CHAPTER 5: REQUEST FOR COMMENT

203. This consultation paper is based upon the Exchange's conclusions and proposed way forward set out in the New Board Concept Paper Conclusions on attracting companies from emerging and innovative sectors. The Exchange invites public comments on (a) the substance of the proposals, as well as (b) the draft Rule changes that would give effect to the proposals (assuming that the proposals are to be implemented as proposed in this consultation paper).

204. To the extent the proposals are modified (after the Exchange has considered the public comments received in response to this consultation paper), those modifications will be incorporated in the final Rule amendments. Any final Rule amendments and details regarding implementation would be published in a conclusions paper after the Exchange has considered the public's views.

205. When providing your comments please give reasons for your views. To assist our collation of information, please submit your written comments using the following headings as applicable:

- Biotech Companies
- Issuers with WVR Structures
- Secondary Listings of Qualifying Issuers
- Draft Amendments to the Rules

- -

[redacted]

Title: [redacted]

E[redacted]

Disclosure of Identity:

HKEX may publish the identity of the respondent together with the respondent's response to the members of the public. Respondents who do not wish their identities to be published should check the box below:

☑ I/We do not wish to disclose my/our identity to the members of the public.

第75段关于医药器械的注释，是（应该）参考医药审批的，就像CFDA，包括全球FDA共同标准一样.

7) (ii) 建议修改：该创新器械产品通过主管当局的技术检测，并取得检测合格报告和评价意见，该报告可作为启动临床实验依据。

(iii) 器械评审的数据要求，与药完全审批流程时间差不多，会很多时间。另外，器械也不一定要等完全审批才能走一线用的。请见illumina的测序设备在FDA之前17年上市，市值几亿美金。2013年才拿FDA；市值100亿。其间可作科研市场——市场才更有效。另外，例如CLIA认证实验室可用也[illegible]市场可用。

总之，器械审批之前，可以让用户判断。市场来检验，不要只靠评审！