

## What is a Domestic Responsible Agent?

The Domestic Responsible Agent concept was first introduced into the Chinese legal cosmetics regime by the Notification 2017 No.7. Initially the concept was trialed in the Shanghai Pudong New Area. After a successful trial the program has now extended to cover all of China.

The concept of Domestic Responsible Agent was (and indeed remains) that in respect of imported cosmetics there must be a party situated in China that can be held accountable in the event of a safety issue arising in respect of such product. The Domestic Responsible Agent is a pre-requisite to apply for a NMPA Product Registration – and therefore in order to have a product registration in China means you will need to have a Domestic Responsible Agent. For this reason, international brands that have limited themselves to cross border ecommerce did not need NMPA product registrations and therefore did not require a Domestic Responsible Agent.



## What has changed?

Although, the Domestic Responsible Agent has been in place since 2017 the regulations and requirements were relatively lax. There was no specific qualification, no requirement to have a quality management system (QMS), no requirement on personnel, no recall systems in place. Although there was an obligation upon the Domestic Responsible Agent in respect of quality and safety these requirements were vague. The Regulations on Supervision and Administration of Cosmetics (化妆品监督管理条例) have changed this dramatically. The Domestic Responsible Agent now must meet specific (rigorous) requirements and are subject to very serious potential liability (major fines, employment bans and even criminal liability).

## Who can be a Domestic Responsible Agent?

Legally, the main requirement is that the Domestic Responsible Agent **must** be established in China. Initial reports are that the NMPA is carrying out rigorous on-site inspections and grading of Domestic Responsible Agents. Unqualified candidates will not be permitted to act as Domestic Responsible Agent.

Accordingly, the Domestic Responsible Agent for international brands in China are likely to be one of the following:

### 1) Chinese Distributor (or JV or other partner)

We have some experience with international cosmetics companies using their distribution partners as a responsible agent. Based on this experience our measured, technical legal advice in the past was NO, NO, NO, NO. The difficulty is that often the Chinese distributor will not follow the rules laid down by the international brand and that also having the NMPA registration in its name does give a lot of leverage to the distributor. The new regulations and especially the greater scrutiny in screening Domestic Responsible Agents will likely lead to many international brands going back to this model as they will not, at least in the short term, have the resources to do this by themselves.

Accordingly, if an international brand intends to appoint its Chinese distributor to act as the Domestic Responsible Agents it is important to: 1) select the right partner; 2) have a clear contractual basis; 3) have an audit and supervision plan in place; and 4) an exit plan in the event the relationship sours in the future. The exemptions for animal testing will very likely lead to even more Chinese distributors reaching out to hip brands who have not yet launched in China. Make sure you pick the right one, have the right contract and keep a close eye on them.

## 2) Regulatory Experts or Consultants

In the past in order to avoid providing the Chinese distributor with too much leverage many international brands would appoint a third party – often a regulatory advisor or even just an independent consultant. This is likely to be less common going forward as 1) few of these third parties will meet the NMPA requirements or pass the inspection; and 2) those who have sufficient experience will be very wary of the potential liability (e.g. including responsibility for document submission authenticity; product recall).

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## 3) Wholly Foreign Owned Enterprise (WFOE)

China has a relatively liberal attitude to establishing WFOEs for cosmetic companies. There are great advantages of using a WFOE – greater control, no misalignment with a distributor (or JV partner) and having your own team on the ground. The procedure is quite straightforward – you will need to apply for the establishment of a WFOE that has a business scope that includes “sale and import of cosmetics” and complete relevant registration formalities with customs. Generally, the establishment of such a WFOE will require approximately 6 to 8 weeks. The main bottlenecks are 1) the investor moving forward; and 2) a lease.

A WFOE which is intended to function at least in part as a Domestic Responsible Agents will need to have an actual, physical office (i.e. not a virtual office). The Domestic Responsible Agents must have an actual office as the NMPA will carry out an on-site inspection as well as warehousing space. It should also be noted that if the international brand intends to import products into China from ports other than the local port where the WFOE is registered then a relevant filing of consignee location must be completed on the NMPA system before imports can commence. The WFOE will also be responsible for product distribution registration and also report adverse reactions regularly.

In addition to office and warehouse requirements, as outlined above, the WFOE will need to have a number of employees including specialists. If the WFOE will act as Domestic Responsible Agent for a domestically manufactured product then the WFOE will as applicant be required to hold the requisite quality and management systems (QMS). We understand that there is relevant software available on the market but the WFOE staff will need to be trained in such regard. If the WFOE will be the Domestic Responsible Agent for an imported product then only the foreign applicant and the production enterprise will need to provide the QMS.

It should be noted that the above are not pre-requisites to establishing a WFOE but will need to be fulfilled if the WFOE should function as the Domestic Responsible Agents.

## Points to consider

The new 2021 exemption from animal testing for certain imported cosmetics will lead to even greater interest on the part of international cosmetic brands.

China's animal testing regime has meant many cruelty free brands have avoided the China market or only supplied via cross border ecommerce. Accordingly, the vast majority of international cosmetic brands do not have NMPA registrations and therefore have not come across the Domestic Responsible Agent concept in the past.

However, in order to make use of the exemption and trade more widely in China this will require NMPA registrations and also appointment of a Domestic Responsible Agent. Many brands will establish WFOEs to support their market entry but it is likely that in most cases the WFOE will not (at least in the short term) will be able to meet the requirements of being a Domestic Responsible Agent. Accordingly, many such brands will need to rely on Chinese partners. In such cases it is crucial that international brands select the right partners. This is one that understands the business and has a team that can meet the Domestic Responsible Agent requirements. Regardless of the partner the international brands should ensure that they have a detailed and sound contract detailing the relationship and an exit plan if the relationship does not work out. In particular, international brands will be well advised to ensure they keep as much of their IP and business details confidential and also remain involved in the China business so they can keep of track of all developments.



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## A sample of our experience

### SEPHORA

Advised Sephora on potential construction contract dispute

### Charlotte Tilbury

Advised Charlotte Tilbury on contract review, dealing with ecommerce platforms and other daily support

### PAULA'S CHOICE

Advised Paula's Choice on their China market entry and company establishment

### MIKIMOTO COSMETICS

Advised Mikimoto on sales of cosmetics in China

### MARY KAY®

Perennial counsel for Mary Kay



Represented Christian Louboutin on patent infringement litigation

### L'ORÉAL

Advised L'Oréal on product related legal matters

### Johnson & Johnson

Advised Johnson & Johnson on its 100% acquisition of Beijing Dabao Cosmetics Co., Ltd.

### L'OCCITANE EN PROVENCE

Advised L'Occitane on opening its flagship T-Mall store, contract review, and other legal issues



Advised Percy & Reed on distribution contracts

### NU SKIN®

Advised Nu Skin on sales contracts and foreign direct investment and real estate issues



Advised Alain Delon on patent infringement case



500+ Partners globally  
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\$53bn worth of deals completed in APAC M&A in 2019  
Mergermarket, 2019

# # 1

✓ Ranked law firm for M&A in the Asia Pacific

Mergermarket, 2019

✓ Only law firm to be ranked Band 1 for M&A in AU, PRC and HK

✓ Ranked law firm in PRC and AU by Chambers and Partners, 2019

## Awards and recognition

### #1 in Acritas Asia Pacific Law Firm Index

Acritas, 2020

### Strategy and Changing Behaviours

Accessing New Markets and Capital

Financial Times Asia-Pacific Innovative Lawyers Awards 2019

### Restructuring and Insolvency Law Firm of the Year

ALB Award 2019

### Asia Pacific Law Firm of the Year

Chambers Asia-Pacific Awards 2018

### Regional Law Firm of the Year

IFLR Asia Awards, 2017/2016/2013/2011

### North Asia Firm of the Year

AsiaLaw Awards, 2017

### Hong Kong Firm of the Year

AsiaLaw Awards, 2017

### Innovation in Legal Expertise

Financial Times Asia-Pacific Innovative Lawyers Awards, 2017

### Innovation in the Business of Law

Financial Times Asia-Pacific Innovative Lawyers Awards, 2017/2016

### Best International Firm in China Practice

Euromoney Asia Women in Business Law Awards

### M&A Legal Adviser of the Year

mergermarket, 2017

### Best Law Firm (Revenue over \$200m)

AFR Client Choice Awards, 2017

### Commercial Team of the Year

Lawyers Weekly Australian Law Awards, 2017

### Transaction Team of the Year

Lawyers Weekly Australian Law Awards, 2017

### Most Innovative Firm of the Year

China Law & Practice Awards, 2017

### #1 Asia-Pacific Legal Brand

Acritas, 2016

### Most Innovative Law Firm in China

Financial Times Asia-Pacific Innovative Lawyers Awards, 2016

### China Law Firm of the Year

Who's Who Legal, 2016/2015/2013/2011/2010/2009/2007/2006

### National Firm of the Year – China

IFLR Asia Awards, 2016/2014/2012/2010/2008/2007

### Firm of the Decade (10 Year Anniversary Special)

China Law & Practice Awards, 2016

### China Law Firm of the Year

ALB China Awards, 2016

### Most Innovative Law Firm Asia-Pacific

Financial Times Asia, 2015/2014

### International Law Firm of the Year

Australasian Law Awards, 2015

### Business Excellence Award for Services

AustCham-Westpac Australia China Business Awards, 2015

### #1 for M&A in Asia Pacific (excl Japan) by deal count and deal value

Bloomberg, Thomson Reuters, Mergermarket, 2016

### Structured Finance and Securitisation Team of the Year

IFLR Asia Awards, 2016/2015/2014

### Law Firm of the Year in Asia (Fund Formation)

Private Equity International Annual Awards, 2015

### Law Firm of the Year in Asia – Private Equity

Private Equity International's Infrastructure Awards 2015



## A little bit about us



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