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## 第五章：                    征求意见

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203. 本咨询文件建基于联交所对《有关建议设立创新板的咨询总结》中关于吸引新兴及创新产业公司来港上市事宜所作的总结及未来发展方向。联交所诚邀公众人士就下述两方面提出意见：(a)建议的内容；及(b)落实有关建议（假设按本咨询文件所载实施）所需的《上市规则》修订拟稿。
204. 若有关建议最终（在联交所因应公众人士就本咨询文件提交的响应意见进行考虑后）有所修订，修订的内容将直接载于最后落实的《上市规则》修订本。联交所将于听取各方意见后刊发咨询意见总结，详列《上市规则》修订的最终版本及落实建议的细节。
205. 提出意见/响应时请说明理由。为方便我们收集资料，响应人士请尽量按以下标题（如适用）呈交书面意见：
- 生物科技公司
  - 采用不同投票权架构的发行人
  - 合资格发行人第二上市
  - 《上市规则》修订草拟本

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香港交易所可能会将响应人士的身份及响应意见公开发布。若响应人士不希望公开其身份，请在以下方格加上[✓]号：

本人/本公司不希望向公众披露以上资料。

### **Regenerative Medicine**

#### *Background*

Regenerative Medicine Advance Therapy (RMAT) Designation granted by FDA serves to expedite development of beneficial regenerative medicine therapies. Sponsors of certain cell therapies, therapeutic tissue engineering products, human cell and tissue products, and certain combination products may obtain the RMAT designation if there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs for certain diseases or conditions with the submission of an investigational new drug application.

RMAT of the above sponsors may not fall into classical categories or in the form of Pharmaceutical (small molecule drugs), Biologics or Medical Devices, thus being excluded.

#### *Proposal*

As RMAT can very much improve quality of life as well as prolong life expectance, it would be beneficial if HKEX can consider an expansion of Point 75, to include RMAT, per following comment:

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Regenerative Medicine Advance Therapy (RMAT) Designation

In case of a Core Product that is a new regenerative medicine product, the applicant must demonstrate that it has at least completed one clinical trial conducted on human subject and the relevant Competent Authority has no objection for it to commence Regenerative Medicine Advance Therapy (RMAT) Designation.

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If you need further information, please do not hesitate to contact me. You can seek for more information from FDA websites (or others):

<https://blogs.fda.gov/fdavoices/index.php/2017/03/this-is-not-a-test-rmat-designation-goes-live/>

Thanks for considering the above comment and congratulate every success of HKEX.

Best regards,  
Simon, YEUNG Sze Man