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GLOBAL CASE STUDY

1 CLIENT • 10 COUNTRIES

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- China
- Singapore
- Indonesia
- Vietnam

Multi-Country Market Access Support

From NHP to Cosmetic compliance

Client Synopsis:

A client is a well-established Australian Cosmetic Manufacturer. They have marketed their product all over the world through distributors and online marketplaces. They reached out to GRP to scope WW registration of their product . Secondly, as their formula is a trade secret, they need to ensure that the vendor shares information with partners or internal employees with the upmost prudence.

The client already had their product submitted and marketed in many countries without their permission. The client wants to start controlling the marketing, compliance and information of their product.

Nature of the product is that can be registered in a couple different regulatory pathways. The clients wants to evaluate registration as cosmetic, and if not possible either see if other pathways are possible or ultimately decide not to enter the countries market.

USA

SERVICES:

- ✓ GAP Analysis done based on local guidelines.
- ✓ Regulatory Strategy.
- ✓ Notification to FDA using the VCRP program.
- ✓ Regulatory strategy.

CONCLUSION:

After GAP Analysis it was discovered that Label and product Name was not compliant as cosmetic per USA regulations.

The Label was revised to meet FDA compliance. Once the Label was compliant the VCPR was set up for the client. Submission of Establishment Registration and Cosmetic Ingredient Filling was submitted.

CANADA

SERVICES:

- ✓ GAP Analysis based on local guidelines to notify products to Health Canada.
- ✓ Label and claim review based on local guidelines.
- ✓ Regulatory Strategy to be able to notify the product as cosmetic rather than Natural Health Product.
- ✓ Preparation of Cosmetic Notification for Health Canada.

CONCLUSION:

After GAP Analysis and Label and claim assessment, the results demonstrated that the name of the product and one of the functions of an ingredient prevented the product to be considered as cosmetic.

GRP proposed a strategy to avoid changing the formula but declare another function of the ingredient which would be acceptable.

JAPAN

SERVICES:

- ✓ GAP Analysis based on local guidelines to notify products to PMDA
- ✓ Label and claim review based on local guidelines.
- ✓ Regulatory Strategy to be able to notify the product as cosmetic rather than pharmaceutical product or quasi drug.
- ✓ Preparation of documentation and submission to PMDA.
- ✓ Local Representation(MAH): Service provided GRP

CONCLUSION:

After GAP Analysis and Label and claim assessment, the results demonstrated that the name of the product and one of the functions of an ingredient prevented the product to be considered as cosmetic.

GRP proposed a strategy to avoid changing the formula but declare another function of the ingredient which would be acceptable.

MALAYSIA

SERVICES:

- ✓ Regulatory Intelligence Report on Local Representative Responsibilities.
- ✓ GAP Analysis of product according to Malaysian Cosmetic Labeling Guidelines

CONCLUSION:

The Client is already registered and marketed in Malaysia as traditional medicines with an old distributor.

The client wanted to change the distributor and asked GRP for Regulatory Intelligence on the responsibilities a Local Representative in Malaysia has for cosmetics and traditional medicines in order to create proper contract with their new distributor.

The client also asked GRP for a GAP Analysis of their products to see if it´s feasible to see if they can register their product in the future as cosmetic. The GAP Analysis showed it was acceptable.

KOREA

SERVICES:

- ✓ GAP Analysis based on local guidelines to notify products to MFDS.
- ✓ Label and claim review based on local guidelines.
- ✓ Regulatory Strategy to be able to notify the product. : Service provided by GRP product as general cosmetic rather than functional cosmetic.
- ✓ Preparation of documentation and submission to MFDS.
- ✓ Local Representation Support.
- ✓ Regulatory Intelligence on importation requirements & Documentation

CONCLUSION:

After GAP Analysis and Label and claim assessment, the results demonstrated that the name of the product and one of the functions of an ingredient prevented the product to be considered as general cosmetic. GRP proposed a strategy to avoid changing the formula but declare another function of the ingredient which would be acceptable.

SOUTH AFRICA

SERVICES:

- ✓ GAP Analysis based on local SAPHRA guidelines on the Label and Ingredients.
- ✓ Preparation of Product Ingredient File (PIF).

CONCLUSION:

After GAP Analysis and Label and claim assessment, the results demonstrated that the name of the product and one of the functions of an ingredient prevented the product to be considered as cosmetic. GRP proposed a strategy to avoid changing the formula but declare another function of the ingredient which would be acceptable.

The client doesn't have a local representative/distributor but wants to control the information being shared with them. GRP also prepared the local PIF for the client. Consequently, when they scout out the LR, all they need is to revise the PIF and submit to the HA.

Note: *SOUTH AFRICA is self-regulated market, no notification nor registration is required by SAHPRA.*

CHINA

SERVICES:

- ✓ GAP Analysis based on local NMPA guidelines of their Label and ingredients.
- ✓ Regulatory Intelligence and Strategy.

CONCLUSION:

The client already has a distributor in China that is doing the registration on their behalf. The client contacted GRP for support as they are aware if have an office in China.

The client was frustrated with their distributor as there was a lack of communication between them for multiple reasons. They asked GRP If they could do a secondary check on their label to ensure compliance as the client had a doubt with what the distributor was needing and asking of them.

GRP supported the client by doing a GAP Analysis for their label for China, answered their doubts and even shared a Chinese cosmetic regulation that was translated into English with them for their internal clarification into China Process.

SINGAPORE

SERVICES:

- ✓ GAP Analysis based on local guidelines for traditional medicines to HSA.
- ✓ Regulatory Intelligence on Local representative Responsibilities in Singapore.

CONCLUSION:

The client is already registered and marketed in Singapore as traditional medicines with an old distributor.

The client wanted to change the distributor and asked GRP for Regulatory Intelligence on the responsibilities a Local Representative in Singapore for cosmetics and traditional medicines in order to create proper contract with their new distributor.

The client also asked GRP for a GAP Analysis of their current products to ensure product compliance as traditional medicine and review its feasibility as cosmetic. The GAP Analysis showed it was acceptable.

INDONESIA

SERVICES:

- ✓ GAP Analysis based on BPOM local guidelines to notify products in Indonesia as cosmetic.
- ✓ GAP Analysis based on BPOM local guidelines to notify products in Indonesia as OTC/traditional medicine.

CONCLUSION:

GAP Analysis results showed that the name was incompliant as well as a couple of ingredients needed more information.

GRP is currently evaluating other pathways for registration in a secondary GAP Analysis.

VIETNAM

SERVICES:

- ✓ GAP Analysis based on local guidelines to notify products DAV & ASEAN Regulations and guidelines.
- ✓ Regulatory Strategy for Vietnam market entry.

CONCLUSION:

GAP Analysis revealed that certain ingredients needed more information from the manufacturer to ensure safety. One of these ingredients was a banned ingredient but can be used, if full refining history can be provided.

The Label also was not compliant per regulations. As there is required information that needs to be translated into Vietnamese.

The client was suggested next steps for Market entry.

If interested, please Contact Us!

Get in touch with GRP to learn more about our services WW.

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From Concept to Market