

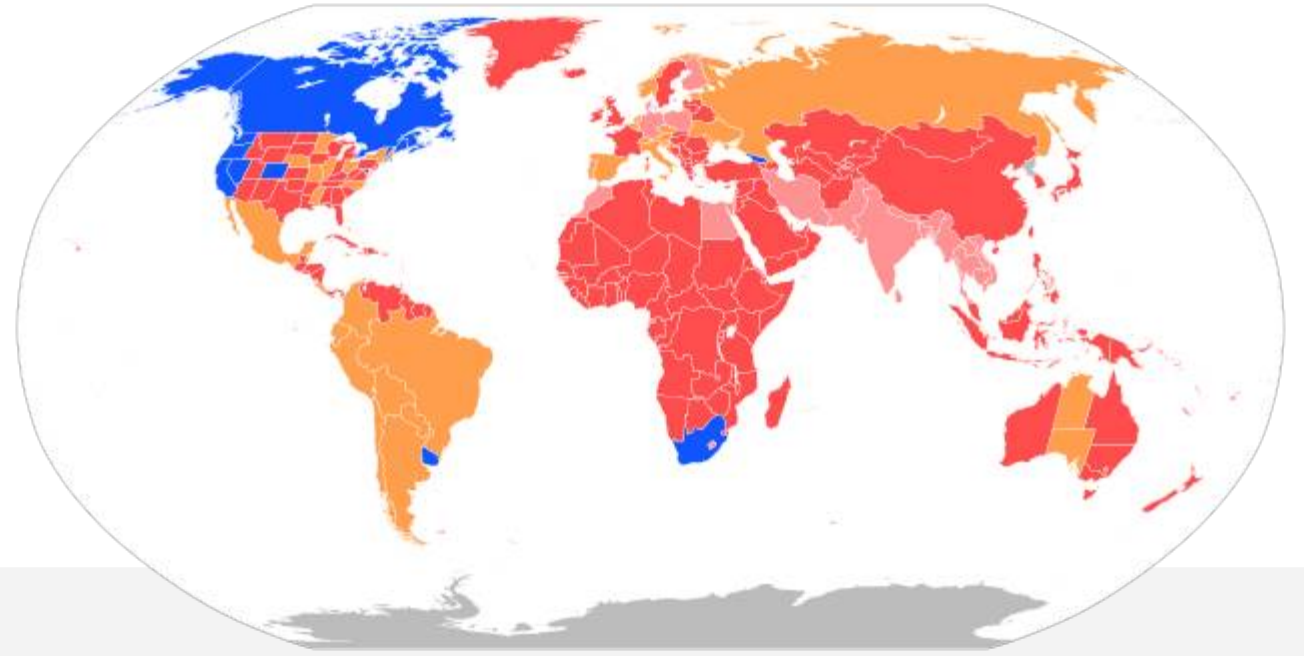
ENSURING A RELIABLE, ECONOMIC, PRACTICAL AND SAFE CANNABIS REGULATORY FRAMEWORK

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REGULATORY FRAMEWORKS

Panama has entered
the cannabis sector
late.

It now has the
advantage of leap
frogging other
nation states.



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INTRO:

Review of regulatory models that required rapid evolution to react to departmental, court driven and market pressures relating to diversion and quality assurance.

Lessons learned as to how to create a successful and pro-active regulatory framework to meet and exceed international cannabis market requirements.

We are **NOT** in uncharted waters, we are **NOT** needing to re-invent the wheel, the path is already well trodden!

THE PROBLEM

Most new jurisdictions fail to adequately plan, design, implement and manage a successful cannabis sector framework of regulations.

THE RESULT

- * Harm to patients / end users,
- * Civil action against departmental employees/departments,
- * Escalating costs of program management and monitoring,
- * Loss of law enforcement, banking, medical, retail and public tax payer support
- * Bolstering the black / grey market

MEDICAL / RECREATIONAL - STANDING ON THE SHOULDERS!

Argentina	Germany	Netherlands
Australia	Greece	Norway
Canada	Israel	Peru
Chile	Italy	Poland
Colombia	Jamaica	Romania
Croatia	Lesotho	San Marino
Cyprus	Luxembourg	Switzerland
Czech Republic	Macedonia	Turkey
Denmark	Malta	Uruguay
Finland	Mexico	Zimbabwe

Alabama	Hawaii	Massachusetts	New York	Texas
Alaska	Idaho	Michigan	North Carolina	Vermont
Arizona	Illinois	Minnesota	North Dakota	Virginia
Arkansas	Indiana	Mississippi	Ohio	Washington
California	Iowa	Missouri	Oklahoma	West Virginia
Colorado	Kansas	Montana	Oregon	Wisconsin
Connecticut	Kentucky	Nevada	Pennsylvania	Wyoming
Delaware	Louisiana	New Hampshire	Rhode Island	
Florida	Maine	New Jersey	South Carolina	
Georgia	Maryland	New Mexico	Tennessee	

As well as multiple indigenous communities within the above

COMMONALITIES

- ✓ Driven by:
 - ✓ law suit against the government (Federal / Civil Suit) and / or
 - ✓ plebiscite and / or
 - ✓ an election in a Federal Campaign
- ✓ Rarely ever by:
 - ✓ policy planning or long term objectives
 - ✓ comprehensive review of existing legislation
 - ✓ produced by committees that include industrial cannabis sector experts



Regulatory Framework

Goals:

MANAGE DIVERSION

- ✓ Risk of criminality
- ✓ Risk of enticing under age
- ✓ Risk of black market status quo
- ✓ Risk of creating a grey market

MANAGE QUALITY

- ✓ Risk of Harm
 - ✓ Contamination
 - ✓ Risk of Biological
 - ✓ Risk of Chemical
- ✓ No Perceived Benefit
 - ✓ Not properly prescribed
 - ✓ Uncontrolled Variability

NOW THAT WE HAVE YOUR ATTENTION!

Administration Rarely Considers	Operational Rarely Provides	Audit Rarely Implements
The number of applications	Adequate approval cycle time (should be <90 days)	International Standards
Ongoing policy review process	Adequate process review and accountability	Whistle Blower Registry
Qualified Staff Credentials	Promotion of applications based on merit / not place in line	Public Announcement of infractions and / or suspensions
Internal review error accountability	Direct access to the review officer(s)	Well defined audit procedures / check lists
Registry of qualified / certified industry consultants	Registry of qualified / certified operational staff (register once / review annually)	Patient / doctor / end user feedback loops
Policing internal corruption	Well defined reporting / need for product registry	

Pillars of Regulatory Framework:

PREVENT DIVERSION

- ✓ Remove criminal element
- ✓ Prevent under-age use
- ✓ Reduce and Eliminate black market
- Prevent grey market

MANAGE ACCESS

- ✓ Benefit patients
- ✓ Ensure properly prescribed
- ✓ Thwart Black Market

MANAGE PRODUCT QUALITY

- ✓ Risk of Harm / Lower Efficacy
- ✓ Contamination
 - ✓ Risk of Biological
 - ✓ Risk of Chemical

VERIFICATION

- ✓ Compliance proved
- ✓ Align with International Conventions
- ✓ Enable economic benefit

Timely License Processing Ensures Legal Supply

TIMELY APPLICATION REVIEW

Goals:

90 Day Review Period

45 Day Security Clearance

Score applications for Merit

Cull out applications within the first 30 days that do not meet a minimum score.

BE PROACTIVE AND PREPARED

Write clear regulations and guides

Be Clear Not Cryptic!

Overestimate number of applications

Hire sufficient staff

Train the staff to review the same way every time

Use forms to make the process easy and repeatable

Adequate Legal Supply Thwarts the Black Market

REGULATORY FUMBLES, CRIMINAL SMILE

AVOID:

Licensing stall-outs (90 days becomes 1 year, and investment pulls out)

Limited Distribution Networks

Repeated changes of Regulations (Please apply again?)

UNDERSTAND THE DEMAND AND PREPARE TO MEET IT

Access must be available for patients

Educate Doctors and Pharmacists

Set high standards and a transparent licensing process

Consider personal cultivation – most courts will rule this a human right

Track production out against money in

Theracann's Recommended Framework

Section on Diversion	Section on Quality	Other Critical Sections
Federally define terms of who / where / when / amount / age	Define Analysis Methods and specification limits	Operator qualifications SPIC / RPIC / QAP etc.
Require LP to adopt secure ERP roll based audit-able software for record keeping	Confirm ISO 32000, 22000, 27001	Registry of qualified / licensed personnel to facilitate cross employment within the sector
Require registration of plant DNA and DNA tracking	Confirm certification / accreditation under ISO 17025(2017)	Confirm what will result in license suspension / cancellation
Confirm level of security for building and transport	Do not permit "lab shopping" / "cherry picking" of label information	Confirm the application / monitoring process and time line
Define what is a plant for home growers – don't permit growing more than can consume	Define acceptable level of variation as between batches / between individual products	Confirm that a license will be granted under satisfaction of x requirements

Panama Regulatory Low Hanging Fruit:

Establish a globally acceptable cannabis statute and regulation

Adopt technology that will ensure tracking every gram / every penny for KYC and AML

Permit vertically integrate indoor production, processing and distribution

Control root causes of variation to ensure high quality and ease of audit-ability

Permit doctors, patients and LP's to determine what products to produce using existing country data - Canada / United States / Israel

Ensure a well planned / well staffed / speedy review and approval process!

Provide transparency with respect to application process / LP audit reviews / internal whistle blower activities!



CANNABIS IS HERE TO STAY

By slowing down and / or otherwise impeding the licensing process, Panama is perpetuating the black market - no control over quality, no control over diversion, no control over money laundering!

PANAMA HAS A UNIQUE OPPORTUNITY!

- ✓ Regulatory Recipe for Success:
 - ✓ Repeatable (able to flex to new conditions)
 - ✓ Economic (both for Regulator and LP)
 - ✓ Practical (simple to implement and comply)
 - ✓ Safe and Secure (manages diversion and quality)
- ✓ If done in phases:
 - ✓ Roll out the road map early
 - ✓ Recycle existing foreign jurisdiction regulation components
 - ✓ Signal to the World **R.E.P.S.S** will be in play!

**REMEMBER TO WEAR
SUNSCREEN!**



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