The crimson papers **#3**

The review(s)

Pre- and Critical review: insights into the processes and procedures of the WHO scientific abuse liability assessment for drugs.

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The World Health Organization (WHO) is mandated by international law to review, assess and recommend appropriate levels of control to apply to each drug already included in the lists of the international Conventions, or susceptible to enter.

The process to come up with a public health benefit-risk assessment of drugs, plants, products, and substances liable to produce harms or addiction, is precisely defined by the rules and procedures of the WHO. Yet, it is complicated and leaves room for interpretation.

This paper aims to resume, explain and untangle the numerous doubts and uncertainties surrounding this process.

Reading of Crimson Paper #1 (The Schedules) and #2 (The Experts) is advised, complementary to the present document.

This paper briefly clarify what the review process is, define its time frame and the documentation edited on this occasion, before exploring more in detail the different steps of the very reviews. The paper then synthesizes the methodology and scheduling criteria used by the ECDD, to conclude with a description of what happens after the assessments are over, once the ECDD emits scheduling recommendations to the United Nations system.

Author:
RIBOULET ZEMOULI Kenzi

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What is (are) the review(s)?

1. The **WHO drug evaluation procedure** is the official mechanism that goes through all the existing data and knowledge about a medicine (a product with known or supposed therapeutical properties, may it be a plant, a substance or a complex preparation) in order to determine the due policies and regulations for countries to apply to it.

2. Officially, the purpose of this *abuse liability assessment* is to "evaluate substances for international control" and "provide scheduling advise".

3. This process, also called "**review of psychoactive substances for international control**", is mandated by international treaties (**⇒ See Crimson Paper #1**) to the World Health Organization (WHO), which entails with this work a group of independent experts specially called for the occasion.

4. This group, the **Expert Committee on Drug Dependence** (or ECDD **⇒ Read more about it in Crimson Paper #2**) analyzes all the existing information concerning drugs, plants or substances submitted to them, in order to establish the potency, assessed therapeutic effects, as well as the health-related or social harms and risks that can be produced by these.

5. After having undertaken this sort of **global public health risk-benefit balance**, the ECDD recommends to the United Nations system and to the governments of the world through the UN Commission on Narcotic Drugs (CND) their opinion and recommendations on the level of control that should be applied (**⇒ See Crimson Paper #1 about the schedules and Crimson Paper #4 about the measures and levels of control**).

How does a review begin & when does it end?

6. The proposal to review a drug, plant or substance, may it or not be included already in the Schedules of the 1961 or 1971 Conventions (**⇒ See Crimson Paper #1**), can come from different stakeholders, namely:

   - ➔ One or several of the Experts of the ECDD themselves,
   - ➔ The WHO,
   - ➔ The United Nations Office on Drugs and Crime (UNODC),
   - ➔ The International Narcotics Control Board (INCB),
   - ➔ Observers (necessarily NGOs in an official status of relations with the WHO),
   - ➔ Explicit request of the Commission on Narcotic Drugs (CND),
   - ➔ Notification by a country member of the Conventions.

7. It is hard to frame with precision the chronology of a review, as the timeline is decided by the WHO in accordance with the work to be undertaken, being also subject to an important pressure coming from the scarce funding provided by countries.

8. Theoretically however, the ECDD is expected to meet once a year, ahead enough of the annual CND meeting to be able to provide recommendations in time. Therefore for a few years now, its meetings have been set in November, four months before the regular session of the CND in March.

Documentation of the review process.

9. Along the "review process" or "evaluation process", which starts when a proposal is made (see §6), several documents are edited and published. Only the last of these reports has a definitive and binding opinion on the substance, plant or product reviewed.

10. The list of the reports produced is as follows, and is detailed in the flow charts next pages:

    - ➔ Pre-review report, presented to ECDD *[Uploaded in PDF version on who.int]*,
    - ➔ Outcome report of the pre-review meeting *[Edited and published in the WHO Technical Report Series]*,
    - ➔ Working-report on the questionnaires *[Confidential]*,
    - ➔ Working-report on the scientific part *[Confidential]*,
    - ➔ Preliminary critical-review report for peer-review *[Confidential]*,
    - ➔ Critical-review report, presented to ECDD *[Uploaded in PDF version on who.int]*,
    - ➔ Outcome report of the critical-review meeting *[Edited and published in the WHO Technical Report Series]*.

The very review process.

11. The review process is composed of **two reviews** undertaken by the Experts, corresponding to two different meetings, according to the rules established by WHO. Each of these two reviews can be subdivided between **preparation**, and **evaluation** process.

    - ➔ **Pre-review.** The purpose of this review is for the Experts to determine whether the data submitted to them justifies that attention should be increased on the substance, and that a thorough review should be made on the basis of comprehensive data.

    - ➔ **Critical review.** It's the central duty of the Experts; its purpose is to consider whether they should recommend the scheduling of the substance, a change in its current scheduling status or its withdrawal from the Schedules.

12. The **preparation process** consists of gathering all relevant data concerning the substance or product under review. It is undertaken by civil servants of the WHO (the so-called "ECDD Secretariat", **⇒ See Crimson Paper #2 §10**). There are three methods of data collection:

    - ➔ Routine data collection by the Secretariat,
    - ➔ Questionnaires sent to countries to collect field information and data from national drug use monitoring systems,
    - ➔ Sub-contraction of an Expert or advisor to redact a scientific report

13. The **evaluation process** consists in the very meeting of all the experts of the ECDD, plus some external advisers usually appointed among experts of relevant international institutions (often the UNODC, the INCB and the European monitoring center on drug addiction).

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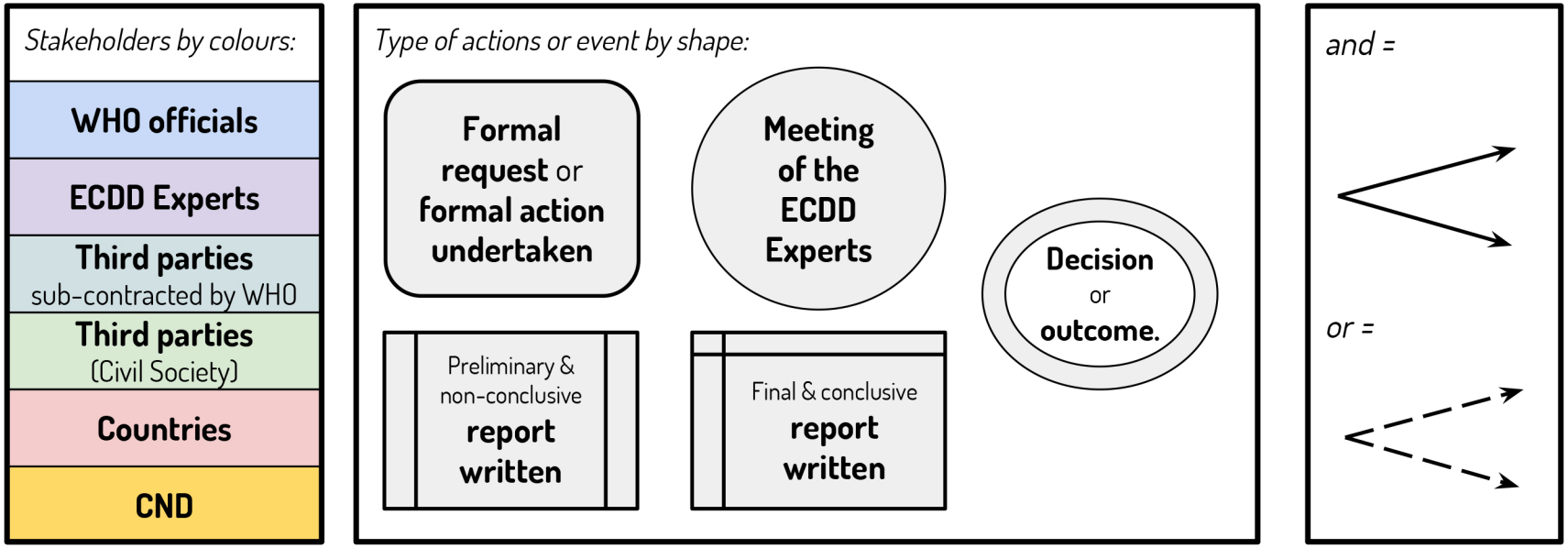
Key



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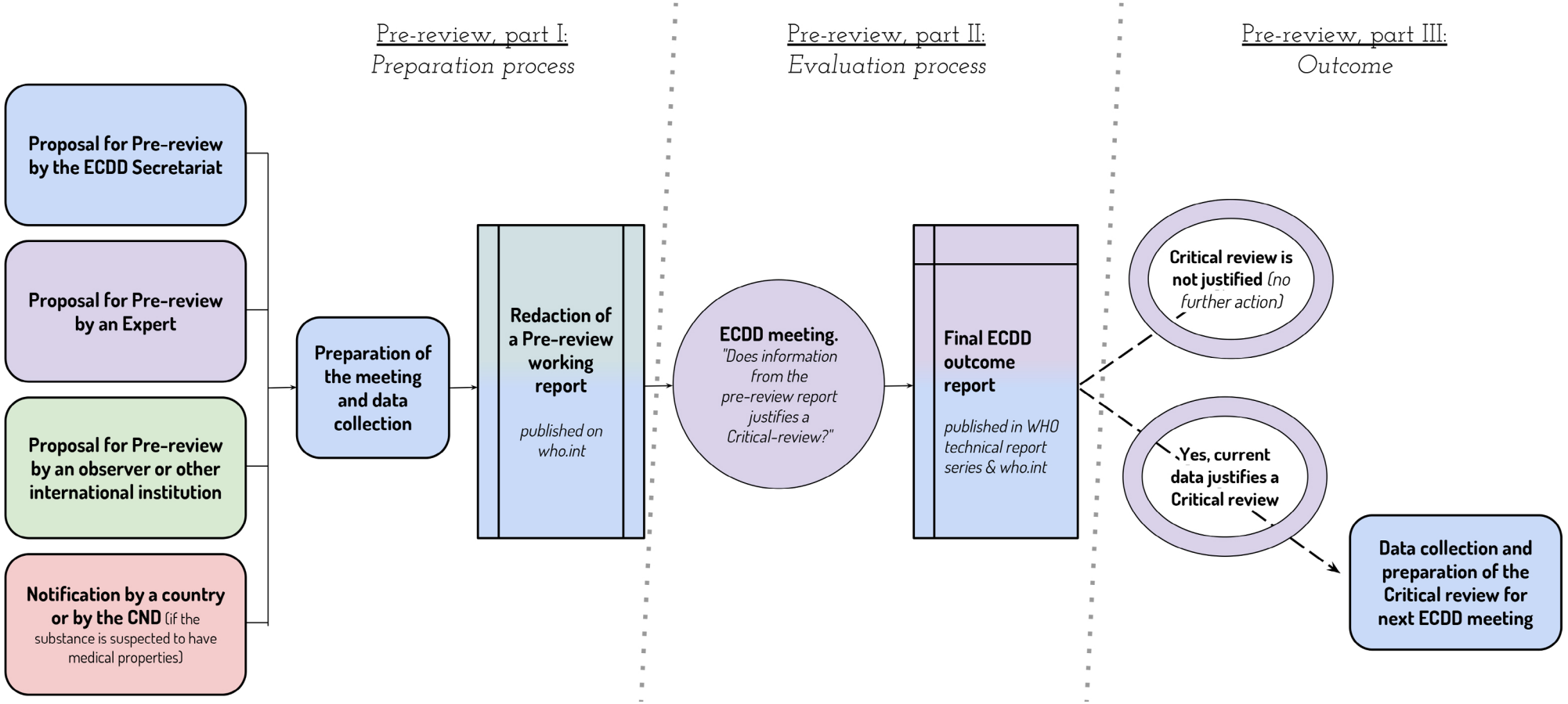
Flow-chart of the pre-review procedure.



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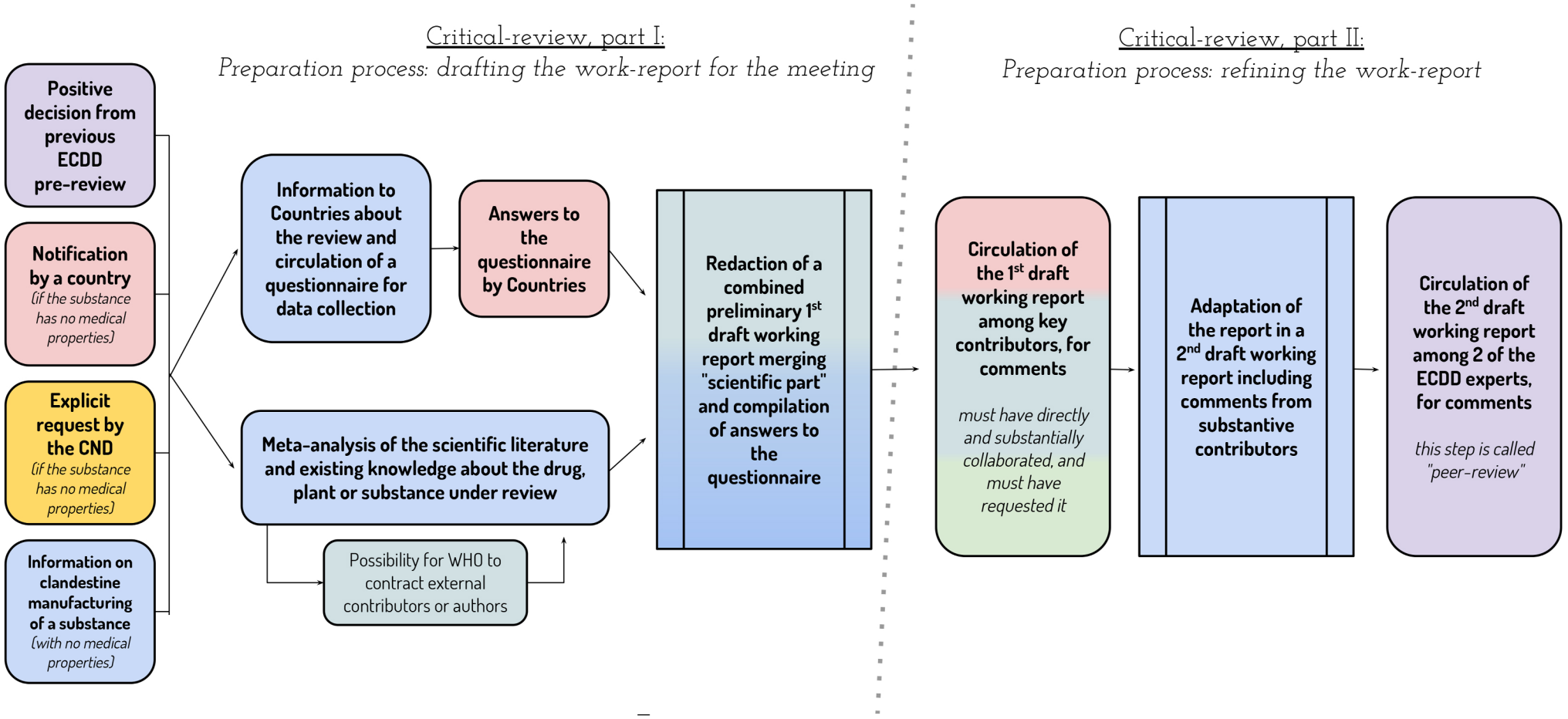
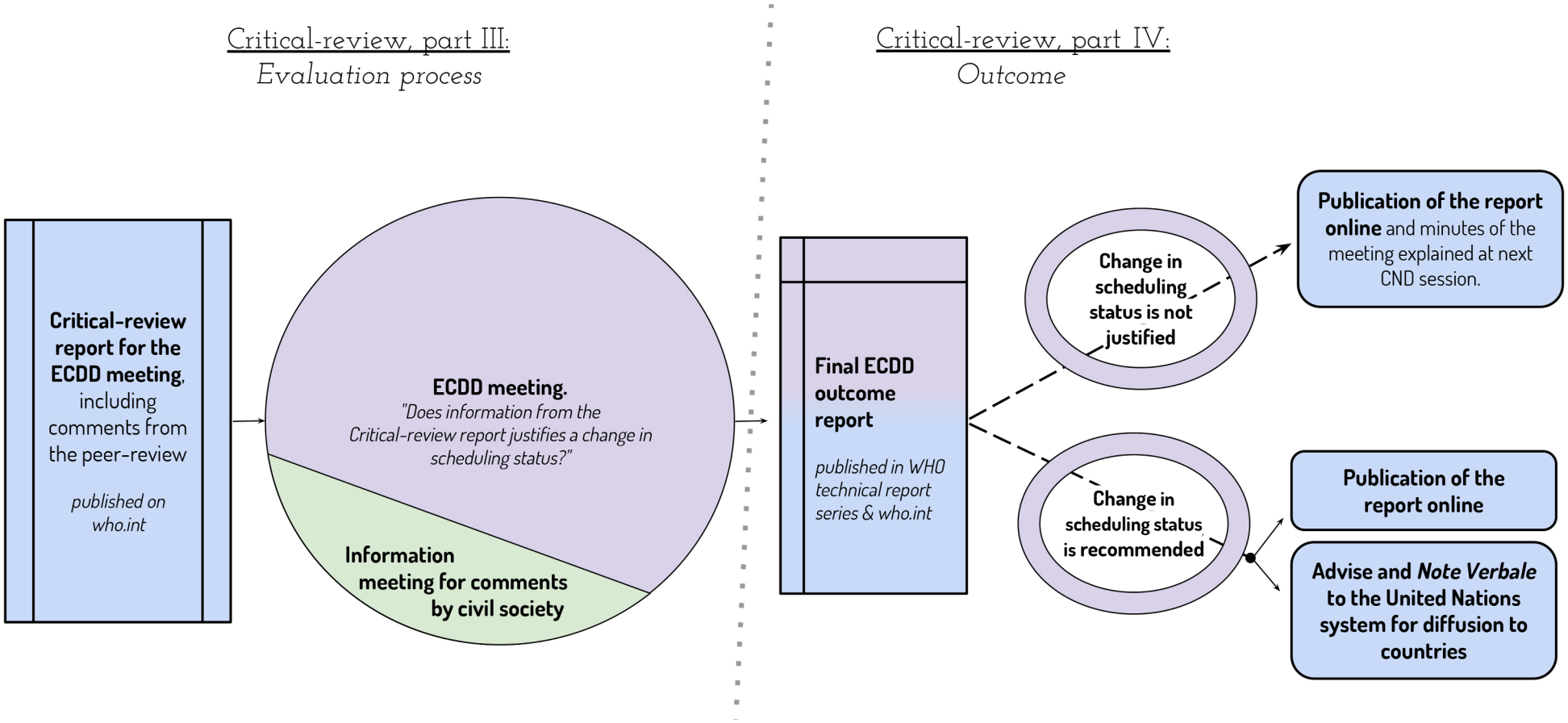
Flow-chart of the critical review procedure (1).



Flow-chart of the critical review procedure (2).



Criteria for changes in the scope of drug control.

14. The criteria for the Experts to recommend the placement under control of a drug, plant or substance follows a strict and formal, although illogical, assessment index, simplified in the chart below. The same index grid is used for proposing the change of a drug from a schedule to another, or for recommending the withdrawn of a drug from the schedules.

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,	**1961** SINGLE CONVENTION ON **NARCOTIC DRUGS**
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",	
	>	***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",	**1971** VIENNA CONVENTION ON **PSYCHOTROPIC SUBSTANCES**
	>	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.	

After the review.

15. Once the meetings finished, the ECDD Secretariat takes care of editing the outcome of the discussions, to shape it in the form of an outcome report. It is then cleared by the internal WHO administration and ultimately endorsed by the Director-General of WHO.

16. The WHO DG takes then two steps:

    - ➔ Transmission of the content of the recommendations to the Secretary-General of the United Nations, for the emission of a *Note Verbale* to countries, an official letter announcing the result of the ECDD meeting and announcing the votes to come at the Commission on Narcotic Drugs (CND).

    - ➔ Transmission of the report to the Executive Board of WHO for adoption and final publication in press by the WHO Technical Report Series.

17. Every year in March, the CND meets and discusses the recommendations of the Expert Committee on Drug Dependence. The Commission has a 2-years rotating membership of 53 countries. These are the ones that have the right to vote on the scheduling recommendations of the ECDD.