Gifu Pharmaceutical University

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拝啓

初冬の候、御社におかれましては、ますますご清祥のことと心よりお喜び申し上げます。岐阜薬科大学グローバル・レギュラトリー・サイエンス寄附講座では、医薬品開発に関する様々な課題に対して、レギュラトリーサイエンスの観点から研究を実施しております。今回、下記のように調査を実施しますので、何卒ご協力頂けますようお願い申し上げます。

敬具

平成２８年１２月吉日

岐阜薬科大学
グローバル・レギュラトリー・サイエンス寄附講座
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記

「医療政策」「マーケットアクセス」「薬事」あるいは薬価政策関連部門のご担当者様への医療技術評価（HTA） に関する調査協力のお願い

現在 2018 年度からの本格導入に向け、薬価算定に医療技術評価（Health Technology Assessment, 以下 HTA）が試験的に導入されています。規制側も企業側も模索段階ですが、今後の医療イノベーションと医療費抑制のバランスを見出す有益な情報として HTA が活用されるべきと考えられます。我々は HTA に関する日本市場の現状を把握し、問題点を抽出して、日本の薬価制度に適した HTA、または HTA を導入に適した日本の薬価制度のあり方を分析したいと考えています。

調査は研究担当学生が御社担当者様と面談にて実施する予定です。調査結果は、関連学会および論文で発表を予定しています。発表に際してはご協力いただいた企業様を特定できないよう、細心の注意を払いますが、業態、規模、国内外資の別、売上規模別等の分析カテゴリーにより企業名が推測可能となる恐れがあることを、ご了承いただきたくお願い申し上げます。

調査にご協力のご検討をいただけるようでしたら、あらためて御担当者様にご連絡差し上げ、調査の日程等調整したく思っております。ご不明な点がございましたら担当者までご連絡いただけますと幸いです。

Research on the Introduction of Health Technology Assessment (HTA) in Japan

<Introduction>

In 2016, Japan introduced Health Technology Assessment (HTA) for the pharmaceutical pricing system on trial basis, in order to consider its official introduction for the pricing review scheme in 2018. Some researchers claim that Japanese HTA has already been incorporated under the current reimbursement scheme to meet the Japanese system. However, it is still uncertain to what extent pharmaceutical companies understand the difference in pricing system between Japanese and other countries, which fully utilize HTA for pricing and reimbursement, and/or what the outcome the Japanese government expects by HTA introduction. It is obvious that HTA introduction is a part of government policies to curb the rise in health care expenditures as a result of Japan's lower birth rate and longevity, and low economic growth. However, the government also seeks more effective way how Japan can control expenditures while maintaining necessary innovations and patient access.

<The purpose of this research>

The aim of this research is to survey both domestic and global pharmaceutical companies whose products are launched into the Japanese market, and clinical trial research organizations which may help to generate HTA data for pharmaceutical companies, in order to find out how companies currently understand HTA in the Japanese market. Then, we extract the issues and analyze what sort of HTAs can be appropriate to meet the Japanese pharmaceutical and reimbursement environment and the scheme could be at the time of introduction of HTA.

<The survey method and its reporting>

The survey is conducted through face-to face or phone interviews. The survey results will be submitted at HTAi 2017 Annual Meeting to be held in June and for publication as a research paper. Companies who contribute to the survey will be acknowledged and receive the research report. The survey is conducted in either Japanese or English, however, the research report will be provided in English.

The survey will require about 1 hour. Questions are indicated in the main pages.
Thank you very much for considering the survey.

Gifu Pharmaceutical University, Global Regulatory Science
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Questions

Company information	
Number of Employees in Japan	
Sales in 2015 in the Japanese market	In million JPY
Type of business	Pharma (NCE), Pharma (generic), others
Contact person details	
Japanese or non-Japanese	Japanese or non-Japanese
Any products launched into the Japanese market in the past 3 years?	Y or N How many?
Therapeutic areas of focus	If any
Any person or group who engages on HTA issues? If yes, how long the person has been working for it? What his/her background?	Y or N Please describe
Do you have any third party who can consult HTA issues? Is it possible to disclose the details? (if applicable)	
If your company is headquarted outside of Japan, which site (country) is responsible to generate HTA data and which site is responsible to analyze the data for the Japanese market?	Non-Japanese company only
How do you secure your HTA budget? Which department and divisions hold a HTA budget in your company?	Such as Market Access, Pharmaceutical Policy, Regulatory Affairs, Marketing, Clinical trial department, or a part of research development budget and/or sales budget
Where (which country) does your company run the studies for HTA purpose? Does your company run these studies through collaborator (partner)? If the trials were conducted outside of Japan, how do you interpret the data to meet HTA in Japan?	

Understanding of HTA	
How does our company see the reason why the Japanese government decided to	Such as to reduce the price, to benefit innovative drug, and/or innovator company.

introduce HTA for the pharmaceutical pricing and reimbursement scheme in Japan?	
Which type of studies is your company conducting or planning in the future? Which type of data is your company trying to gather or planning to gather in the future?	
Did your company receive information and/or guidance that how your company should collect necessary data to analyze, consult with the appropriate third parties, make necessary reports for HTA evaluation? If yes, from whom? Or how did your company get the guidance?	
Is your company familiar with any consultancy companies and/or organizations which may conduct HTA evaluation instead of your company? If yes, please list up the organization/company name.	
How we should incorporate HTA for the pharmaceutical industry, heath innovation, patient access, etc? How we should utilize HTA not only for pharmaceutical pricing but also for other health care services (diagnostic agents, hospital, physician, medical device, care giving)?	
Other comments, if available	

We do not disclose your company name in the presentation and/or publication unless your company requests to do so, however, as we analyze the data per the size of company, type of business, and other categories, people may guess specific companies.

If your company has any questions and requests for this survey, please do not hesitate to ask the investigator.

Thank you very much for your cooperation.