



# Accreditation Service for Testing and Certification of Chinese Medicines

## 中藥測試及認證的認可服務



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香港認可處

Hong Kong Accreditation Service





# Hong Kong Accreditation Service (HKAS)

## 香港認可處

- ✦ **HKAS is part of Innovation and Technology Commission of the Hong Kong Special Administration Region (HKSAR) Government.**

香港認可處是香港特別行政區政府創新科技署屬下工作組別



- ✦ **It was set up in 1998 (previously known as HOKLAS since 1985)**  
於**1998**年成立 (前身為香港實驗所認可計劃，自**1985**年成立)
- ✦ **It is the official accreditation body in Hong Kong**  
是香港正式的認可資格頒授機構
- ✦ **It provides independent and impartial accreditation services**  
提供獨立及公正的認可服務

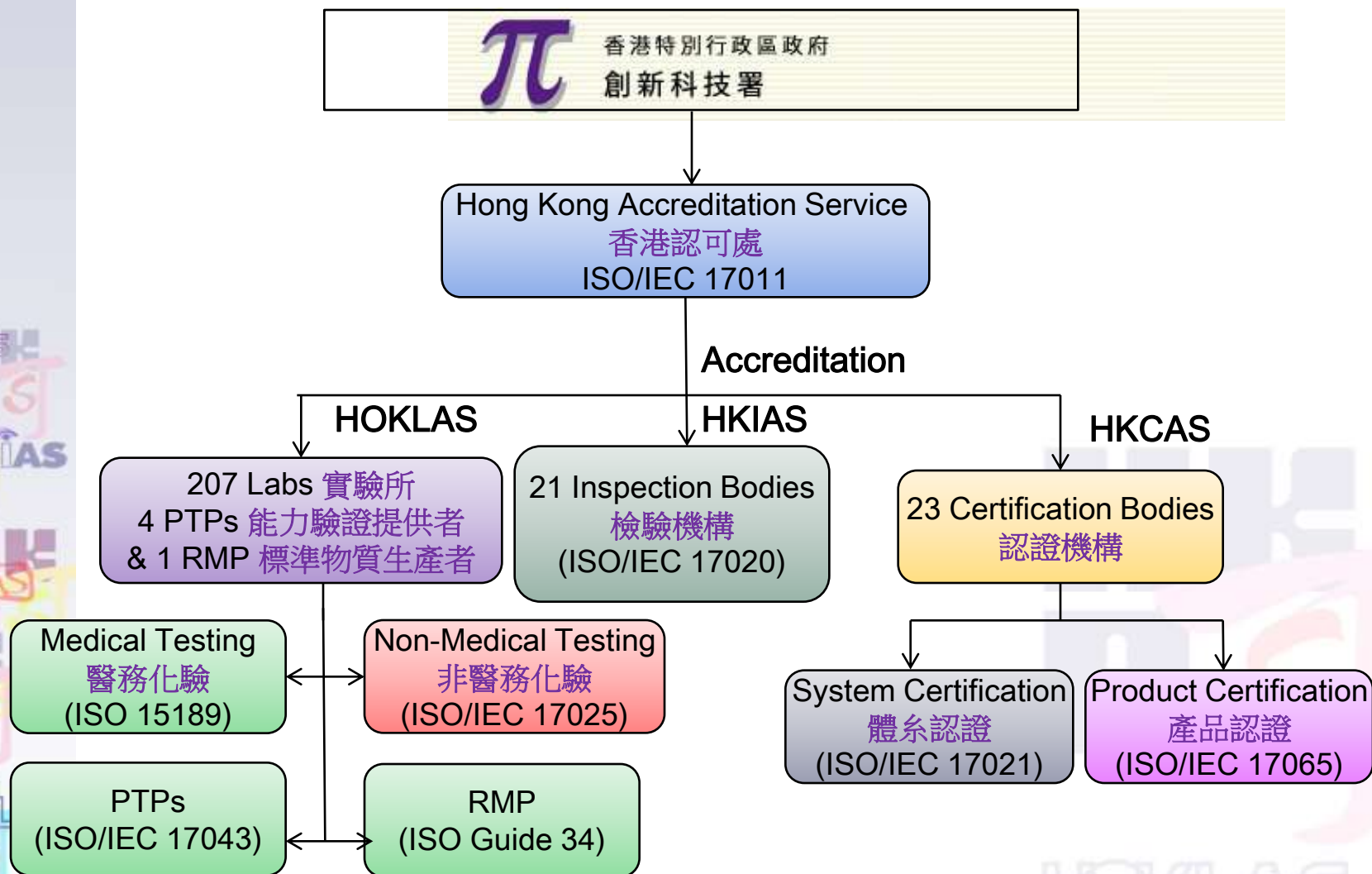
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- HKAS provides accreditation services to testing laboratories, certification bodies and inspection bodies through the following 3 schemes:

透過以下三個認可計劃，香港認可處向實驗所、認證機構及檢驗機構提供認可服務：



- **HOKLAS** (香港實驗所認可計劃)
- **HKCAS** (香港認證機構認可計劃)
- **HKIAS** (香港檢驗機構認可計劃)

# Schematic Diagram of Accreditation



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- ✦ **Participation in the 3 schemes is voluntary**

三個計劃屬自願參與性質

- ✦ **The schemes are operated in accordance with the requirements of the international standard ISO/IEC 17011 and criteria set by relevant international and regional cooperations of accreditation bodies, e.g. ILAC, IAF, APLAC & PAC**

三個計劃均根據國際標準ISO/IEC 17011的要求及相關國際及區域認可機構合作組織 (如 ILAC, IAF, APLAC & PAC) 訂立的準則運作

# Chinese Medicine Testing Services

## 中藥測試服務

- Chinese medicines are tested for safety and quality  
中藥測試包括安全及品質項目

- Safety tests include:

安全測試包括:

- Heavy metals and toxic elements, e.g. of cadmium, lead, mercury, arsenic, etc.  
重金屬及有毒元素，如鎘、鉛、汞、砷等含量
- Pesticide residues, e.g. contents of organochlorine pesticide residues  
農藥殘留，如有機氯農藥殘留量
- Microbiological examination, e.g. aerobic bacterial count, yeast and mould count, Salmonella, etc.  
微生物檢查，如細菌數、酵母菌與霉菌數、沙門菌等





- **Quality tests for Chinese Materia Medica (CMM) include:**

中藥材的品質測試包括:

- **Quality testing of CMM to standards such as the Hong Kong Chinese Materia Medica Standard or the Pharmacopoeia of the PRC**

根據《香港中藥材標準》或《中國藥典》等標準進行的中藥材品質測試

- **Quality tests for Chinese Materia Medica (CMM) include (con't):**

中藥材的品質測試包括 (續):

- **Identification of CMM e.g. by chemical means or microscopic examination**

中藥材鑒別，例如利用化學方法或顯微觀察



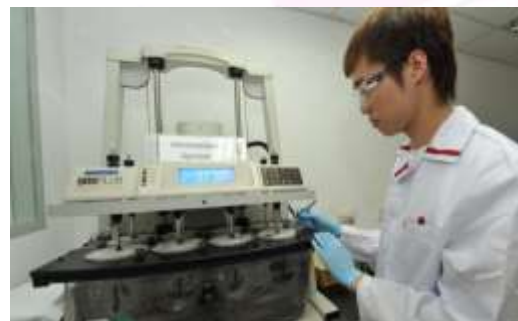


- **Quality tests for proprietary Chinese medicines (pCm):**

中成藥的品質測試包括

- **Quality testing of pCm to standards e.g. Pharmacopoeia of the PRC**

根據標準 (例如《中國藥典》) 進行的中成藥品質測試





- **Other tests:**

其他測試

- **Stability test for pCm registration**  
為中成藥註冊而進行的穩定性測試
- **Testing to product specifications**  
產品規範測試

# Use of Test Results

## 測試結果的用途

Needs to know  
a parameter  
需要了解一個參數

To support decisions on health, safety, regulations, research, trade, manufacturing, etc.

用以支持決定，例如有關健康、安全、法規、研究、貿易、製造等

Test results  
測試結果

Are the results accurate and reliable?

有關結果是否準確及可靠?

Decision  
決定

Inaccurate or unreliable results may result in wrong decisions

不準確或不可靠的結果可引致錯誤決定



# Value of Accreditation

## 認可服務的意義

Assess the competence of  
a laboratory to perform  
specific tests  
評審實驗所進行特定測試的能力

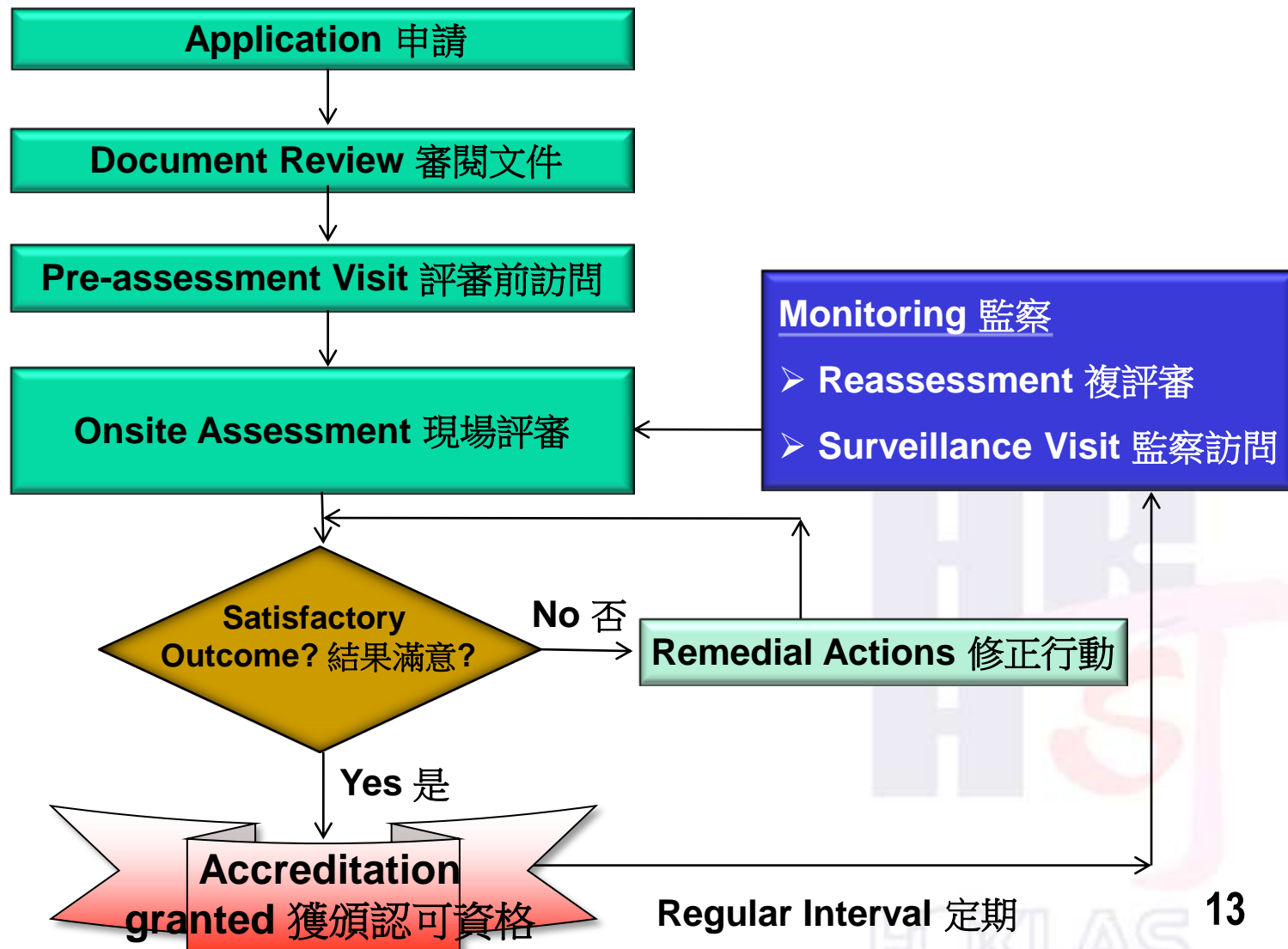


Grant accreditation to  
the competent laboratory for  
the specified tests  
向有能力的實驗所就有關測試  
頒發認可資格

Basis 基礎:  
International Standards  
國際標準,  
e.g. ISO/IEC 17025,  
ISO 15189

Effect 效果:  
Declare to the public that  
the laboratory is competent  
in performing the specified  
tests. The quality and  
reliability of the test results  
produced can be assured.  
向公眾聲明該實驗所有能  
力進行特定測試，其測試  
結果的質素及可靠性有保  
證。

# Accreditation Process 認可程序





# Test Reports & Certificates Recognised Internationally

## 測試報告及證書獲國際承認



- ✦ HKAS is signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) and International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA)  
香港認可處 (**HKAS**) 是國際實驗所認可合作組織 (**ILAC**) 及國際認可論壇 (**IAF**) 等機構的多邊互認協議簽署成員
- ✦ Endorsed test reports and accredited certificates issued by HKAS accredited organisations are recognised by HKAS's MRA / MLA partners (involving **91 accreditation bodies in 73 economies in the world**)  
香港認可處的多邊互認協議夥伴 (當中包括 **91經濟體系共73個認可機構**) 均承認獲香港認可處認可機構所發出的認許測試報告及認可證書

(as of 14 July 2015)



# APLAC MRA and PAC MLA

## 亞太區域認可合作組織 (APLAC) 及 太平洋區域認可合作組織 (PAC) 多邊互認協議



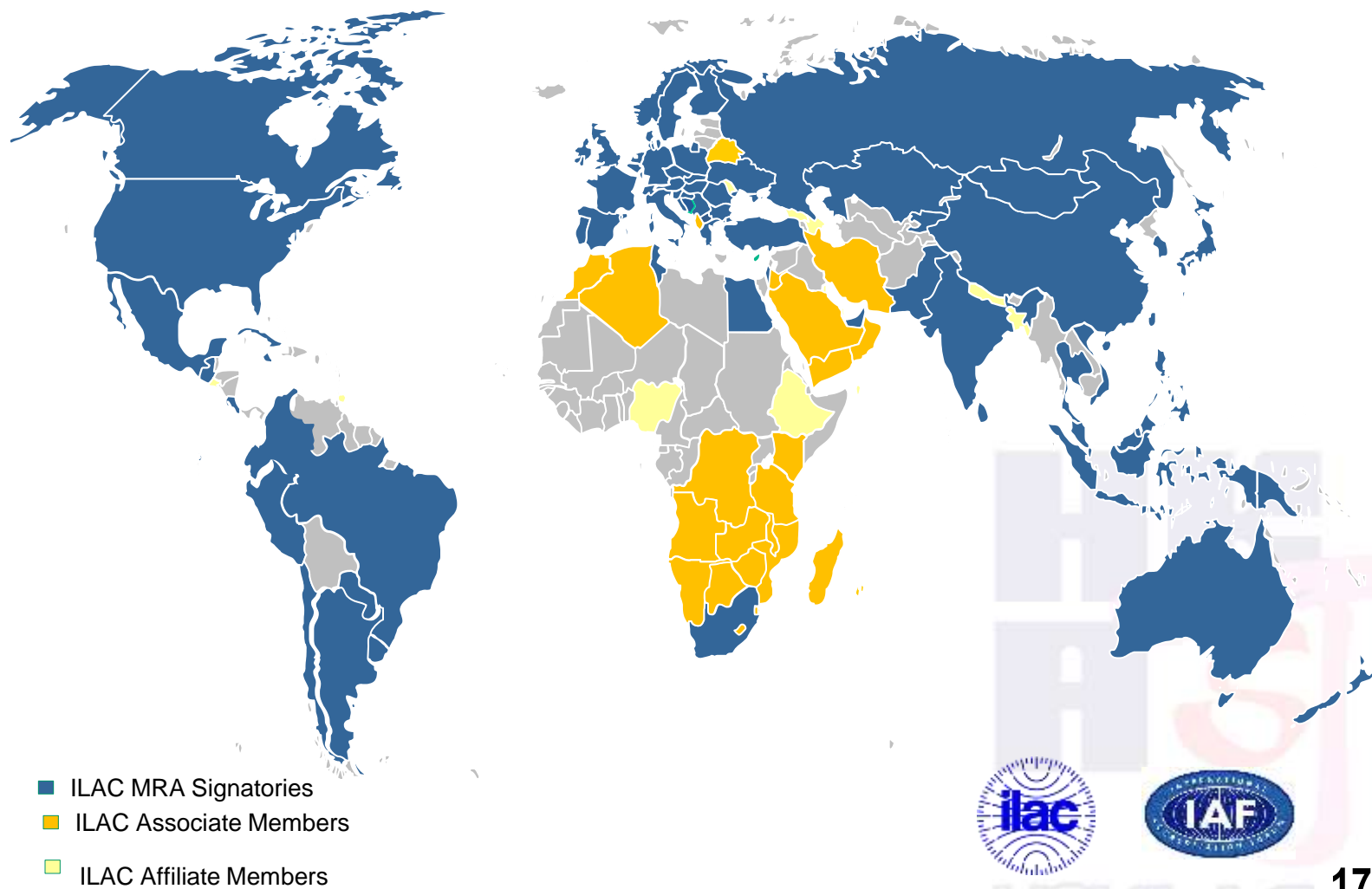
# ILAC MRA and IAF MLA

## 國際實驗所認可合作組織 (ILAC) 及 國際認可論壇 (IAF) 多邊互認協議



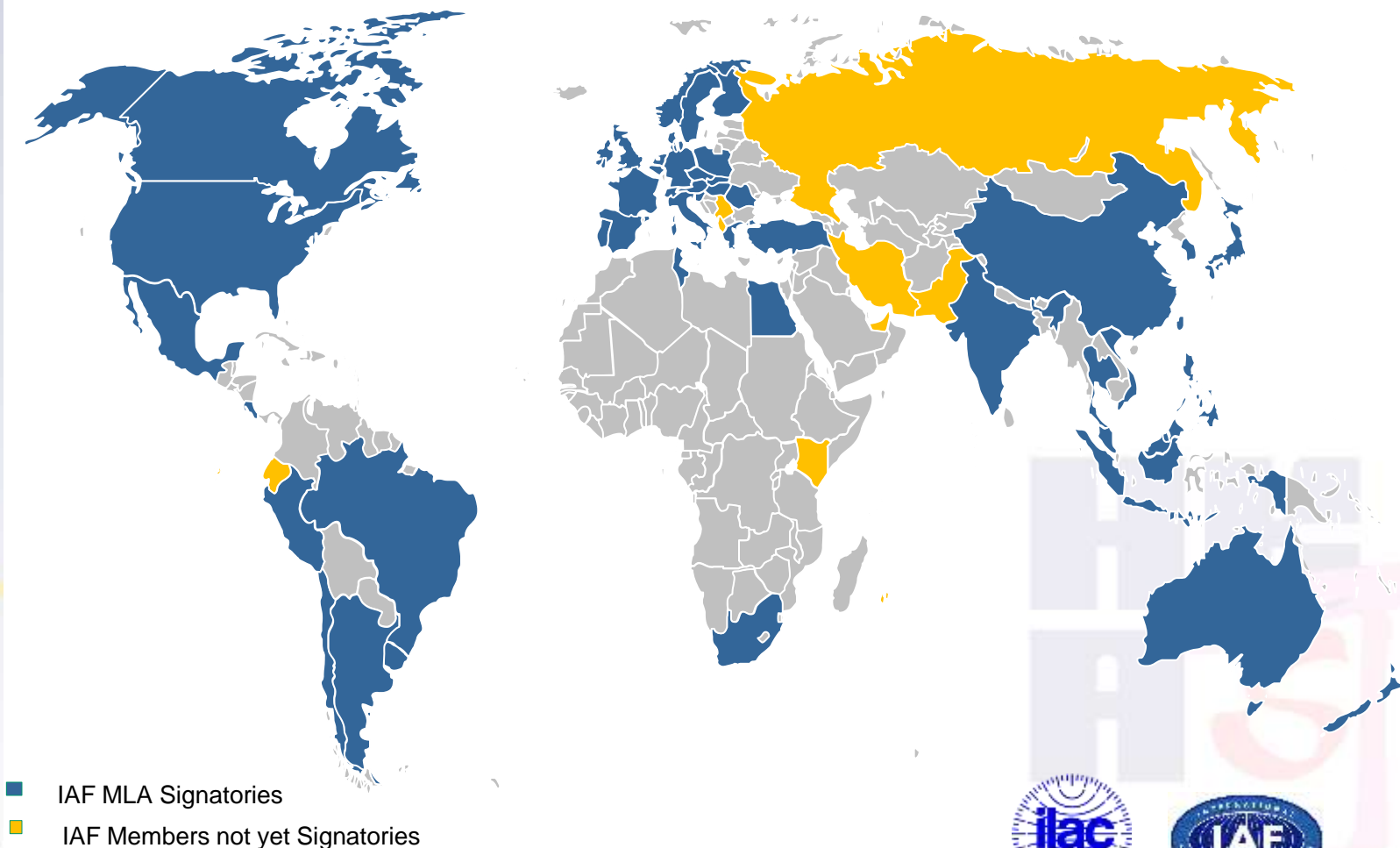
# Coverage of the ILAC MRA (March 2015)

國際實驗所認可合作組織 (ILAC) 互認協議覆蓋範圍



# Coverage of the IAF MLA (August 2013)

## 國際認可論壇 (IAF) 多邊承認協議覆蓋範圍





# Reports and Certificates Bearing HKAS Accreditation Symbol

## Symbol under HKAS Accreditation Schemes

香港認可處認可計劃 載有香港認可處認可標誌的報告及證書



- ⊕ **Unless otherwise approved and specified, only results of accredited activities can be shown in reports or certificates bearing the HKAS accreditation symbol**

除非經批准及清楚註明，否則獲認可機構只可就獲得認可資格的活動發出載有香港認可處認可標誌的報告或證書

- ⊕ **Since the competence of the accredited activities has been assessed, the reliability of the related results can be assured**

由於獲認可機構在獲得認可資格的活動上其能力曾經接受嚴謹的評審，有關結果會為更可靠



# IAF and ILAC Marks

## IAF 及 ILAC 標誌

- Accredited laboratories and certification bodies can use Laboratory Combined ILAC MRA Mark and Certification Body Combined IAF MLA Mark

獲認可實驗所及認證機構可使用 ILAC MRA 實驗所組合標誌及 IAF MLA 認證機構組合標誌



Laboratory Combined ILAC MRA Mark  
ILAC MRA 實驗所組合標誌



Certification Body Combined IAF MLA Mark  
IAF MLA 認證機構組合標誌



# Accreditation Services for Testing and Identification of Chinese Medicines

## 與中藥測試及鑒別有關的認可服務

- Microbiological examination and quality testing of pCm to the Pharmacopoeia of the PRC, e.g. microbial limit test, general requirements for preparations, etc.

根據《中國藥典》對中成藥進行的微生物檢查及品質性測試，例如微生物限度檢查法、製劑通則等。

- **Testing of pCm and CMM for heavy metals, toxic elements and pesticide residues.**

測試中成藥及中藥材中的重金屬、有毒元素及農藥殘留含量。



- **Safety, chemical and physicochemical testing of CMM to the HKCMMS, e.g. aflatoxins, assay, ash, water content, extractives, etc.**

根據《香港中藥材標準》對中藥材進行的安全性、化學及理化測試，例如黃曲霉毒素測試、含量測定、灰分、水分、浸出物等。



- **Physicochemical and chromatographic identification of CMM to the HKCMMS.**

根據《香港中藥材標準》對中藥材進行的理化及色譜鑒別。

- **Microscopic identification of CMM to the HKCMMS.**

根據《香港中藥材標準》對中藥材進行的顯微鑒別。

- Accreditation service may be provided to laboratories performing individual tests given that the relevant accreditation criteria are fulfilled, e.g. assay of specific chemical markers in pCm

認可處亦會就個別測試項目向實驗所提供認可服務 (例如在中成藥中個別化學物標誌物的含量測定)，條件是實驗所要符合有關的認可準則。



# Chinese Medicine Testing Laboratories Accredited by HKAS (as of July 2015)

## 獲香港認可處認可的中藥測試實驗室 (截至2015年7月)

- The following organisations provide one or more accredited Chinese medicine testing services to the public. Please contact the organisations for details.

下列機構為公眾提供一項或多項獲認可的中藥測試服務，詳情請向有關測試機構查詢。

機構 名稱	
ALS Technichem (HK) Pty Ltd.*	
Bureau Veritas Hong Kong Ltd 立德國際公證香港有限公司	
Castco Testing Centre Ltd . 佳力高試驗中心有限公司	
CMA Industrial Development Foundation Ltd. * 香港中華廠商聯合會工業發展基金有限公司	

機構 名稱	
Eurompharm Laboratories Company Limited – Q. C. Laboratory *	
歐化藥業有限公司 – 品質控制實驗室	
Hong Kong Productivity Council - Environment and Product Innovation Laboratory	
香港生產力促進局 – 環境及產品創新化驗室	
Intertek Testing Services Hong Kong Ltd.	
天祥公證行有限公司	
Pharmtech (Hong Kong) Limited – Quality Control Laboratory	
科達藥業有限公司 – 品質控制實驗室	
SGS Hong Kong Limited *	
香港通用公證行有限公司	
The Hong Kong Standards and Testing Centre Ltd.*	
香港標準及檢定中心有限公司	
Wellab Limited*	
匯力實驗室有限公司	

# Proprietary Chinese Medicine Testing Laboratories

## 中成藥測試實驗所

In the registration of proprietary Chinese medicines (pCm), the Chinese Medicine Board (CMO) of the Chinese Medicine Council of Hong Kong accepts endorsed test reports issued by accredited pCm testing laboratories.

在中成藥註冊時，香港中醫藥管理委員會中藥組會接納獲認可中成藥測試實驗所所發出的認許測試報告。



**If a laboratory has been collectively accredited for testing of pCm for toxic elements & pesticide residues; and microbiological examination of pCm according to the Pharmacopoeia of the PRC, the CMO will also accept reports of other tests required for pCm registration (e.g. stability test) issued by the same laboratory.**

如果實驗所同時已獲取測試中成藥中有毒元素、農藥殘留及按《中國藥典》進行的微生物檢查的認可資格，中藥組亦會接納該實驗所發出有關中成藥註冊的其他測試項目(例如穩定性測試)的測試報告。



# Certification of Chinese Materia Medica

## 中藥材認證

- Through its Hong Kong Certification Body Accreditation Scheme (HKCAS), HKAS is providing accreditation service to local certification bodies, including those providing public certification service for products. The products involved are mainly construction materials, consumer products and food (not including Chinese medicine at present). The applicable accreditation standard is ISO/IEC 17065.

透過香港認證機構認可計劃 (HKCAS)，香港認可處向本地認證機構提供認可服務，當中包括為公眾提供產品認證服務的認證機構，而相關產品主要包括建築材料、消費品及食品(暫不包括中藥)，所採用的認可標準為 ISO/IEC17065。

- **The Hong Kong Productivity Council (HKPC) has recently issued a new certification scheme viz. ‘Product Certification Scheme for Chinese Materia Medica’ specifying criteria for certification of Chinese Materia Medica.**

香港生產力促進局 (HKPC) 最近推出了一個新認證計劃「香港中藥材認證計劃」為中藥材產品提供認證準則。

- **HKAS is ready to provide accreditation service to those certification bodies who are interested in providing certification service according to the scheme.**

香港認可處亦準備為有意根據該計劃提供認證服務的認證機構提供認可服務。





# Conclusion

## 總結

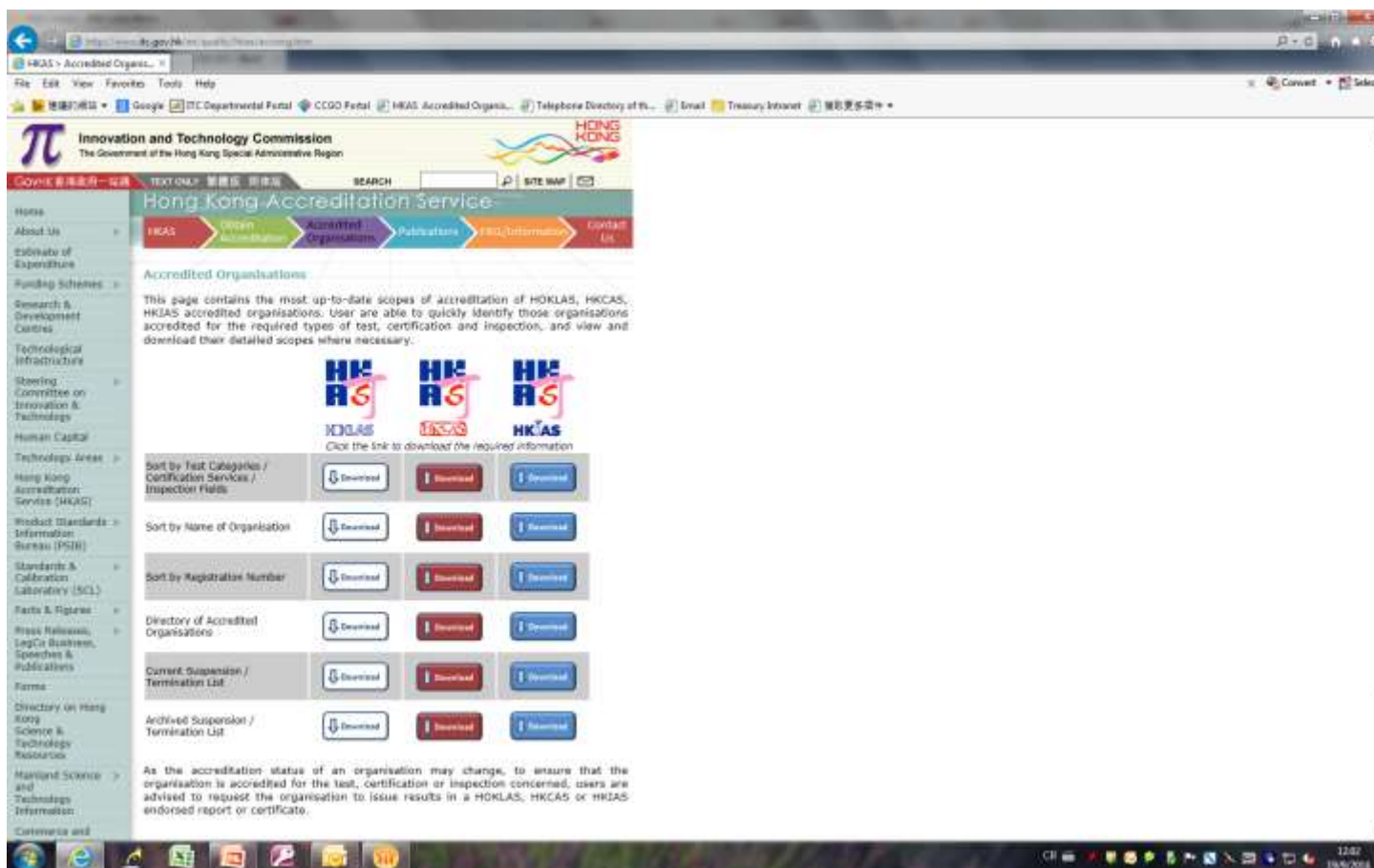
Hong Kong Accreditation Service provides accreditation service to local laboratories and certification bodies for testing and certification of Chinese medicines. The process involves vigorous assessments to ensure their competence and operation to international standards; their service and associated results are more reliable and have global recognition.

香港認可處向本地實驗所及認證機構提供認可服務，為申請認可的中藥測試及認證機構進行嚴格評審，以確保其能力及運作體系符合國際標準，服務及結果更為可靠，同時獲國際承認。

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For more information, please visit our  
website at [www.hkas.gov.hk](http://www.hkas.gov.hk)

詳情請瀏覽香港認可處網頁  
[www.hkas.gov.hk](http://www.hkas.gov.hk)





*Thank you*  
*多謝各位*

