

The Regulatory regime for Medical Devices in the People's Republic of China

Comments from ABHI (Association of British Healthcare Industries)

Review of the existing framework

(1) The SFDA appears to be engaged in a significant overhaul and revision of the existing regulatory framework for medical devices. We are expecting a revision of Decree 276 on medical device good manufacturing practices. This process is proceeding with the appearance of many "draft" documents, but there is apparently no publicly available plan or overview of the process and its objectives. We urge that MoH and SFDA provide a public overview of its plans. We also urge that substantial time and opportunity be provided for regulated industry, including foreign industry, to submit comments on that plan and that those comments are given significant consideration.

(2) As China conducts this overhaul of medical device regulation, there have been several instances of new regulatory requirements appearing without advance notice and without opportunity for public comment. This is particularly difficult because these requirements take effect immediately upon issuance (for example GMP requirements and implementation guidance for sterile and implantable medical devices issued on 31 December 2009 and took effect from 1 January 2010). When SFDA issues new regulatory requirements, it would be helpful to industry if it also provided responses to comments received and guidance on interpretation and application of those new requirements.

(3) When industry submits comments on proposals, it appears they are mostly disregarded by SFDA and that final requirements do not take industry views into account (for example February 2010 re-proposal of 2008 draft guidance on medical device recalls and the recent proposal of submission requirements for implantable pacemakers). Because it takes foreign industry some time to learn of new proposals and to translate them, foreign industry is at a significant disadvantage in responding to proposals.

(4) There is no apparent evidence that SFDA is taking this opportunity of the ongoing overhaul of medical device regulatory requirements to harmonise them with those of major trading partners and GHTF guidance. This is especially disappointing inasmuch as China SFDA currently chairs the Asian Harmonization Working Party (AHWP). We urge SFDA to seize this opportunity and to outline in its public plan how it intends to harmonise its regulatory requirements.

The Use of Standards

(5) As part of the pre-market conformity assessment of medical devices, the manufacturer is required to prepare and submit a dossier and technical standard outlining the performance and safety of the device. That technical standard typically refers to test methods outlined in existing China national standards. Unfortunately, those China national standards are often based upon earlier, obsolete international (i.e., IEC and ISO) standards, not the current versions applied in Europe and elsewhere. This means the manufacturer is confronted with

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products being evaluated against out-of-date standards. We urge the timely adoption of current versions of international standards as China national standards.

(6) We urge that, consistent with ISO, IEC, and GHTF guidance, China make conformity with standards a voluntary (rather than compulsory) means by which the manufacturer may demonstrate conformity with regulatory requirements.

(7) Quality Management Systems: SFDA is apparently working to revise its 'good manufacturing practice' requirements for medical devices (beyond those mentioned in (2) above). We urge that SFDA take this opportunity to adopt and recognise ISO 13485 (and associated GHTF guidance) as the substantial basis for those requirements.

Registration

(8) Pre-market conformity assessment registration delays: China's review process is one of the longest in the world. SFDA also often does not achieve its stated review time lines and is reported to have long review backlogs. We urge SFDA to take steps to consult with industry and to streamline the review process.

(9) Re-registration delays: For several years, SFDA has had long backlogs on reviews of the required periodic re-registration submissions. This creates uncertainty and inconvenience for manufacturers and importers. More recently, such delays, and SFDA's failure to issue timely re-registration approvals have meant that products previously accepted in national tenders can no longer be supplied. This unfairly leads to potential breaches of tender conditions and supply contracts.

(10) Re-registration of product changes: Current regulations require submission and review of "any" changes to a medical device once approved for marketing. This results in a substantial burden on manufacturers and importers and contributes significantly to the delays outlined in (8) and (9) above. It also does not reflect the typical life cycle and continuous improvement characteristic of most medical devices (being apparently derived from the medicines regulatory system where, once approved, the composition of a medicine is rarely changed). As in (7) above, we urge that such changes be controlled and evaluated through the manufacturer's QMS design control, change management, and corrective and preventive action subsystems of the QMS, and that only the most significant changes that may affect safety, performance, quality, and/or conformity with standards be subject to re-examination.

Device/Drug Combination Products

(11) SFDA recently issued new guidance that requires approval of the medicinal element of a combination product in the country of origin of that combination product before submission in China. This is not only unreasonably burdensome, but discriminates against imported devices (as a China-based manufacturer may apply immediately, but a foreign supplier must wait until a product is approved in its "home" country before applying in China). We urge that the following points are taken into consideration:

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- Both drug and device elements of a combination product are clinically evaluated, reviewed and approved in the combined form.
- Separate prior drug approval will delay, and in some cases, even deny Chinese patients access to combination products. The additional Country of Origin drug approval cycle time will add a significant time lag to China's product approval and market launch. There will be cases where the product will become obsolete even before the approval.
- Most regulatory systems in the world do not require separate drug approval for combination product registration, so this will be additional effort and expenses just for China, increasing the cost without additional benefits to the Chinese patients.
- There are also cases where the drug supplier has not obtained, and does not intend to obtain, registration for the medicine as a medicine, e.g., because the market is too small.

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