Hogan Lovells

NDRC Measures on the Investigation of Ex-Factory Prices of Pharmaceuticals (Trial Implementation)

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On 1 December 2011, *the Measures on the Investigation of Ex-Factory Prices of Pharmaceuticals (Trial Implementation)* (药品出厂价格调查办法试行) (the "**Measures**") issued by the National Development and Reform Commission ("**NDRC**") came into effect. The Measures set out the general authority of the Drug Pricing Evaluation Center ("**DPEC**") of the NDRC to conduct investigations on the ex-factory prices of pharmaceuticals, and the obligations of drug manufacturing enterprises to submit pricing information. The Measures serve as the most recent attempt by the NDRC to tighten scrutiny over ex-factory prices of drugs in China.

1. BACKGROUND

In general, the retail prices of domestic drugs and repackaged import drugs[1] in China are determined on the basis of their ex-factory prices and the permitted difference between the ex-factory and retail prices ("**Price Difference on Circulation**"). As the Price Difference on Circulation for drugs under regulation is fixed by the authorities, the ex-factory prices is one of the most significant elements used to determine retail prices. To take advantage of the above, it is often reported that drug manufacturing enterprises tend to include as many non-direct production and other costs as possible to achieve a higher ex-factory price to bolster their profit margins. Such practice has been criticized for making artificially inflating drug prices in China.

To strengthen control over drug prices in China, the NDRC has conducted around seven investigations on the ex-factory drug prices since March 2010 to ascertain the actual cost and pricing structure of these manufactured pharmaceuticals. To date, local branches of the NDRC and pricing bureaus have investigated around 896 types of drugs, involving around 927 drug manufacturing enterprises.[2] The Measures are the first comprehensive legislative act regulating how investigation of ex-factory prices of drugs should be conducted, including the scope of investigation and the obligations of the drug manufacturing enterprises.

2. SCOPE OF INVESTIGATION

The Measures are applicable to the investigation of ex-factory prices organized by the NDRC, acting through the DPEC or the government departments in charge of pricing at the provincial level.

All companies manufacturing domestic drugs and repackaged import drugs are subject to the ex-factory price investigations under the Measures. The NDRC will select certain drugs and investigate their ex-factory prices within a designated period. The investigation will generally cover information relating to the ex-factory prices and sales of the selected drugs.

3. OBLIGATIONS OF DRUG MANUFACTURERS UNDER INVESTIGATION

The drug manufacturer under investigation is obligated to fill in and submit two standard forms, namely (1) *"Investigation Form on the General Information of the Drug and the Drug Manufacturer"* ("**General Form**"), and (2) *"Investigation Form on the Ex-Factory Price of the Drug"* ("**Ex-Factory Price Form**").

The drug manufacturer under investigation is required to provide information and submit supporting materials under the General Form regarding, among others, the following: (i) the name of the drug manufacturer; (ii) the organizational code of the drug manufacturer; (iii) the name of the legal representative of the drug manufacturer; (iv) registered address, manufacturing address and contact information of the drug manufacturer; (v) the financial information of the drug manufacturer (including total assets and liabilities, owner's equity, asset-liability ratio, costs and revenue of main business, business taxes and surcharges, expenses for the given period, gross profit, net profit and number of employees); and (vi) the general information of the drug (including drug's name, specification, patent information, new drug registration information, etc.).

The Ex-Factory Price Form, on the other hand, requires information and materials from the drug manufacturer including: (i) drug's name, specification and pricing unit; (ii) current retail price (determined by the state, province

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1 "Repackaged import drugs" refer to the drugs which are produced overseas, and imported into China for repackaging with the Imported Drug Certificate issued by the State Food and Drug Administration.

2 Notice regarding the Investigation of Ex-Factory Prices of Certain Kinds of Drugs issued by NDRC on 1 July 2010.

of origin or the manufacturer, as the case may be); (iii) sales method (i.e. independent sales, sales by agent, or OEM); (iv) sales information, including sales amount, revenue and number of sales representatives; and (v) ex-factory price before tax, including lowest ex-factory price, highest ex-factory price and average ex-factory price.

In addition, the drug manufacturer under investigation is obligated to provide the following supporting materials: (1) a letter of undertaking regarding the validity and authenticity of the materials submitted; (2) relevant company documentations, including business license, drug registration approvals, employment contracts, etc.; (3) materials regarding R&D and innovation of drugs, including certificates of new drug, patent certificates, national pricing certificates, etc.; (4) materials regarding sales, including sales contract, etc.; (5) financial and accounting materials, including financial reports, detailed sales ledger, accounting vouchers including invoices, records of receipt, storage and delivery, list of employees, salary payment records, etc.; Other relevant materials as may still be necessary for the investigation.

4. APPROACHES AND PROCEDURES OF THE INVESTIGATION

After the drug manufacturer under investigation provides all forms and materials mentioned above, the investigator will verify information of the drug and the drug manufacturer, including but not limited to:

(a) The specifications of drugs based on the actual production circumstances of the manufacturer and select 1 to 2 specification(s) to conduct the investigation. The official pricing documents issued by the pricing authorities will be used as a basis for the investigator to verify the current retail price of the investigated drug;

(b) The sales amount and revenue of the investigated drug by reviewing the detailed sales ledger and records of receipt, storage and delivery, and verify the number of sales representatives by reviewing the list of employees, salary payment record and employment contract, etc.;

(c) The highest and lowest ex-factory price of the drug by reviewing the detailed sales ledger, and calculating an weighted average ex-factory price; and

(d) The authenticity and accuracy of the ex-factory price by random examination of the accounting records, such as invoices.

The investigator is required to follow opinions from the drug manufacturer under investigation. The manufacturer may also provide further explanations and/or submit additional materials. If the investigated drug is not sold, or the sales method or the manufacturer has changed, the investigator shall verify the same and may require the manufacturer to submit relevant explanation materials. After investigation, the investigator will prepare an investigation report and fill out a standard summary form.

5. SIGNIFICANCE

The Measures serve as the most recent attempt by the NDRC to tighten scrutiny over ex-factory prices of drugs in China. In particular, by investigating the accounts and records of the drug manufacturers and requiring letters of undertaking regarding the accuracy and authenticity of the ex-factory prices reported, the Measures enable the NDRC to collect more information about ex-factory prices of drugs, and to a certain extent, discourage drug manufacturers from including non-direct production or other costs to show higher ex-factory prices. However, it remains uncertain whether the issuance of the Measures indicates the NDRC's intention to set "maximum ex-factory prices" in the near future, which was designated as far back as 2005 by the NDRC as a possible price control measures over drugs in China.[3] If that is the case, this may substantially affect the profitability of drug manufacturers in China even on the ex-factory level. And more, if this practice is adopted, it may potentially create the basis for medical device sector, which is also experiencing similar ex-factory pricing issues. Hogan

[3] The 2005 NDRC Notice (《国家发改委关于对部分药品从出厂环节制定价进行试点的通知》) indicates that NDRC will set maximum ex-factory prices for certain types of drugs as a pilot scheme, and explained how ex-factory prices are determined. *Please see: http://jgs.ndrc.gov.cn/zcfg/t20051209_53056.htm*

Lovells will follow up closely in this regard and keep you posted of any major developments.

KEY CONTACTS

Beijing

Steven Robinson
Partner
steven.robinson@hoganlovells.com
T +86 10 6582 9568

Jun Wei
Partner
jun.wei@hoganlovells.com
T +86 10 6582 9501

Roy Zou
Partner
roy.zou@hoganlovells.com
T +86 10 6582 9596

Sophie Fu
Associate
sophie.fu@hoganlovells.com
T +86 10 6582 9536

Jessie Xie
Associate
jessie.xie@hoganlovells.com
T +86 10 6582 9553

Shanghai

Philip Cheng
Partner
philip.cheng@hoganlovells.com
T +86 21 6122 3816

Andrew McGinty
Partner
andrew.mcginty@hoganlovells.com
T +86 21 6122 3866

www.hoganlovells.com

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