of radioligand therapy in China.

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