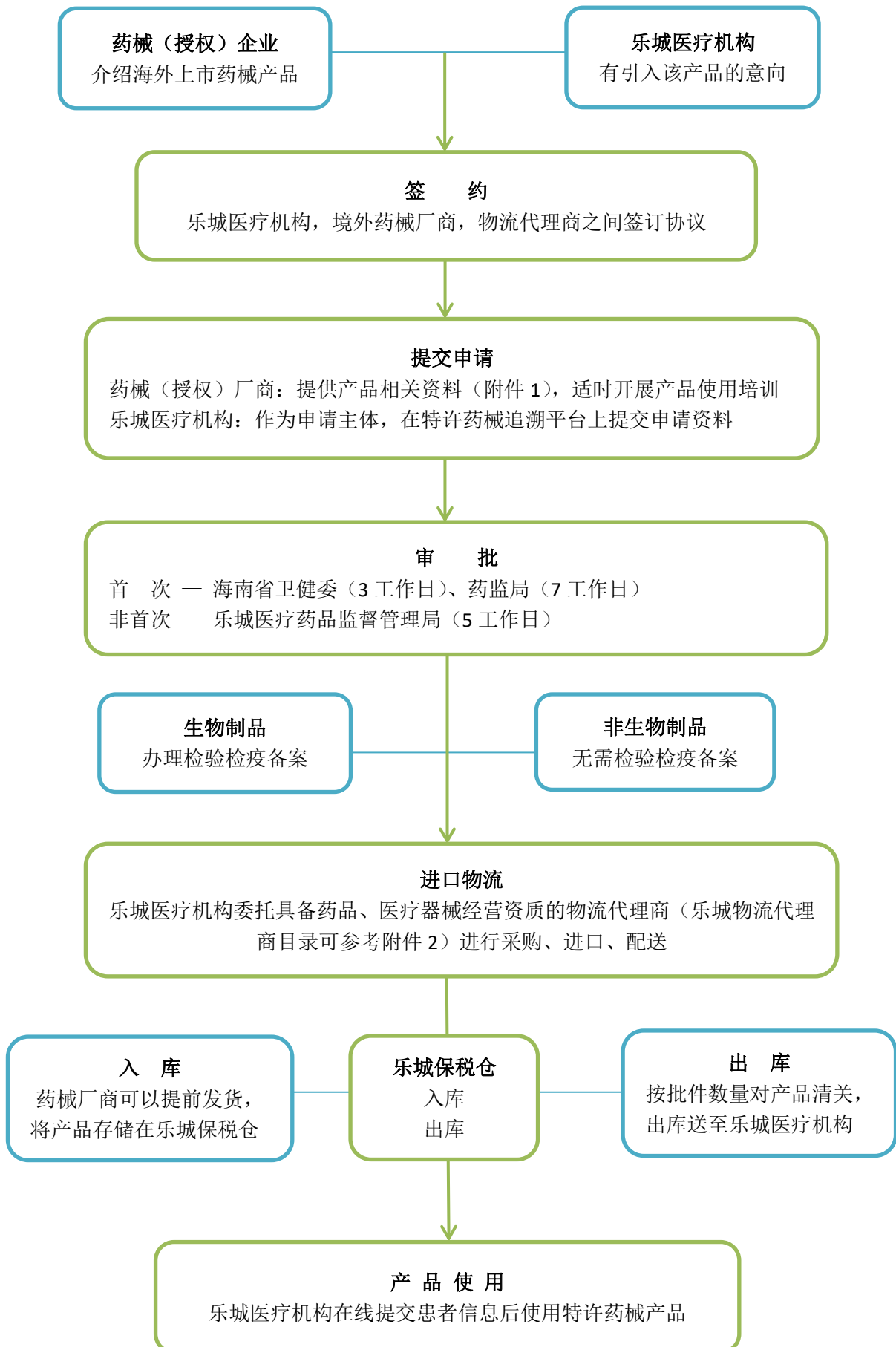
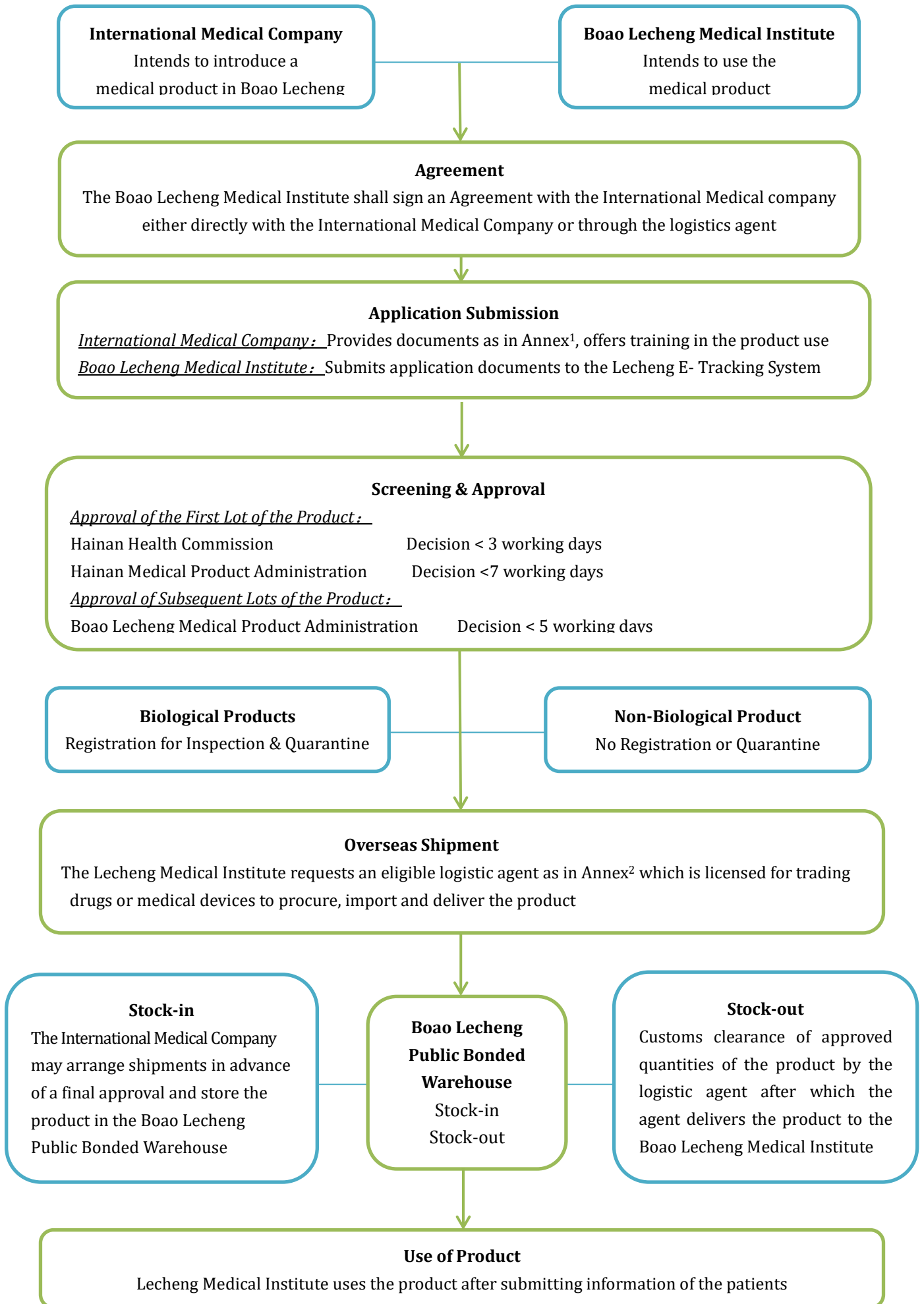


国际创新药械产品落地乐城流程图



Boao Lecheng Introduction Flow Chart for International Innovative Medical Products



药品厂商提交资料清单

List of Materials to be Submitted by a Drug Company

序号 NO.	类别 CATEGORY	提交资料 MATERIALS TO SUBMIT
1	资质证明 Certificate	境外药品上市销售许可证明（或药品管理部门网站公开信息等） Certificate showing the drug was approved by official authorities overseas such as the FDA, CE, PMDA, etc (or a reference to a webpage published by an overseas medical product administration)
2	产品综述 Product Review	药品主要成分、治疗机理 Main composition of the drug and the drug action mechanism
3		境外获批适应症 Indications approved by the overseas agency
4		中国境外上市及临床应用情况 Current conditions and clinical applications under which the product is approved by an overseas agency
5		全球不良反应概述 All observed adverse effects
6		临床研究综述、人种差异风险评估 Clinical research review and risk estimation regarding racial differences (if any)
7		同类型产品在中国获批注册情况 The same kind of products registered in Chinese Mainland (if any)
8		中国境内是否有替代产品的情况说明 Examples of similar products approved in Chinese Mainland (if any) showing innovative differences and advantages of the concerned product
9		药品实物、包装、条码标签、说明书的照片，及说明书中文译文 Pictures of the original product including packaging, labeling, specifications and a Chinese translation of the specifications
10	协议 Agreement	与医院签订的采购协议、与物流代理商签订的配送协议等 The contract signed with the Lecheng Medical Institution as well as the contract signed with a logistics agent

注：药品首次落地时，需提供以上资料；后续非首次落地时，如与首次资料一致，则无需再次提交。

Note: The above materials must be provided when the drug is introduced into Lecheng for the first time.

For subsequent lots, there is no need to provide the same materials again if its contents remain the same.

医疗器械厂商提交资料清单

List of Materials to be Submitted by a Medical Device Company

序号 NO.	类别 CATEGORY	提交资料 MATERIALS TO SUBMIT
1	资质证明 Certificate	境外上市销售许可证明 Certificate showing the medical device was approved by official authorities overseas such as the FDA, CE, PMDA, etc
2		该医疗器械生产企业符合医疗器械质量管理体系的证明 Declaration of the product manufacturer in conformity with Medical Devices Quality Management System, such as ISO13485, etc
3	产品综述 Product Review	产品结构、原理、功能、原材料等基本情况介绍 Description of the structure, mechanism, function and basic materials of the product
4		适用范围及人群（适应症、禁忌症） Indications, contra-indications and intended population
5		中国境外上市及临床应用情况 Current conditions and clinical applications under which the product is approved by an overseas agency
6		全球不良反应概述 All observed adverse effect
7		临床研究综述、人种差异风险评估 Clinical research review and risk estimation regarding racial differences (if any)
8		同类型产品在中国获批注册情况 The same type of products registered in Chinese Mainland (if any)
9		中国境内是否有替代产品的情况说明 Examples of similar products approved in Chinese Mainland (if any) showing innovative differences and advantages of the concerned product
10		产品实物、包装、条码标签、说明书的照片,及说明书中文译文 Pictures of the original product including packaging, labeling, specifications and a Chinese translation of the specifications
11	协议 Agreement	与医院签订的采购协议、与物流代理商签订的配送协议等 The contract signed with the Lecheng Medical Institution as well as the contract signed with a logistics agent

注：医疗器械首次落地时，需提供以上资料；后续非首次落地时，如与首次资料一致，则无需再次提交。

Note: The above materials must be provided when the medical device is introduced into Lecheng for the first time.

For subsequent lots, there is no need to provide the same materials again if its contents remain the same.

Annex 2

乐城物流代理商目录参考

Logistic Agents Available in Boao Lecheng

Notes: The following list is up to date as per August, 2021.

1	恒大医药	Guangdong HengDa Pharmaceutical Co., Ltd. http://www.gdhdy.com/
2	上海医药	Shanghai Pharmaceuticals Holding Co., Ltd. ("SPH") http://www.sphchina.com/index/
3	成美药业	Chengmei Pharma of The First Investment Holdings Group http://www.firstgroup.com.cn/firstgroup/fq2/fq2_1/fq2_1_1/201702/t20170204_773.html
4	深圳市怡亚通医疗供应链管理有限公司	Shenzhen Eternal Asia Medical Supply Management Co., Ltd. http://www.eascs.com/
5	国药器械（广东）医学科技有限公司	Sinopharm (Guangdong) Medical Technology Co., Ltd. of China National Pharmaceutical Group Corporation(SINOPHARM) http://www.sinopharm.com/en/1156.html
6	上海嘉事明伦医疗器材有限公司	Shanghai CACHET Minglun Medical Devices Co., Ltd. of CACHET Pharmaceutical Co., Ltd. http://www.cachet.com.cn/english/
7	科园信海（北京）医疗用品贸易有限公司	Keyuan Xinhai (Beijing) Medical Products Trade Co., Ltd. http://en.kybeijing.com/
8	江苏恩华和信医药营销有限公司	Jiangsu Nhwa Hexin Pharma Marketing Co., Ltd. of Jiangsu Nhwa Pharmaceutical Co., Ltd. https://www.nhwa-group.com/about/he-xin.htm
9	北京嘉事唯众医疗器械有限公司	Beijing CACHET Weizhong Medical Devices Co., Ltd. of CACHET Pharmaceutical Co., Ltd. http://www.cachet.com.cn/english/
10	海南广药晨菲医药有限公司	Hainan GP Chenfei Pharmaceutical Co., Ltd. http://www.hngycf.com/front/home/home
11	广东通用医药有限公司	Guangdong General Pharm Co., Ltd. of China Meheco Group Co., Ltd. http://www.gdGPC.net/
12	上药科园信海医药海南有限公司	Kyun Xinhai Pharmaceutical (Hainan) Co., Ltd. of Shanghai Pharmaceuticals Holding Co., Ltd. ("SPH") http://www.sphkyuan.com/
13	华润医药商业集团国际贸易有限公司	International Trade Co., Ltd. of China Resources Pharmaceutical Commercial Group Co., Ltd. https://www.crpcg.com/
14	海南康虹药业有限公司	Hainan Kanghong Pharmaceutical Co., Ltd.
15	海南九州通康达医药有限公司	Hainan Jointown Kangda Pharmaceutical Co., Ltd. of JoinTown Pharmaceutical Co., Ltd. https://www.jztey.com/ENViews/Home/index.html
16	携泰健康科技股份有限公司	Xietai Health Technology Co., Ltd. http://www.xt-health.com/
17	华润海南裕康医药有限公司	Hainan Yukang Pharmaceutical Co., Ltd. of China Resources Pharmaceutical Commercial Group Co., Ltd. https://www.crpcg.com/
18	北京普尔伟业生物科技有限公司	Beijing Purevalley Biotech Co., Ltd.
19	宁波海高优服医疗科技有限公司	Ningbo Heico Excellent Service Medical Technology Co., Ltd. of China Heico Holding Group http://www.chinaheico.cn/medicalTreatment.html
20	广药器化医疗设备有限公司	Guangzhou Qihua Medical Treatment Equipment Co., Ltd. of Guangzhou Pharmaceutical Holdings Limited (GPHL) http://en.gpc.com.cn/