## 1. Summary

- Issue

Is the distribution to doctors of reports containing introduction of unregistered drugs permissible under PRC law?

- Answer

No. The distribution to doctors of reports containing introduction of unregistered drugs is not permissible, since under PRC law, the said report would be deemed as a drug advertisement under, and only registered drugs are allowed to be advertised.

## 2. Analysis

(1) Drug advertisements are subject to regulation by drug administrations

First, in accordance with the *Advertising Law of the PRC* (《中华人民共和国广告法》), the *Drug Administration Law of the PRC* (《中华人民共和国药品管理法》), and the *Provisions for Drug Advertisement Examination* (《药品广告审查办法》), no one is allowed to release any drug advertisement for special purpose drugs such as narcotic drugs, psychotropic drugs, toxic drugs, radioactive drugs, etc.

Second, under those laws and regulations, apart from those listed above as special purpose drugs, advertising for other types of drugs is allowed, but required to be approved and issued an approval number by drug administrations on the provincial level. Additionally, in accordance to the list of documents required to be submitted for obtaining the said approval number, only registered drugs may be approved to be advertised.

Third, under PRC law, the scope of advertising for prescription drugs is also restricted. In accordance with the *Drug Administration Law of the PRC* and its implementing regulations, prescription drugs may ONLY be introduced in medical or pharmaceutical publications jointly designated by the Ministry of Health and the State Food and Drug Administration, and may NOT be released to the general public by mass media or by other means.

Therefore, if the report provided by you is deemed as a "drug advertisement" under PRC law, it will be subject to the above prohibition, restriction or approval requirements by the drug administrations in the PRC, as the case may be.

(2) Drug introduction contained in the report will be considered as a drug advertisement

In accordance with the *Advertising Law of the PRC*, the term "advertisement" means any commercial advertisement that ***directly*** or ***indirectly*** promotes any kind of commodities or services through certain media or forms, at the expense of the suppliers of the said commodities or services.

In addition, the *Provisions for Drug Advertisement Examination* provides that the term "drug advertisement" refers to any advertisement which is released through various media or forms, and contains drug name (药品名称), indications (适应症) / functions (功能主治) ***or*** other relevant information.

Based on the above, an advertisement is deemed as a "drug advertisement" under law, provided that the advertisement:

(1) directly or indirectly promotes a kind of drug;
(2) is at drug supplier's expense;
(3) is released through certain media or forms; and
(4) contains any of the following:
    i. the showing of the name of a drug;
    ii. the description of indications/functions of a drug; or
    iii. the description of other relevant information of a drug.

According to your email dated Jan, 11th and the report you provided with us, the two parts of the report titled "Oxycodone/naloxone tablets – A possible solution for improved patient outcomes?" and "The buprenorphine patch – efficacy in the osteoarthritic patient" are summaries of presentations introducing certain oral tablets and certain skin patches. We think that the report would be deemed as satisfying the above element (1), which falls into the broad scope of the "indirect" promotion of certain kinds of drugs. It will also fulfill elements (2) and (3) if distributed to doctors in PRC by your company's sales representatives.

Regarding the above element (4), the report you provided with us explicitly refers to the two kinds of drugs as the "oxycodone/naloxone tablets" or "oxycodone/naloxone PR", and "buprenorphine patch" or "buprenorphine transdermal patch", which is very likely to be deemed as the disclosure of the

generic names of the two drugs. The report also discusses the indications and functions of the two drugs demonstrated during clinical trials. Hence we think that the report fulfills the above element (4).

Therefore, the report satisfies all of the elements (1) to (4) mentioned above. Several officials of Beijing Drug Administration confirmed our reasoning during our anonymous consultation with them.

## 3. Conclusion

We think that the report you provide with us would be deemed as a "drug advertisement" under PRC law, for it satisfies all of the constituent elements of the same if distributed to doctors in PRC, and hence would be subject to the prohibition, restriction or approval requirements by the drug administrations as mentioned above.

Furthermore, as both the oxycodone/naloxone tablets and the buprenorphine patches are very likely to be considered as narcotic or psychotropic drugs by drug administrations, any drug advertisement would be prohibited to be released for such drugs in PRC.

Even if the oxycodone/naloxone tablets and the buprenorphine patches produced by your company are not considered by authorities as narcotic or psychotropic drugs, it is unlikely that they would be approved to be advertised, since they are currently not registered with the State Food and Drug Administration.

Therefore, we think that the distribution of the report by the sales representatives to the doctors in PRC would not be permissible under PRC law, if there is not any revision of the report before such distribution.