Dear Sir/Madam,

We, Zhejiang Hisoar Pharmaceutical Co. Ltd., an API manufacturer has forwarded the new rules on active substances under Directive 2011/62/EU to our local competent authorities, and the draft templet as well. Unfortunately, with no feedback till now yet. And here we'd like to share our point of view and some concerns form our end on this new Directive:

If EU do implement the rules as laid down in 2011/62, we will face a kind of export-stop to EU market for reasons as follows:

- **It's hard for our competent authorities to issue a written confirmation. And they haven't make any comment and keep silence till now.**
- **If a written confirmation is not available, China needs to apply at EU for approval as a country with an EU equivalent GMP rules, which our local manufacturers do have concern, since the EU and the US FDA discussed a mutual recognition agreement for nearly 10 years and failed...**

And if export to EU from China do stoped, what will EU generic medicine face? Alternative APIs suppliers in a third country has to be found, which will increase their cost, and it'll take time to make change to EDQM...Also, we thinck this will impact on affordable medicine market in EU...

We just to share our point of view on the new Directive. Hope it could help.

Thank you for your time.

Yours sincerely,

Zhejiang Hisoar Pharmaceutical Co., Ltd.

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