君合研究简讯

JUNHE

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医药健康法律评论

进口医疗器械国产化新路径：《已获进口医疗器械注册证的产品转移中国境内企业生产有关事项公告（征求意见稿）》简评

2020 年 3 月 5 日，国家药品监督管理局（以下简称“**药监局**”）发布了《已获进口医疗器械注册证的产品转移中国境内企业生产有关事项公告（征求意见稿）》（以下简称“**《征求意见稿》**”）。《征求意见稿》提供了进口医疗器械转国产化生产的便利通道，一旦实施将实质性加快进口产品的国产化。本文将对《征求意见稿》的主要内容进行介绍和评述。

一、立法背景

2017 年 10 月 8 日，中共中央办公厅、国务院办公厅联合发布《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》，明确探索医疗器械上市许可持有人制度（也称注册人制度）。截至 2019 年底，已有 21 个试点范围内的省、自治区、直辖市出台了配套制度，允许医疗器械的注册与生产相分离。尽管如此，各地的试点方案都未将进口产品纳入其中。换言之，进口医疗器械的境外注册人无法直接委托境内企业生产注册产品。如果希望实现进口医疗器械国产化生产，境外注册人须先将产品和技术许可或转让给境内企业，再由境内企业将相关产品重新进行国内注册或备案，除第一类医疗器械和部分可免于临床实验的产品外通常需要走完注册检验、临床评价、资料申报的完整流程。这使得注册人不得不就同一产品的注册重复投资、重复准备资料，延缓和制约了一些器械的国产化。

二、主要内容

根据《征求意见稿》，已获进口医疗器械注册证的第二类、第三类医疗器械/体外诊断试剂的进口医疗器械注册人（以下简称“**境外注册人**”）可通过其在中国境内的控股子公司等关联企业（以下简称“**境内注册人**”）就同一产品提交境内医疗器械注册申请。药监局允许境内注册人在提交注册申报资料时，部分申请材料可以提交进口医疗器械的原注册申报资料，以便加快注册进程。我们将具体监管要求整理如下：

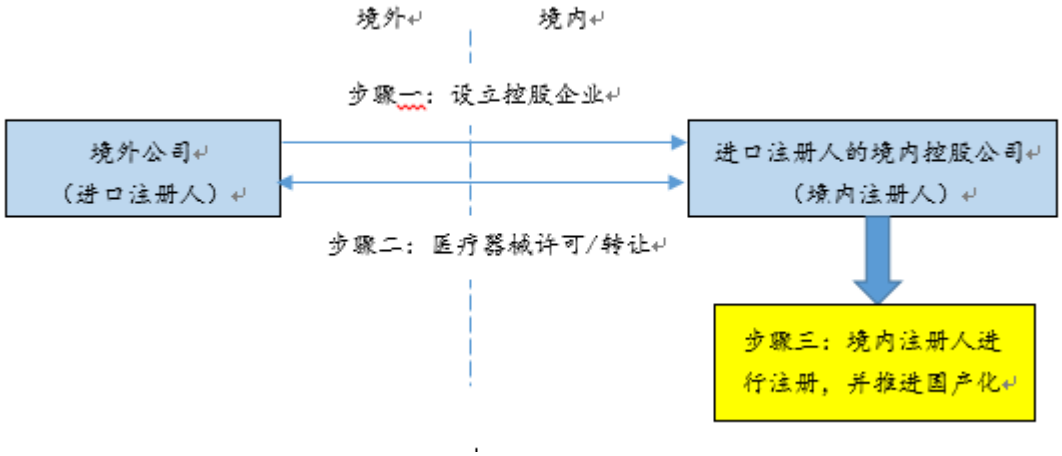
适用的产品范围	已获**进口医疗器械注册证**的第二类、第三类医疗器械/体外诊断试剂
境内注册人主体资格	1、 进口医疗器械注册人在中国境内设立的**外商控股投资企业** 2、 中国境内企业控股境外注册人的，可由**控股境外注册人的中国境内企业**作为境内注册申请人

注册申报材料	1、 申请人应当按照《医疗器械注册申报资料要求和批准证明文件格式的公告》（国家食品药品监督管理总局 2014 年第 43 号公告）、《体外诊断试剂注册申报资料要求和批准证明文件格式的公告》（国家食品药品监督管理总局 2014 年第 44 号公告）等要求提交注册申报资料。 2、 下述注册申报资料**可提交进口医疗器械的原注册申报资料**： a) 对于医疗器械产品：综述资料、研究资料、临床评价资料、产品风险分析资料； b) 对于体外诊断试剂产品：综述资料、主要原材料的研究资料、分析性能评估资料、阳性判断值或参考区间确定资料、稳定性研究资料、临床评价资料、产品风险分析资料。 3、 一致性声明：境外注册人和境内注册申请人应当确保上述注册申报资料与境外注册人提交的原注册申报资料一致。
注册体系核查要求	1、 注册申请人应当提供产品在境外生产质量管理体系的相关资料。 2、 药品监管部门在现场核查时重点关注境内生产质量管理体系与境外质量管理体系在设计开发、采购控制、生产控制、质量控制要求等方面的**一致性、溯源性**。 3、 医疗器械生产许可的现场检查可以与注册体系核查**同步进行**，避免重复核查。
上市后监管要求	1、 取得医疗器械注册证的境内注册人应当按照《医疗器械生产监督管理办法》的相关要求和程序**办理生产许可证**。 2、 境内注册人承担医疗器械产品质量安全的主体责任，并负责医疗器械**全生命周期的质量管理**。

三、要点评析

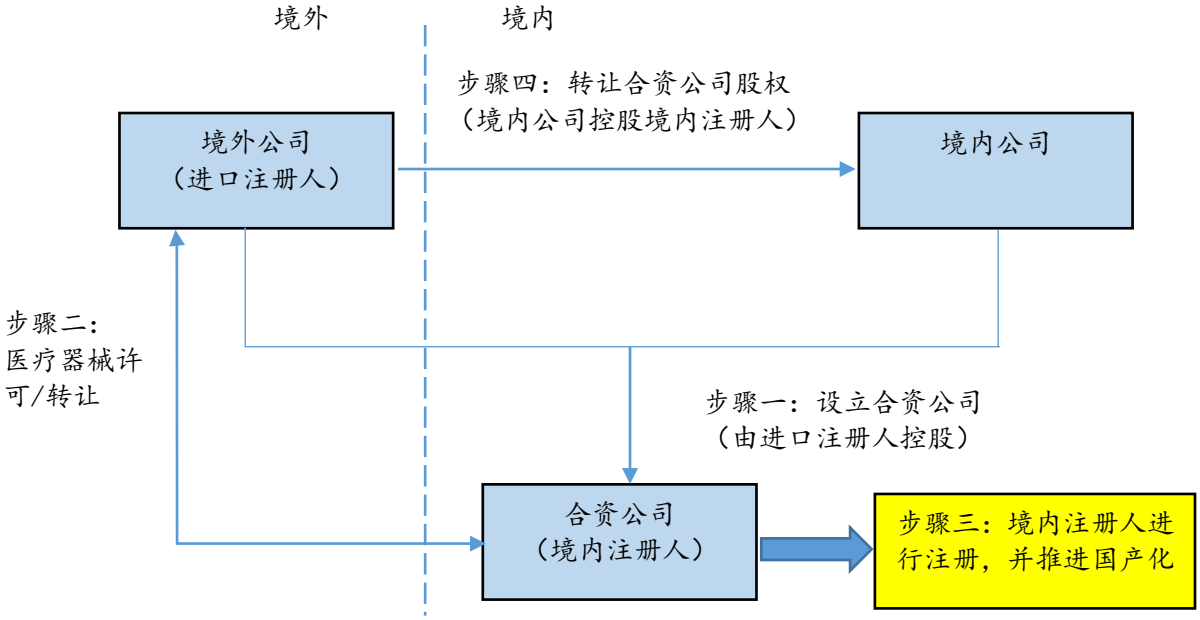
1、 进口医疗器械产品的国产化注册更为便捷

《征求意见稿》最大的亮点在于允许已获注册的进口医疗器械产品较为便捷地实现国产化注册。如前所述，进口医疗器械目前如需实现国产化，需要从头走完境内医疗器械的注册申报流程，耗时耗力。《征求意见稿》规定，在境内注册人进行境内医疗器械注册申请时，可提交进口医疗器械的原注册申报资料，包括临床评价资料。临床评价的进一步简化将为进口医疗器械的国产化提供更多便利。《征求意见稿》实施后，相信会有一批境外器械厂商选择将一些进口品种许可或转让给境内控股企业，由境内控股企业作为境内注册人推进国产化，达到优化供应链条，降低生产成本的目的。具体模式参见下图一：



（图一）

对于希望把一些品种在中国的商业化权利剥离出售的境外器械厂商，可能会采取先与购买方成立合资公司，将产品品种先转由境内控股合资公司持证、生产，然后再出售合资公司股权的方式来实现商业化权利的转移。具体模式参见下图二：



（图二）

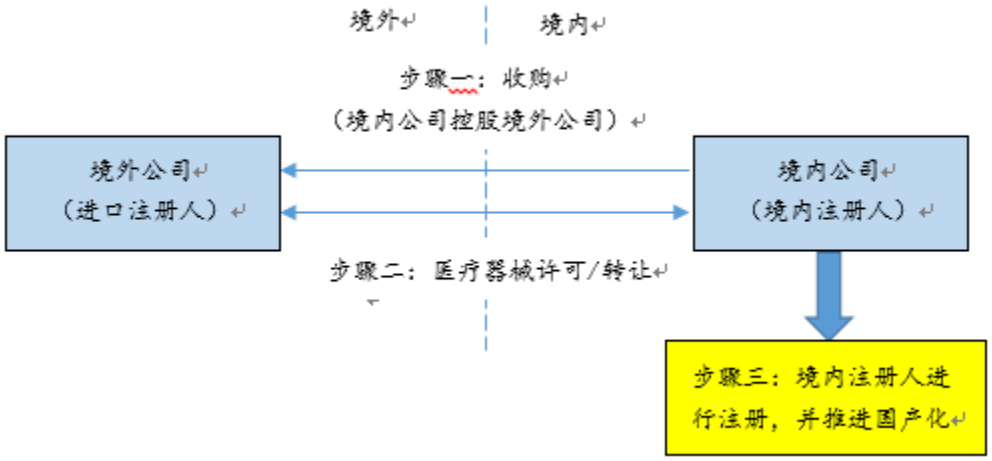
2、 境内注册与生产暂不能分离

略有遗憾的是，《征求意见稿》要求境内注册人在取得注册证后，必须办理相应的生产许可。也就是说，境内注册人需要同时具备生产能力。这一点与目前正积极推进的医疗器械注册人改革所倡导的注册与生产相分离的理念有所差异，也会增加进口医疗器械转国产化生产的操作成本。这可能是药监局出于稳步推进改革，防止申请人滥用制度规避监管的审慎考虑。如有需要，境内注册人可考虑在境内医疗器械注册完成后另行寻求委托生产安

排。

3、 通过海外并购获得品种并国产化

除进口注册人设立的外商控股投资企业可担任境内注册人以外，《征求意见稿》特别提及，对于中国境内企业控股的进口注册人，可由该中国境内企业作为境内注册人。因此，具有国际战略的境内器械企业可以通过并购进口注册人股权的方式间接获得已有进口注册证的品种，然后通过《征求意见稿》设计的路径快速实现该品种的国产化。具体模式参见下图三：



（图三）

4、 境外注册人义务

另外需要注意的是，在境内注册人的注册申请过程中，境外注册人需要承担一些协助义务。根据《征求意见稿》，境内注册人提交的注册申报资料中，应当包括境外注册人提供的如下声明文件：（1）同意注册申报的声明或授权文件，声明同意境内注册人进行注册申报，承担相关生产、法律责任，授权境内注册人使用相应进口产品注册申报资料；（2）质量管理体系一致性声明，声明申请注册产品与相应进口产品生产质量管理体系在设计和开发、采购控制、生产控制、质量控制等方面的一致性；以及（3）所提交资料真实性的自我保证声明。境外注册人应当注意提供以上声明可能导致的法律责任，并寻求境内注册人或者合作方对其提供该等声明给予补偿。

四、结语

总体来说，药监局此次发布的《征求意见稿》是加速进口医疗器械国产化的一项突破。它简化了已获得进口注册的医疗器械的国产化注册程序，使境内注册申请人不必重复走流程，体现了监管部门“简政放权”的执政理念。如《征求意见稿》正式实施，将加速进口医疗器械的国产化，对化解医疗器械产能过剩、促进国产器械的创新发展起到促进和推动作用，增加医疗器械的可及性，更好地满足公众的健康需求。

《征求意见稿》征求意见的时间截止 2020 年 3 月 31 日，不排除后续会根据公众意见有进一步的修改。我们将持续关注最终出台的正式文件的最新进展。

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JUNHE BULLETIN

March 20, 2020

Life Sciences and Healthcare Law

The Localization of Imported Medical Devices and IVD Products Fast Tracked in China

On March 5, 2020, the National Medical Products Administration ("**NMPA**") promulgated *the Announcement on the Transfer of Medical Devices with Imported Registration Certificates to Chinese Domestic Enterprises for Production (Draft for Comment)* ("**Draft Notice**") ("*《已获进口医疗器械注册证的产品转移中国境内企业生产有关事项公告(征求意见稿)》*" in Chinese). The Draft Notice, once adopted, will provide an expedited pathway for the localization of imported medical devices and IVD products. Here is our summary and analysis of the Draft Notice.

I. Background

The *Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation of Medicine and Medical Devices* ("*《关于深化审评审批制度改革鼓励药品药疗器械创新的意见》*" in Chinese) promulgated by the State Council on October 8, 2017 introduced the Marketing Authorization Holder (MAH) system for devices. By the end of 2019, 21 provinces in China had introduced trial MAH programs for devices, which allows the separation of the MAH holder and the manufacturer of medical devices. However, imported devices were not included in these trial programs. In other words, a foreign company which holds the registration certificate for an imported device must manufacture the device outside China. If a foreign company intends to manufacture the device in China, it must license or transfer the product and technology to a Chinese company. The Chinese company then needs to complete the product registration or record-filing of the same device as a domestic device, going through a time-consuming and somewhat repetitive process of registration, testing, clinical evaluation and document submission required by the NMPA, with exemptions only for Class I devices and some products exempted for clinical evaluation.

II. The Draft Notice

According to the Draft Notice, a foreign holder of a registration certificate for imported Class II/III devices or IVD products ("**Foreign Holder**") may have its affiliate in China ("**Domestic Holder**") register the same product as a domestic product and hold the relevant registration certificate. The NMPA allows the Domestic Holder to use certain application materials lodged during the registration of an imported product, to accelerate the registration process. The specific requirements are summarized as follows:

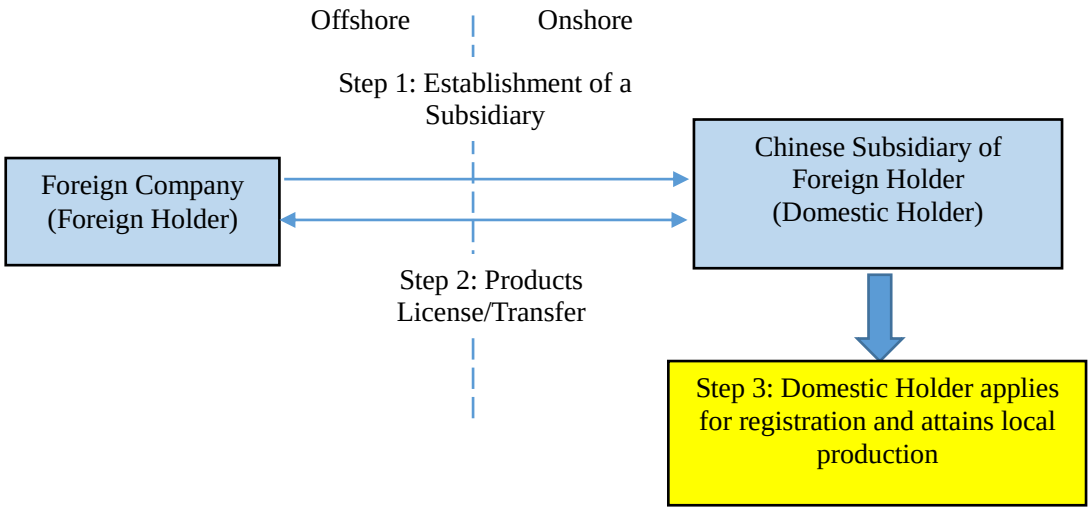
Applicable Products	Class II and Class III medical devices/IVD products already registered with the NMPA
Qualification for Domestic Holders	1. A foreign-invested company in China whose majority interest is owned by the Foreign Holder 2. Where the Foreign Holder is controlled by a Chinese company, the Chinese company can be the Domestic Holder.
Registration Materials	1. Applicants shall submit registration materials in accordance with the NMPA requirements. 2. The following registration materials of the imported products may be used for the registration of the domestic products: (a) Medical devices: general information, research materials, clinical evaluation materials, and product risk analysis materials; (b) IVD products: general information, research materials on raw materials, performance testing materials, materials for positive value or scope, stability materials, clinical evaluation materials and product risk analysis materials. 3. Declaration of consistency: both the Foreign Holder and the Domestic Holder shall ensure that the aforesaid registration materials are consistent with the original registration materials for imported registration.
Inspection Requirements	1. The applicant shall provide the relevant materials on quality management systems for overseas manufacturing. 2. During on-site inspections, the NMPA shall focus on the consistency and traceability of the domestic quality management system and the overseas quality management system in the fields of design and development, procurement control, production control, quality control, etc. 3. Respective on-site inspections pertaining to manufacturing licenses and product registration may be conducted simultaneously to avoid repetition.
Post-commercialization Requirements	1. After obtaining a registration certificate, the Domestic Holder shall apply for a manufacturing license in accordance with the relevant requirements and procedures set out in the *Regulations on the Supervision and Administration of the Manufacturing of Medical*

	Devices ("*《医疗器械生产监督管理办法》*"in Chinese). 2. Domestic Holders shall bear the main responsibility for the quality and safety of the products and be responsible for quality management throughout their life cycles.

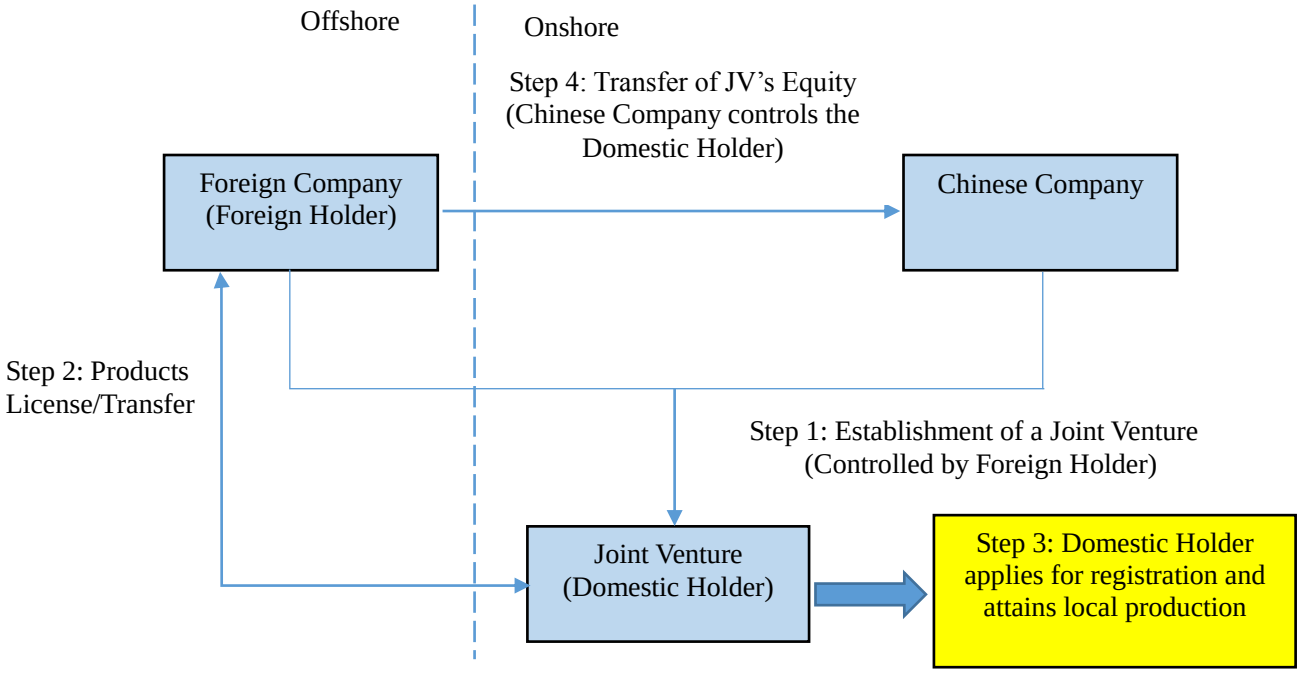
III. Our Observations

1. Localization of imported products fast tracked

A major change introduced by this Draft Notice is that imported medical devices and IVD products which have been registered with the NMPA have now been fast tracked to be registered as domestic products and be produced in China. As mentioned above, under the existing legal regime, it was time consuming and costly to register imported products as domestic products and localize their production in China. Under the new pathway, the NMPA allows applicants to use certain application materials used for registering imported products, particularly clinical evaluation materials, during the registration of the same products as domestic products. The simplification of clinical evaluation will substantially facilitate the localization of imported medical devices. After the implementation of the Draft Notice, certain Foreign Holders may choose to license or transfer some imported products to its subsidiaries in China, which will act as the Domestic Holder to realize local production, so as to optimize its supply chain and reduce production costs. Such a business model is illustrated as follows:



If a Foreign Holder intends to divest and sell the commercial rights of its portfolio products in China, they may also utilize the new pathway by establishing a joint venture company in China with the Chinese buyer, and then transfer the portfolio rights to the joint venture company for registration and local production. After the joint venture company becomes the Domestic Holder of the registration certificates of the portfolio products, the Foreign Holder can then sell its equity in the joint venture company to the buyer and allow the purchaser to control the joint venture company. This business model is illustrated below:

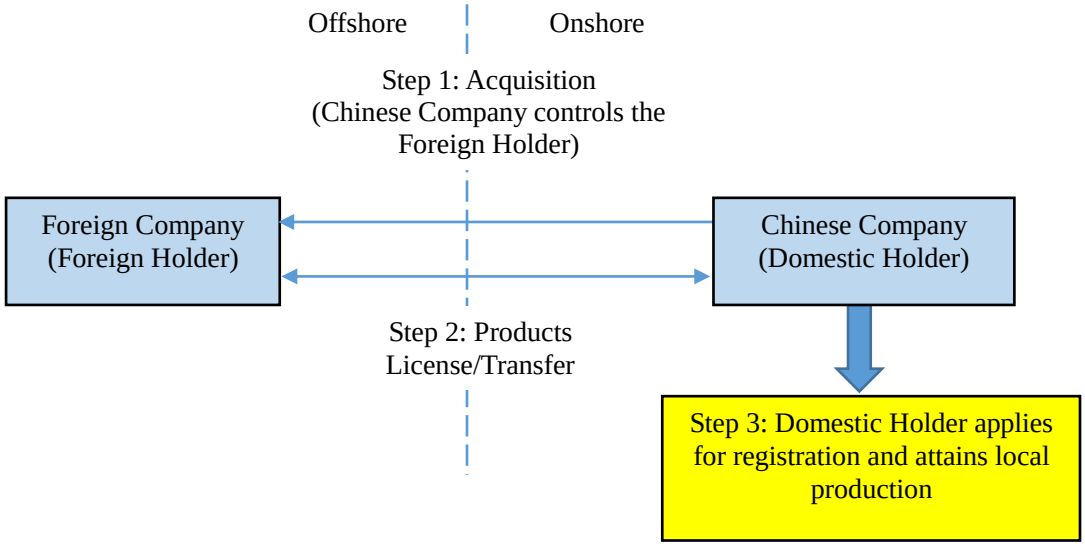


2. Domestic registration and production cannot be separated

Regrettably, the Draft Notice requires that the Domestic Holder must also be the holder of the production licenses of the relevant products. In other words, the Domestic Holder needs to have the full capability to produce the products in China. This increases the operating costs of the Domestic Holder and deviates from the original goal of the MAH system which aims to separate registration from production, as currently advocated by the NMPA. The NMPA may want to introduce the reform gradually and prevent abuse of the new law. The Draft Notice does not prohibit the Domestic Holder from engaging contract manufacturers after the domestic registration is completed.

3. Implications on the acquisition of foreign device companies

The Draft Notice provides that if a Chinese company controls a Foreign Holder, the Chinese enterprise can serve as the Domestic Holder. Therefore, a Chinese company may acquire a Foreign Holder which owns an imported product portfolio already registered with the NMPA and quickly localize the portfolio through the pathways introduced by the Draft Notice. This business model is illustrated below:



4. Statutory obligations of the Foreign Holder

The Foreign Holder is required to undertake certain statutory obligations when the Domestic Holder registers the relevant products as domestic products. According to the Draft Notice, the registration materials lodged by the Domestic Holder must include the following statements given by the Foreign Holder: (1) a statement of approval or power of attorney, which grants authorization to the Domestic Holder to lodge the application, and authorizes the Domestic Holder to use the original registration materials; (2) a statement on the consistency of the quality management systems, stating that the quality management systems of the domestic product and the imported product are the same in the fields of design and development, procurement control, production control and quality control, etc.; and (3) a statement of guarantee on the truthfulness of the submitted materials. The Foreign Holder should be aware of the legal liabilities that may arise from the aforesaid statements and seek indemnity from the Domestic Holder and/or its Chinese partners in relation to losses which may arise from such statements.

IV. Conclusion

The Draft Notice is a breakthrough in accelerating the localization of imported medical devices and IVD products. It simplifies the domestic registration process of imported medical devices and reduces the costs to the applicants. After the Draft Notice is implemented, the localization of imported medical devices will be accelerated, which will encourage domestic production, increase the accessibility of medical devices to patients, and better serve public health demands.

The Draft Notice is open for public comments until March 31, 2020, after which the NMPA will make further revisions to reflect public concerns. We will continue to follow up the development of the law and keep you posted.

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