15th International Conference of the European Industrial Hemp Association (EIHA)

12th – 13th June 2018, Maternushaus (Cologne, Germany)

CBD & the WHO: legal or not?

Elements of history and forecasts about the international scheduling and Treaty control measures over Cannabis *and cannabinoids.*

Kenzi **Riboulet Zemouli**, *head of research,* FAAAT *think & do tank*

For Alternatives Approaches to Addiction, Think & do tank Barcelona • Geneva • New-York • Paris • Prague • Vienna

The international drug control Treaty system... *and its scheduling lists.*

Goals of the international drug control system.

Only addresses medicines. Limit strictly to medical use and scientific research - all production, commerce and uses of medicines with remarkable euphoric effects or whose consumption causes important health damages.

- Grants availability for medicinal or research purposes.
- Binds countries to restrict and control so narrowly (for avoiding "dispersion" towards recreational use) that it turns into prohibitionist policies.

Composition of the international drug control system.

1961 Convention • Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol
mostly deals with plants or pharmaceuticals; recovers the many Treaties on opium and other drugs prior to World War II.

1971 Convention • Convention on Psychotropic Substances of 1971
addresses psychoactive substances and drugs from a more chemical perspective.

1988 Convention • United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988
reinforces the previous two.

The reading and implementation of these 3 Treaties is framed by general international law: Fundamental Human Rights; Cultural, Civil, and Political rights; UN Charter

The "Schedules", lists
of the international drug control system.

The 1961 and 1971 Conventions have, as annexes, the "Schedules": lists of controls in which the plants, products and substances are ordered according to their *danger* and their medical effects on health.

Each Schedule carries different obligations for the countries, and corresponds to various degrees of health-related harms for each product or substance, but also therapeutic value.

Harms and medical value - as well as the belonging of a substance to one Schedule or another - is **evaluated by a committee of independent experts:**
the Expert Committee on Drug Dependence (ECDD) of the World Health Organization (WHO).

Schedules of the 1961 Single Convention (Narcotic drugs)

Less control

Stricter control
Increased restrictions

Schedule III	Schedule II	Schedule I	Schedule IV
Pharmaceutical preparation containing a small amount of narcotic drugs. - It does not lend itself to improper use.	Substances that are less liable to abuse and to produce addiction than those placed in the schedule I.	High liability to abuse and to provoke addiction. - Precursors directly convertible into a drug similarly addictive and liable to abuse.	Already listed in schedule I. - Particularly dangerous properties, especially liable to abuse and to "produce ill-effects" - Little or no therapeutic value; or a substantial therapeutic value that is also possessed by another drug not listed in schedule IV.
	Codein, propriam...	*Opium, **extracts & tinctures of Cannabis**, cocaine, methadone, fentanyl...*	***Cannabis plant material & resin**, heroin, krokodil, fentanyl derivatives...*

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Schedules of the 1971 Convention (Psychotropic substances)

Less control

Stricter control
Increased restrictions

Schedule IV	Schedule III	Schedule II	Schedule I
Regular liability to abuse. - Small but significant risk to public health. - From little to great therapeutic value(s)..	Regular liability to abuse. - Substantial risk to public health. - Moderate to great therapeutic value(s).	Regular liability to abuse. - Substantial risk to public health. - Little to moderate therapeutic value(s).	High liability to abuse. - Especially serious risk and threat to public health. - Very limited or no therapeutic value(s).
tranquilizers, diazepam, amfepramone...	*barbiturates, buprenorphine, pentazocine...*	*methaqualone, Δ-9-THC, amphetamines...*	*LSD, MDMA, cathinone...*

"Hemp" & the international drug control system.

The existence of the non-psychoactive-led *Cannabis* (hemp) market [that we happily witness as EIHA conference celebrates its 15th birthday] is due to two exemptions relating of *Cannabis* plant and its derivatives, from the control measures of the Conventions:

By purpose.

The whole plant is exempted when used in industry or horticulture;

By parts.

Fibers, seeds and leaves are exempted regardless of the use.

(*b*) "Cannabis" means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.
(*c*) "Cannabis plant" means any plant of the genus Cannabis,

Article 1 - 1961 Convention

2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.

Article 28 - 1961 Convention

An ongoing reform of the Conventions:

The **scientific assessment** of *Cannabis* for international scheduling.

*A **ghost scientific assessment** of* Cannabis.

1935

Despite being an absolute requirement prior to the inclusion of any drug in the "Schedules", the scientific review of *Cannabis* has never taken place, not even when drafting the 1961 Convention.

WHO always pretended that the "review of *Cannabis*" had already been made in 1935 by the League of Nations (predecessor of the UN). *FAAAT think & do tank* managed to prove in 2016 that it was false.

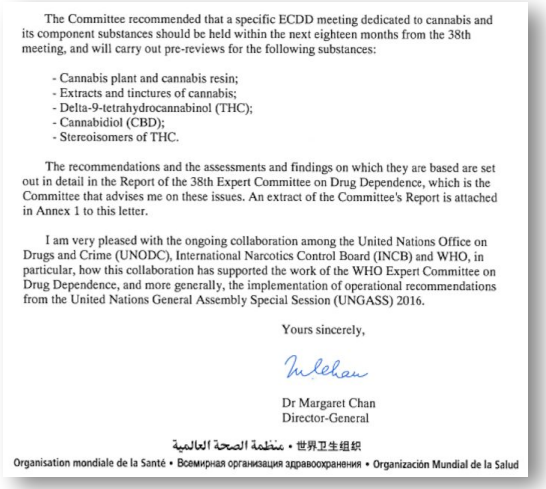
Why did the WHO avoid undertaking the review?

- to avoid assessing the real *Cannabis*-related harms and therapeutical properties;
- to avoid updating the Conventions;
- to avoid frictions between WHO and the rest of the *UN family*.

Half a Century of ripening. 1961-2016

In November 2016, 55 years after the adoption of the 1961 Convention, the WHO finally decided to begin the scientific review process.

1961 and 1971 Conventions give mandate to WHO for scientifically assessing drugs, and providing recommendations to the Countries of the United Nations for adoption (vote at the UN Commission on Narcotic Drugs, CND).



The Committee recommended that a specific ECDD meeting dedicated to cannabis and its component substances should be held within the next eighteen months from the 38th meeting, and will carry out pre-reviews for the following substances:

- Cannabis plant and cannabis resin;
- Extracts and tinctures of cannabis;
- Delta-9-tetrahydrocannabinol (THC);
- Cannabidiol (CBD);
- Stereoisomers of THC.

The recommendations and the assessments and findings on which they are based are set out in detail in the Report of the 38th Expert Committee on Drug Dependence, which is the Committee that advises me on these issues. An extract of the Committee's Report is attached in Annex 1 to this letter.

I am very pleased with the ongoing collaboration among the United Nations Office on Drugs and Crime (UNODC), International Narcotics Control Board (INCB) and WHO, in particular, how this collaboration has supported the work of the WHO Expert Committee on Drug Dependence, and more generally, the implementation of operational recommendations from the United Nations General Assembly Special Session (UNGASS) 2016.

Yours sincerely,

Dr Margaret Chan
Director-General

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The review goes ahead! 2017-2019

Cannabis, nowadays present in the Conventions' Schedules under 3 different categories, is divided into 5 categories for the ongoing review.

3 "drugs" of the *Cannabis* plant are currently under Treaty control:

- Cannabis (plant material) and resin
- Extracts and tinctures of *Cannabis*
- Delta-9-tetrahydrocannabinol

5 items are currently under review:

- Cannabis and Cannabis resin
- Extracts and tinctures of Cannabis
- Delta-9-tetrahydrocannabinol
- *Isomers of Tetrahydrocannabinol*
- *Cannabidiol*

November 2017

Pre-review of cannabidiol

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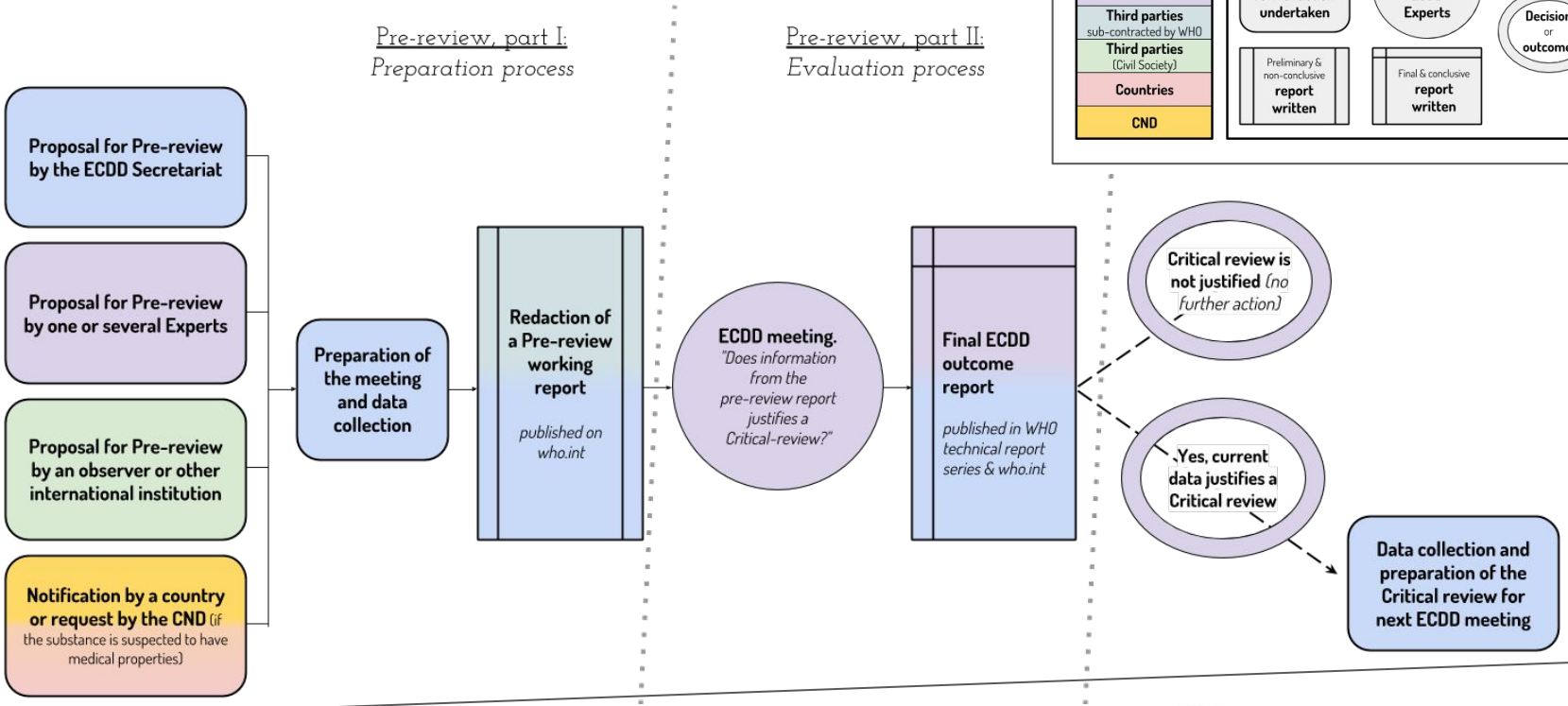
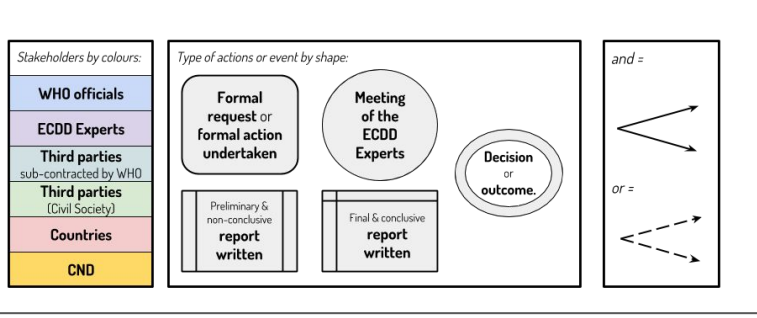
Pre-review process.





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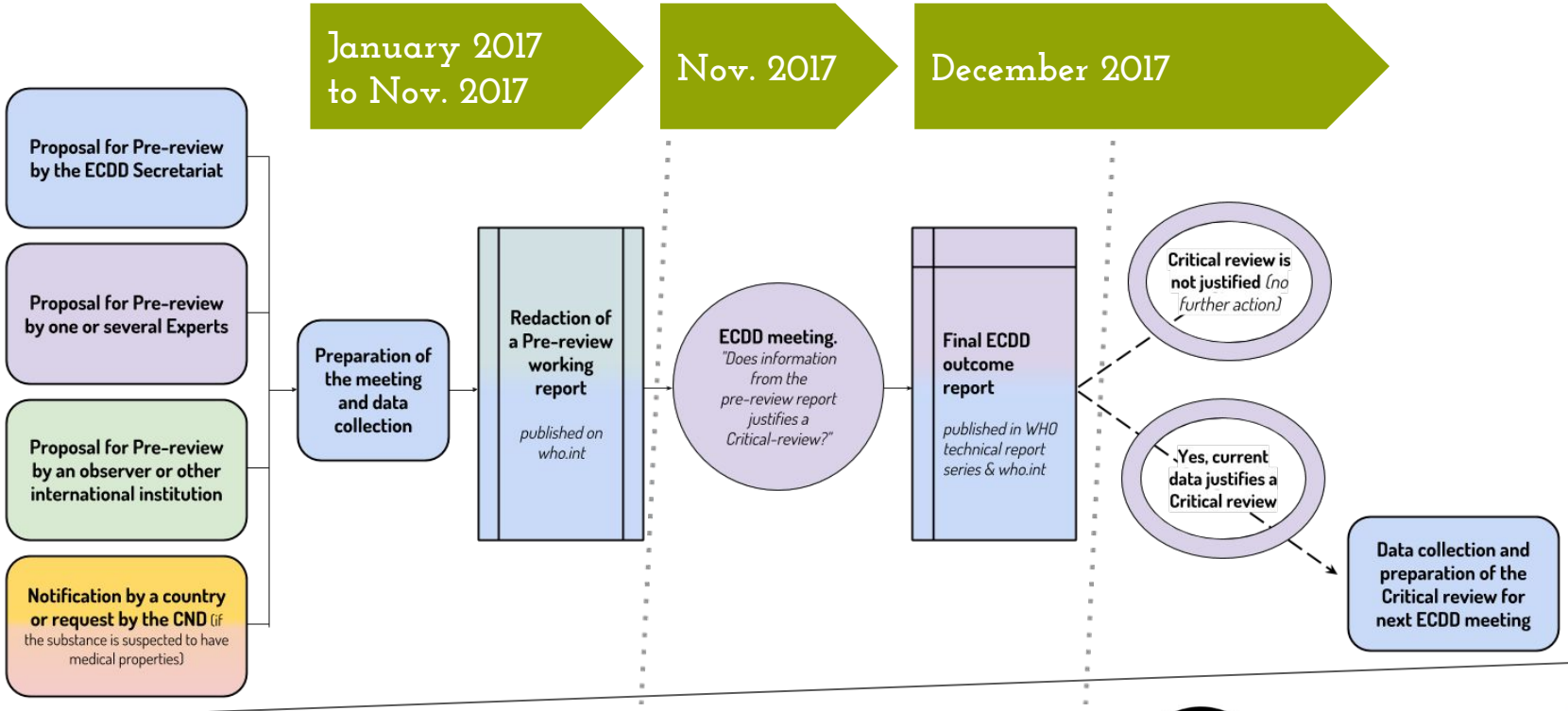
Pre-review of CBD.



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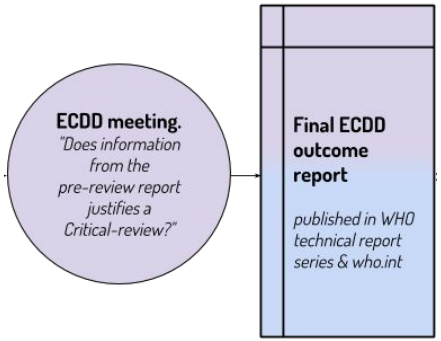
Pre-review of CBD: a positive outcome.



it has placebo-like effects when tested for its abuse liability in human subjects. Furthermore, CBD does not have effects characteristic of THC. It does not produce the cannabimimetic effects in the tetrad battery in mice, and does not substitute for the discriminative stimulus effects of THC in rats. At present, there are no case reports of abuse or dependence relating to the use of CBD. Furthermore, no public health problems (e.g. impaired driving) have been associated with the use of CBD.

CBD is not specifically listed in the schedules of the 1961, 1971 or 1988 United Nations International Drug Control Conventions. There is no evidence that CBD as a substance is liable to similar abuse and produces similar ill effects to substances in the 1961 or 1971 Conventions (including cannabis and dronabinol

"current information does not justify [...] scheduling of the substance"

June 2018

Critical review of cannabidiol

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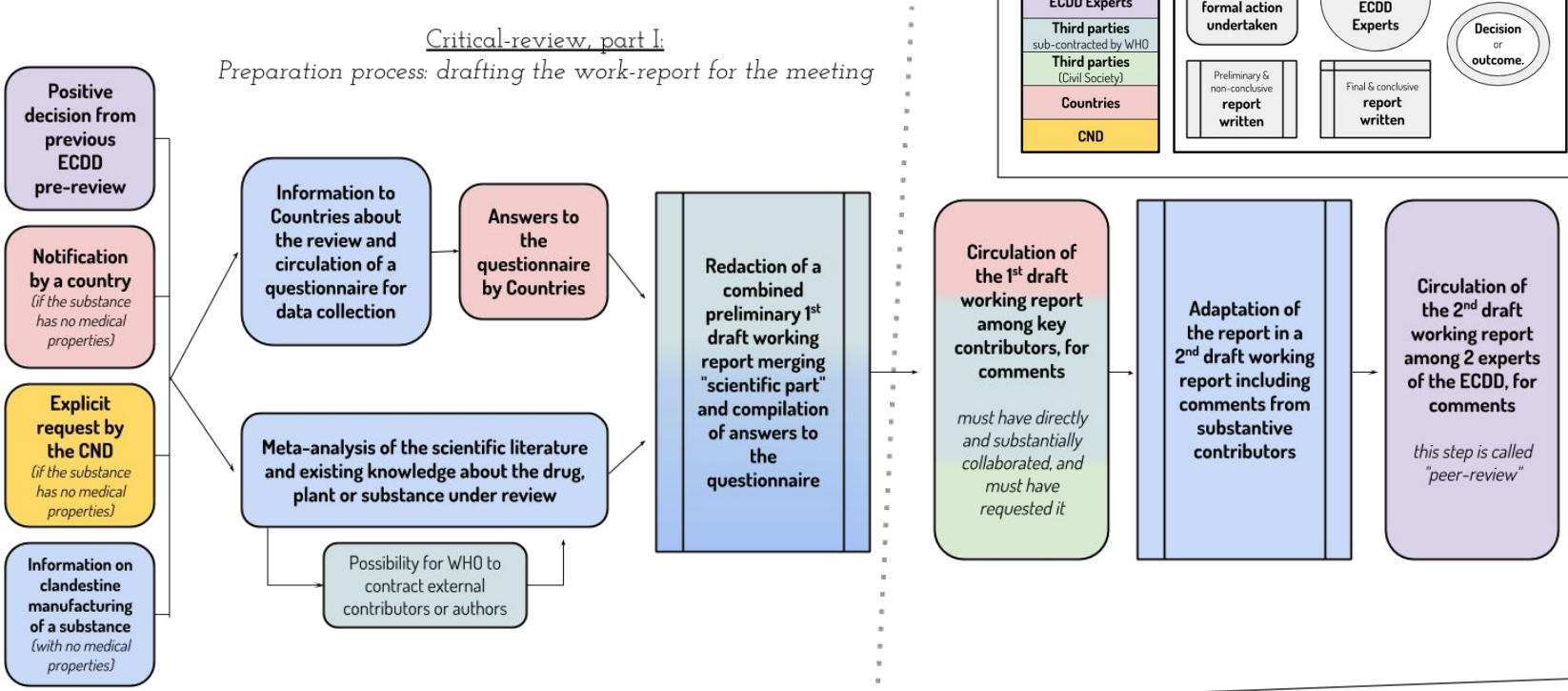
Critical review process (I).



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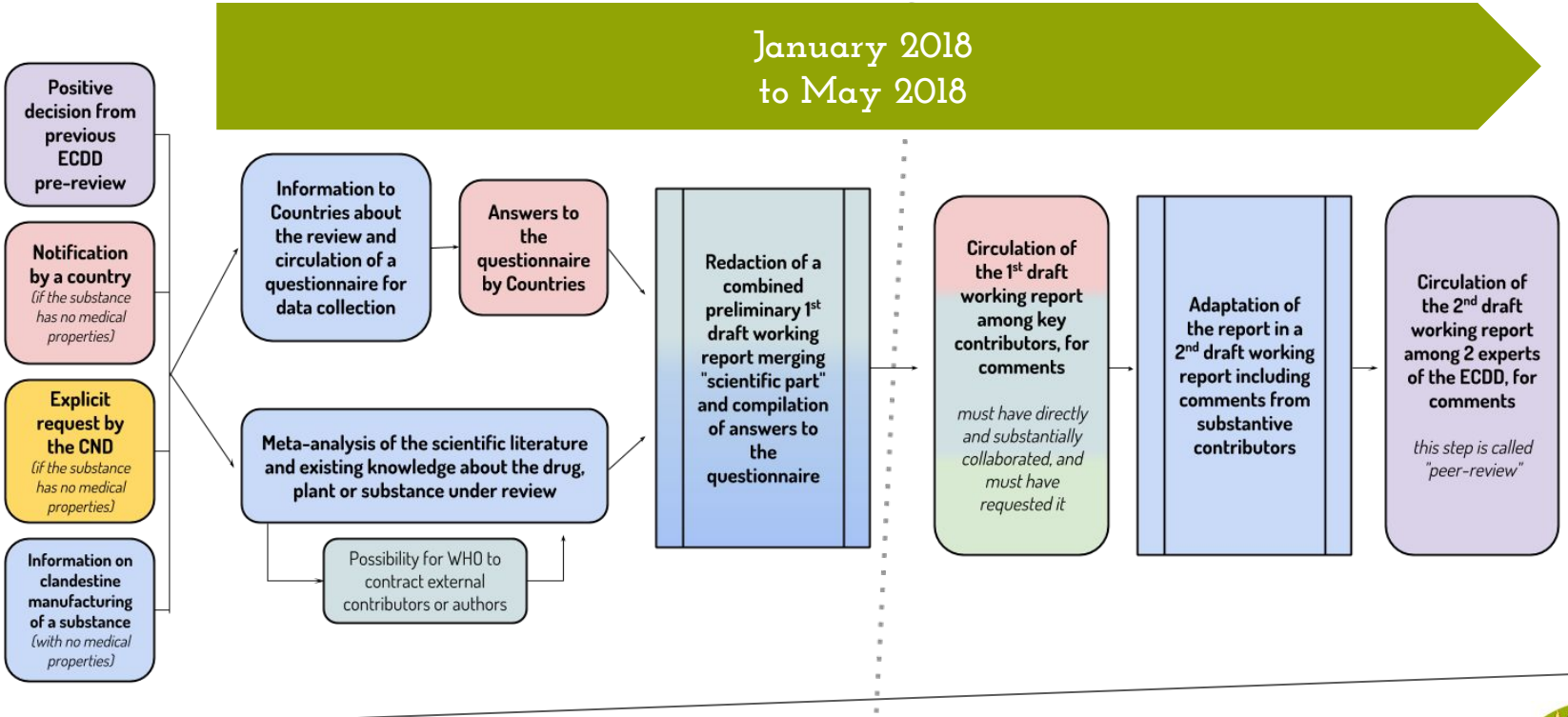
Critical review of CBD (I).



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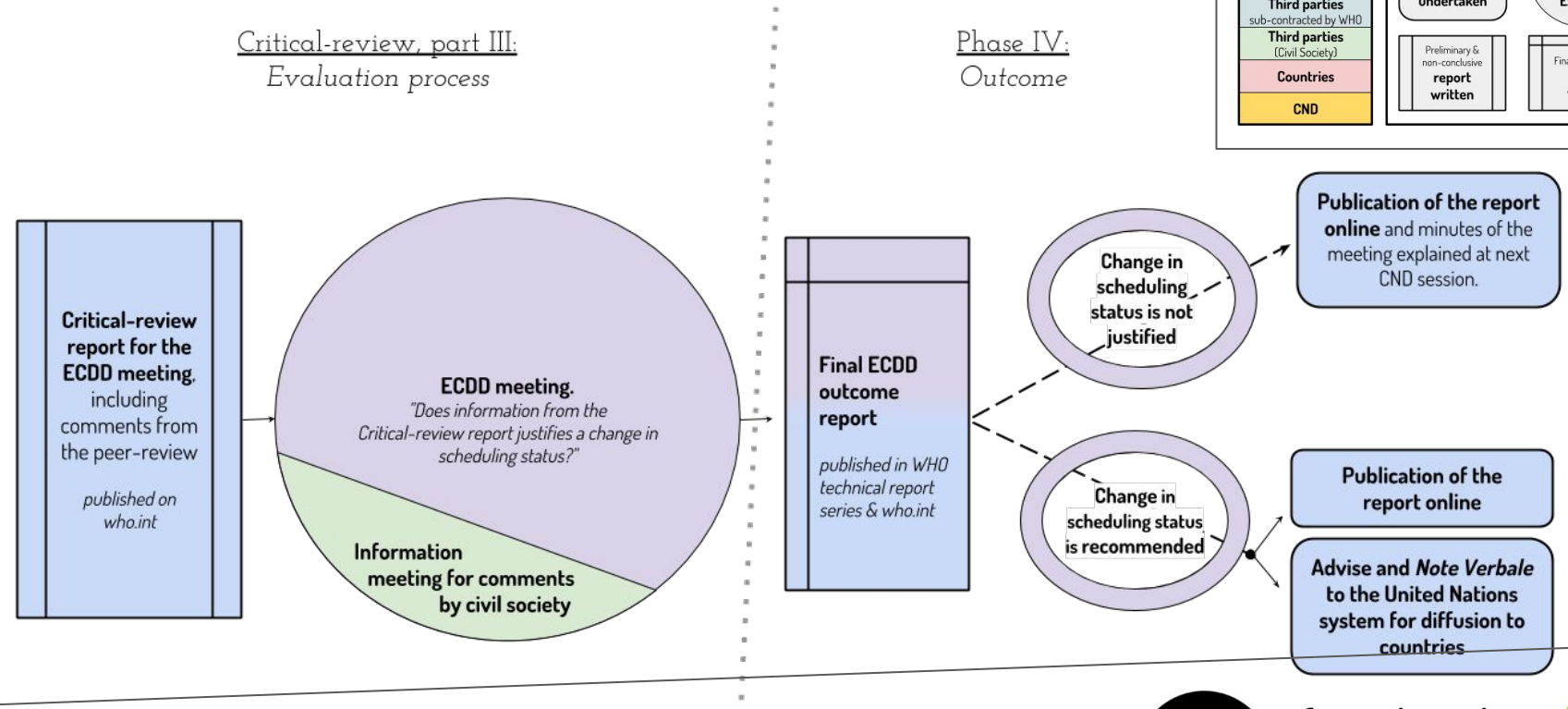
Critical review process (II).



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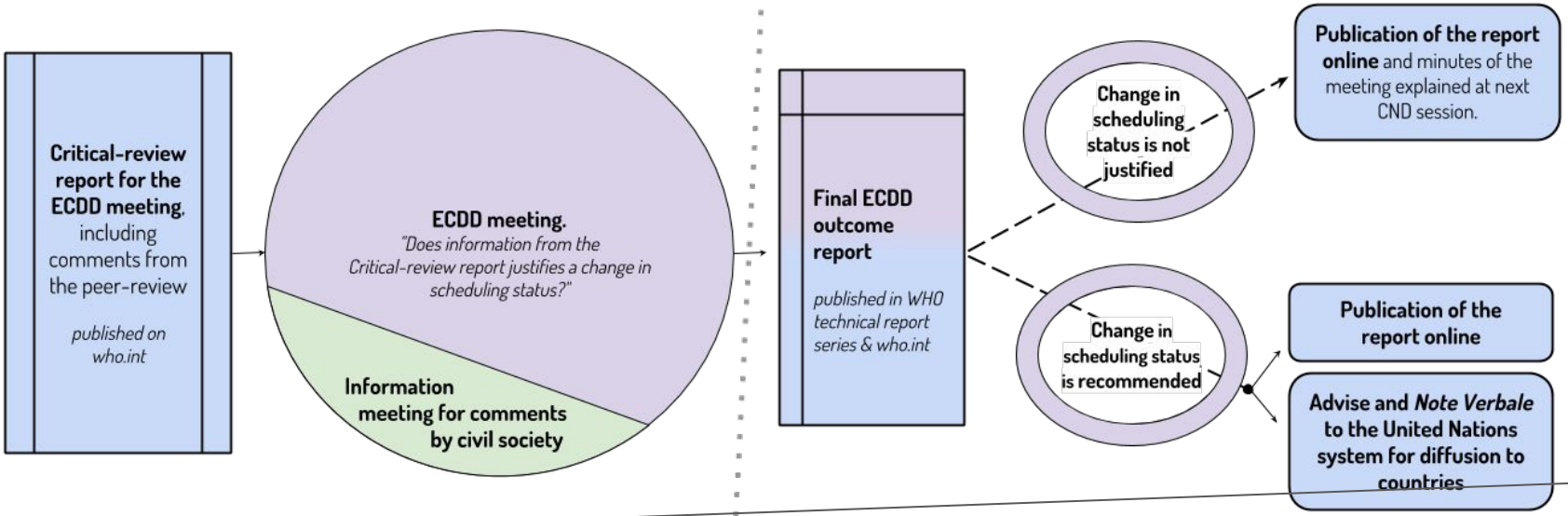
Critical review of CBD (II).

25 May 2018

04 June 2018

Expected between now and September.



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Scheduling criteria

TREATY PRINCIPLE	STEP	CRITERION
	>	If the substance, plant or preparation under review is either:
SIMILARITY	1	"liable to similar abuse, and productive of similar ill-effects as the substances in Schedules I or II" of the 1961 Convention,
CONVERTIBILITY	2	"convertible into a substance already in Schedules I or II" of the 1961 Convention,
	3	"of such a kind as to make it, by the ease of the process and by the yield, practicable and profitable for a clandestine manufacturer to transform the substance in question into controlled drugs",

1961 SINGLE CONVENTION ON **NARCOTIC DRUGS**

TREATY PRINCIPLE	STEP	CRITERION
	>	***or*** if there is "sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem" ***and*** the substance has:
DEPENDENCE	4	"capacity to produce a state of dependence" ***and*** "a central nervous system stimulation or depression, resulting in hallucinations" ***or*** "disturbances in motor function" ***or*** "disturbances in thinking" ***or*** "disturbances in behaviour" ***or*** "disturbances in perception" ***or*** "disturbances in mood",
	>	or if found that substance has no capacity to produce dependence nor a stimulation or depression of the central nervous system, but:
SIMILARITY	5	"has the capacity to produce similar abuse and similar ill-effects as a substance in Schedule I, II, III or IV" of the 1971 Convention.

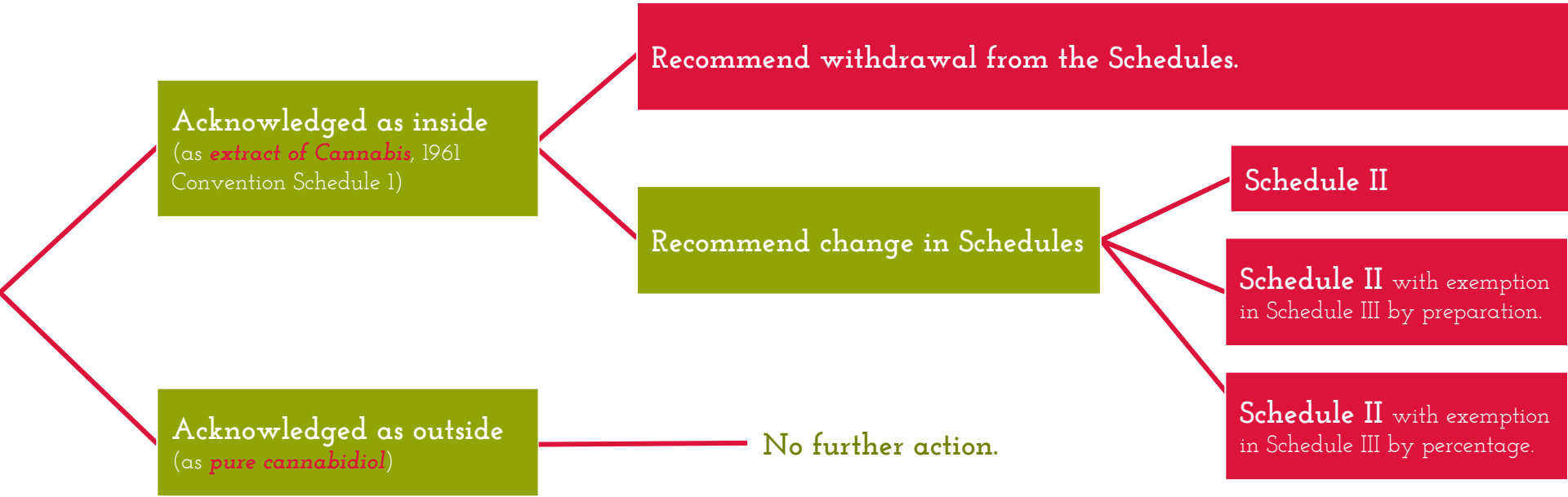
1971 VIENNA CONVENTION ON **PSYCHOTROPIC SUBSTANCES**

It is clear that CBD does not match criteria for scheduling. And the outcome of Pre-review is clear enough, and will highly influence the outcome of the Critical-review.

Cannabidiol will in all likelihood not be recommended for inclusion in the Schedules of the drug control Treaties,

but...

Options for the ECDD given the evidence provided.



A 2nd Critical review for CBD-rich extracts of Cannabis*?*

Experts recommendations on Extracts and tinctures will merge recommendations on CBD-rich preparations with other recommendations on a broad range of "mixture from the leaves and flowers of Cannabis sativa", such as:

Cannabis oils • Butane hash oil • Hemp seed oil • "Hemp oil" • Aqueous extracts • Bhang • marijuana tea • "CBD oil" • Liquid concentrate • hash oil • BHO • shatter • Edibles • Tinctures • concentrated amounts ingested orally • Topical ointments • lotions • salves • balms • Nabiximols (Sativex) • Epidiolex • Arvisol

	ECDD 39 Nov. '17	ECDD 40 June '18	ECDD 41 Nov. '18	CND 62 March '19	Special ECDD along '19	CND 63 March '20
Pure CBD	Pre review	Critical review	*No action expected.*	Vote	*No action expected.*	*No action expected.*
			No action expected.	Vote	*No action expected.*	*No action expected.*
CBD extracts	*No action taken.*	Pre review	Critical review	Vote	Critical review	Vote

Hypothesis 1

Hypothesis 2

Expected timeline...

Gràcies! ¡Gracias! Danke! Thank you! شكرا Merci!

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Gràcies! ¡Gracias! Danke!

Thank you! شكرا Merci !

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