

LEGAL OPIUM PRODUCTION FOR MEDICAL USE IN MEXICO: OPTIONS, PRACTICALITIES AND CHALLENGES.



SUMMARY:

- Many countries legally grow opium for the production of opioid medicines - the scale of this market historically matching illegal opium production for non-medical uses
- Legal opium production, imports and exports take place under the auspices of the 1961 UN drug convention, overseen by the UN International Narcotics Control Board (INCB)
- Turkey and India have successfully managed transitions of traditional small scale illegal opium producers into a legal production model for medical uses within the UN system
- There are no practical reasons why Mexico could not produce opium for domestic markets (helping address domestic shortages), or for export
- Mexico would face different circumstances and unique local challenges - and such a transition would need to be carefully managed as part of a wider social development program
- Legal opium production in Mexico for medical uses would, however, not affect N. American demand for illegal non-medical uses, and it is likely that illegal opium production would simply be displaced
- Part of a longer term solution could see interests North and South of the Mexico/US border coordinated - in line with the 'shared responsibility' philosophy - with legal Mexican opium production supplying innovative harm reduction responses to the opioid crisis in North America (including medical prescribing of opium, hydromorphone & heroin)

LEGAL OPIUM PRODUCTION: BACKGROUND.

Opium is the latex or gum extracted from the opium poppy (*Papaver somniferum*). Opium contains a array of active compounds, most notably the analgesic alkaloids:

- Codeine
- Thebaine (synthesised into oxycodone, hydrocodone, hydromorphone)
- Morphine (which can be synthesised into diamorphine or heroin)

21 countries currently grow opium poppies legally for processing into medicines for the domestic and international medical pharmaceutical markets.¹ Most legal production harvests the poppies whole, using combine harvesters, and then uses an industrial extraction method known as the 'Gregory process' in which the whole plant (pods and stalks) or 'poppy straw', is harvested, processed into Concentrated Poppy Straw (CPS) before the alkaloids are recovered via acid-base extraction, and purified.

Of the legally producing countries, China, Korea, India and Japan routinely cultivate opium poppy for the production of raw opium, although only India exports it.¹⁸ cultivate opium for the

production of poppy straw (China producing raw opium and poppy straw), concentrate of poppy straw (CPS), and extracted alkaloids. Australia, France, India, Spain and Turkey are the five main exporters of opiates.

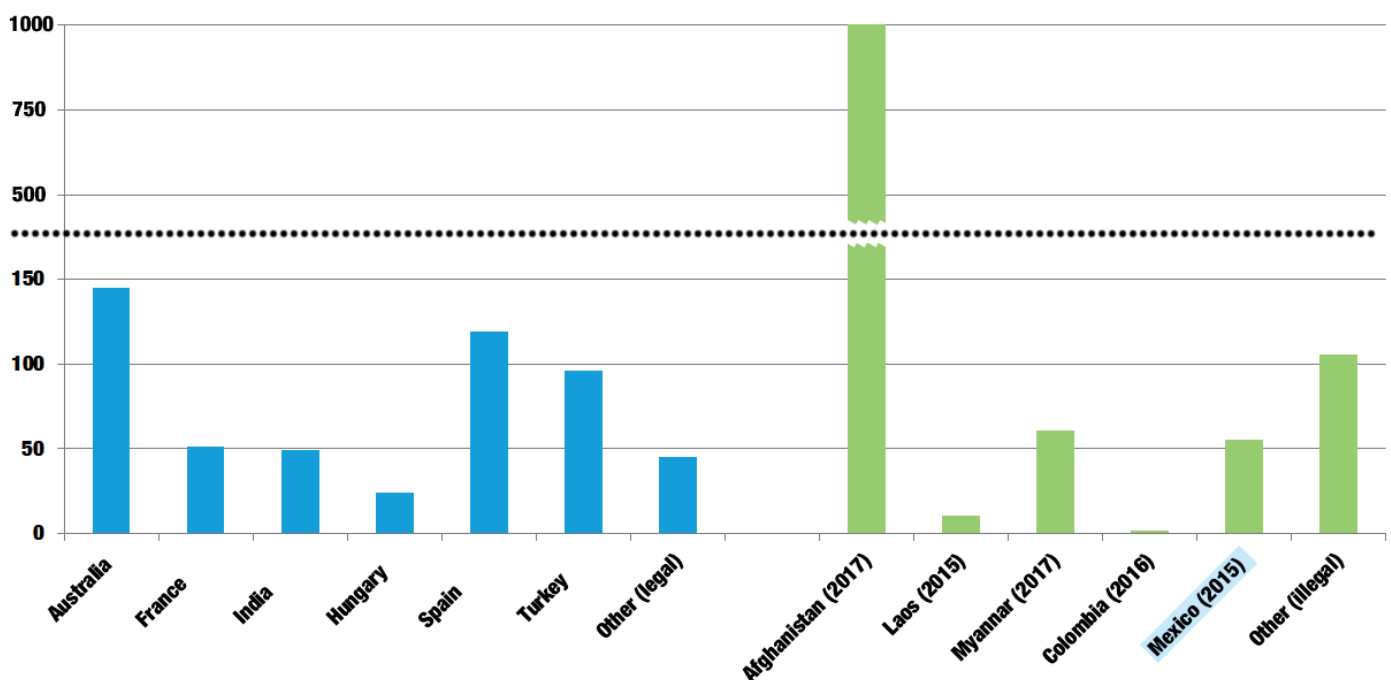
India is the only legal producer of opium that still uses the traditional opium farming method, collected it by hand, scraped from the growing poppy heads.

SCALE OF THE MARKET.

Contrary to popular perceptions of the opium trade, in recent years around half of global opium production has been legally regulated under international and domestic laws.²

Opium production is usually measured in tonnes of raw opium, or the smaller figure of 'morphine equivalent'. The International Narcotic Control Board (INCB) reports that legal production has been declining overall since 1997. In 2011 production was 789.1 tons in gross weight (86.8 tons in morphine equivalent) decreasing to 42.2 tons (4.6 tons in morphine equivalent) in 2016. At the same time, exports and stocks of opium also continued to be decrease, 709.5 tons in 2015 to 411 tons (or 45.2 tons in morphine equivalent) in 2016.

Legal opium production shown in blue (morphine equivalent in tonnes) 2018³, and Illegal opium production shown in green (morphine equivalent) - latest available data from UNODC.^{4,5}



UN TREATY REQUIREMENTS FOR LEGAL OPIUM PRODUCTION.

Any country can cultivate, produce and trade in licit opium, under rules established under the UN Single Convention on Narcotics Drugs of 1961⁶ (export of over 5 tonnes requires additional approval by ECOSOC). Opium is unusual within the UN drug treaties in that (along with coca and cannabis) there are drug specific requirements regarding its licit production and control, rather than the generic requirements for all other drugs within specified schedules. Adherence to these treaty requirements are overseen by the INCB⁷ an 'independent, quasi-judicial expert body established by the Single Convention on Narcotic Drugs of 1961'. The INCB members are experts nominated by Member States and the World Health Organisation. The INCB oversees adherence to and reporting on the broader treaty mandates for regulating the international market in opiates for medical and scientific use (as well as other drugs controlled under the UN drug treaties) as well as their prohibition for non-medical or scientific uses. To note: Mexico already actively participates in this INCB/treaty system regarding imports, estimates for use, and reporting mechanisms regarding medical opiates - but does not yet currently engage the production and export regulatory mechanisms.

Key requirements for legal opium production under the 1961 single convention:

- Article 23 requires that opium production must take place under the auspices of a national opium agency which will determine which licensed producers can grow it, and where. Furthermore the agency is the sole recipient of the opium (within 4 months of harvest) and is responsible for imports, exports and storage (this does not apply to processed opiate products).
- Article 24 requires limits on the amount of opium production in a given member state that relate to global opium demand as determined by the International Narcotics Control Board - and not produce, or increase production if it 'may result in illicit opium trafficking' (INCB calculates the quantity of opium needed to produce opium derived pharmaceuticals annually based on obligatory

annual estimates from member states. These estimates are translated into real quantities the following year to inform quotas, which also reflect stockpiles)

- Article 24 further requires Member states to inform the INCB of details of opium exports - regarding; treaty compliance and destination countries (which INCB may then approve, or 'recommend' against)
- Article 24 further notes that member states are not prevented 'producing opium sufficient for its own requirements' or interestingly 'exporting opium seized in the illicit traffic' (something only Iran currently does).

The INCB itself has no direct enforcement powers or punitive sanctions for violations of agreed systems. Sanctions can, in theory, be agreed through the United Nations Economic and Social Council (ECOSOC) under article 14 of the Single Convention, but this has never happened.⁸ Non compliance issues, either in letter or spirit, have generally been addressed through diplomatic and political pressure behind the scenes, alongside a more public process of 'naming and shaming' in the INCB's annual reports.

The United Nations Office on Drugs and Crime (UNODC) manages the day-to-day monitoring of the situation in each country.

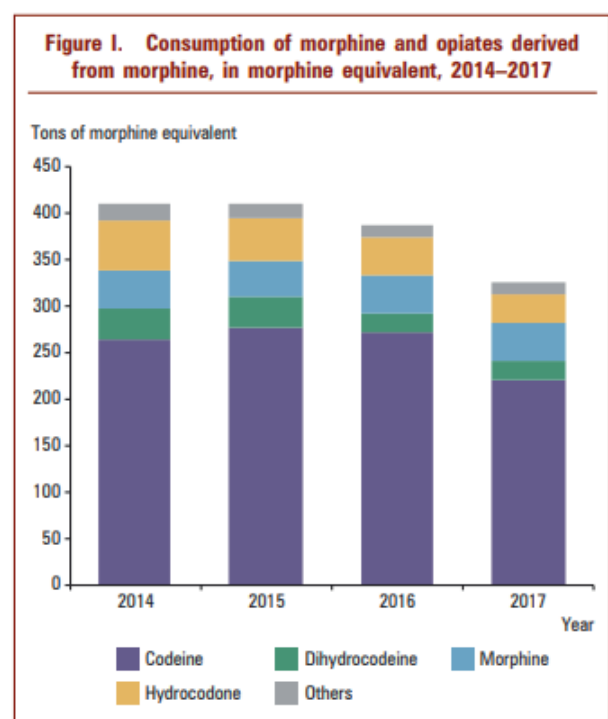
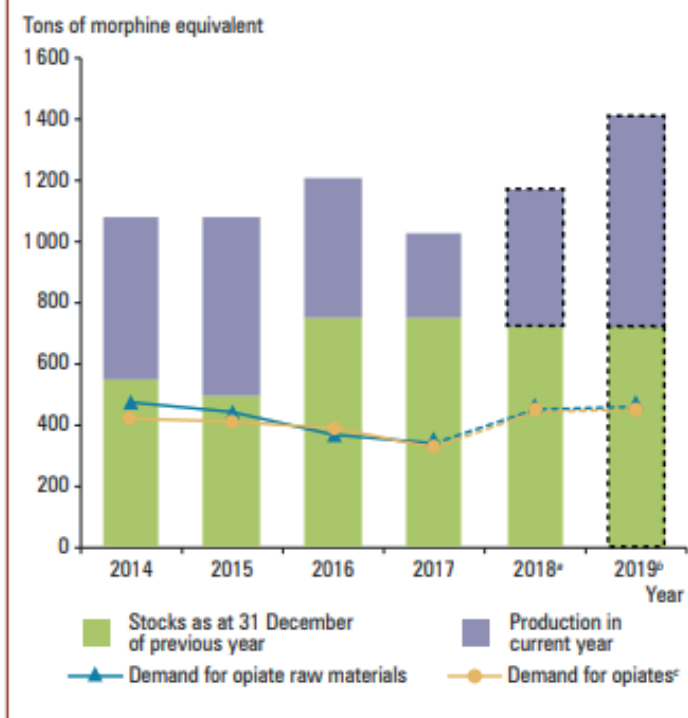


Figure II. Supply of and demand for opiate raw materials rich in morphine, in morphine equivalent, 2014–2019



*Data for production and demand for 2018 are based on advance data (dotted line) submitted by Governments.

*Data for 2019 are based on estimates (dotted line) submitted by Governments.

*Excluding substances not covered by the Single Convention on Narcotic Drugs of 1954 as amended by the 1972 Protocol.

Opium derived medicines; global consumption, supply and demand (INCB 2018)⁹

PRACTICAL CONSIDERATIONS AND SECURITY CONCERNS.

Opium poppies are a hardy plant, and whilst yields may vary, they can be grown in a range of environments, from the UK to Spain, Afghanistan to the tropics.

Substantial quantities of poppy straw are required to produce a relatively small quantity of opium. Converting the harvested plant into opium, and then into heroin, requires a more involved and technical process. There is, therefore, little incentive for, or evidence of, opportunistic theft (for example by small time criminals, or people who use drugs) of opium poppy crops in the farm environment. Security arrangements for opium poppy farming are therefore a minor concern, compared to legal cannabis cultivation for example - where the raw (dried) plant is of high value, making legal cannabis farms an attractive target for criminals, and requiring more farm security measures. Once poppy straw has reached the point of 4.

industrial processing, security issues are then easier to manage indoors, and processed pharmaceutical opiate products, whilst high value, can be managed within existing systems for storage and transit of high value or high risk pharmaceuticals.

Each of the countries that grows opium poppies for export has its own set of legal frameworks in order to prevent diversion into the illicit market. Whilst some are more effective than others, the only significant observations from reviews of such arrangements are that concentrate of poppy straw (CPS) is considerably less likely to find its way into the criminal market than raw opium. As the only country to produce opium latex at the farm gate, India has a bigger problem with illegal diversion than the CPS producer countries; the Government of India estimates it is around 10% of total production.

LICENSING OF TRADITIONAL/ILLICIT GROWERS.

India and Turkey have both managed the transition from small scale traditional illegal opium growers to a legal licensed system. Of these Turkey is arguably more instructive to potential developments in Mexico. Turkey, in line with the Single Convention requirements, uses a state agency (The Turkish Grain Board) to license existing small illegal opium farmers to produce for the legal medical market.

Unlike the large-scale, highly industrialised opium production, in Tasmania for example, in Turkey, legal opium production remains in the hands of the 70,000 to 100,000 mostly small-scale farmers who are licensed every year, each cultivating an average of just 0.4 hectares. In 2005, the The Turkish Grain Board estimated that 600,000 people earn income from poppy cultivation in Turkey. 95% of the morphine (and poppy seed) production is exported, generating an export income of over \$60 million.

The Turkish licensing system can be viewed as a success – providing oversight of the previously illegal unregulated industry, maintaining traditional producers' incomes, creating valuable export revenue, and successfully preventing almost all leakage of opium to the illicit market. The US State Department claims that there is 'no appreciable illicit drug cultivation in

Turkey other than cannabis grown primarily for domestic consumption’, and that, ‘The Turkish Grain Board strictly controls licit opium poppy cultivation quite successfully, with no apparent diversion into the illicit market.’¹⁰

Equally, the UNODC says that since ‘1974 until now [2003], no seizures of opium derived from Turkish poppies have been reported either in the country or abroad.’¹¹ This demonstrates that an orderly transition, with a range of benefits for the producer country, is possible in places with the institutional capacity to deliver the right regulatory framework.

DISCUSSION: THE MEXICAN CONTEXT.

Considering the international experience, there would seem to be no significant practical or legal obstacles to developing domestic opium production, and related processing industry for medical pharmaceuticals in Mexico, for either domestic or international export markets. Such a move would, however, require a series of practical steps and decisions.

Establishment of a national agency overseeing a licensing framework.

- This would need to be done under the guidance of the INCB to maintain compliance with the Single Convention. The licensing framework for farmers and processing activity would be determined by decisions over what to produce; poppy straw, concentrated poppy straw, or extracted alkaloids. There would be no reason to have production of raw opium - and good reasons to avoid it.

Decisions on scale of production, and proportion destined for domestic or export markets.

- The extent of export markets would be significantly shaped by INCB quotas. Exploration of domestic markets is a domestic decision but raises more complex issue than production alone. There is well described under-availability of opioids medicines for pain control and palliative care in Mexico. A 2014 report from Human Rights Watch¹² found that, despite 300,000 people a year needing palliative care in Mexico:

“Palliative care is not available anywhere in seven of Mexico’s 32 states. Another 17 have just one palliative care service, in the capital city in each case. The networks that serve people affiliated with all three of Mexico’s largest health insurers – Instituto Mexicano del Seguro Social, Instituto de Seguridad Social y Salud de Trabajadores del Estado, and Seguro Popular – have few facilities that offer palliative care. Only six of Mexico’s 102 medical schools include instruction on palliative care.

A key barrier is the limited accessibility of morphine and other opioid analgesics that are essential for the treatment of moderate and severe pain. Mexican law requires prescriptions for these medicines to contain bar-coded stickers, which physicians can only obtain in person in state capitals. As a result, very few physicians, especially outside of major cities, are licensed to prescribe these medicines, the report found. Moreover, very few pharmacies stock them.”

Clearly this inadequate access to medical opioid medicines reflects a number of long standing political and institutional challenges rather than restrictions in production and supply *per se*. If these wider institutional issues can be addressed - and there is a compelling and urgent case that they should - then there is obvious potential for Mexican domestic opium/opioid production to meet this need.

Potential for transitioning illegal / traditional opium production into the legal market.

- Turkey’s move from illegal to legal opium production for medicinal use demonstrates that an orderly transition, with a range of benefits for the producer country, is possible in places with the institutional capacity to deliver the right regulatory framework. There are obviously substantial differences between the Turkish and Mexican scenarios - but there are enough similarities to suggest that at least a proportion of future Mexican opium production could be produced by licensing of current small scale illegal producers. This would, however, likely have to be under the auspices of a national rather than state-level

agency, even if policing of production and transport was overseen in coordination with state authorities.

For practical and security reasons it would make sense for production, as in Turkey, to be of dried poppy straw, and for processing to be licensed separately. Small scale illegal opium cultivation in Mexico is mostly the traditional hand collected latex/gum scraped from scored flower heads (as in India), so some adjustment in farming practice would be required, although moving to dried poppy straw would not be problematic.

More challengingly, Mexican production also takes place in some of the most remote and economically underdeveloped regions of the country, often where state infrastructure is weak, corruption and distrust of authorities is endemic, and where organised crime groups have a powerful grip on communities - particularly those directly involved in illicit economies. Again, this does not prevent a transition to legal production, but would present specific challenges for licensing, enforcement and monitoring. Given the unknowns, it might be that smaller scale pilot projects would be a pragmatic first step to identifying challenges and solutions, and establishing best practice before a wider roll out.

Purchase price of a poppy crop from traditional producers would also need to be comparable to existing illegal market rates to make transition an attractive prospect, and there would also need to be technical support, training and investment (for both farmers and local authorities) to facilitate any such a transition. It would be important to draw on best practice in sustainable alternative development thinking - making sure that the interests of the communities are prioritised and that they are involved in the process of policy design and implementation. Crucially, any managed transition into the legal economy would need to be part of a wider social and economic development program tailored for each locale, rather than an isolated reform seen as a panacea. The most effective alternative development programs address individual needs

alongside the wider structural factors driving communities to engage in illegal economies, deploying long-term, carefully sequenced and adequately financed multi-agency support to progressively strengthen institutions, services and infrastructure.

DISCUSSION - IMPACTS ON ILLEGAL PRODUCTION AND POTENTIAL BALLOON EFFECTS.

Turkey is now one of the major legal opiate producers for the pharmaceutical market along with India, Australia, France, Spain, Hungary and some smaller producers, including the UK. There is no reason Mexico could not join this group and benefit economically, regularising at least some of its currently illegal production for a licensed market, and helping to address its own under availability of opioid medicines.

However, USA and Canadian demand for Mexico's illegal opium, processed into heroin, is large and growing, although recent research¹³ has suggested that as North American non-medical opioid use shifts increasingly towards synthetic opioids like fentanyl, demand for Mexican opium may progressively dry up, and that this phenomenon may have already begun, with Mexican opium prices collapsing in recent months.¹⁴ Mexico developing a legal industry, even if it involves transitioning of traditional/illegal opium growers, does not impact on these wider demand dynamics. When Turkish opium production was first banned in 1972, and then legalised and regulated for the production of medicines in 1974, illegal production did not end, it was simply displaced elsewhere - including to Mexico.

Illegal Turkish opium production supplying heroin markets in Europe shifted firstly to Pakistan, Burma and Iran, then later to Afghanistan, which now dominates global illicit production. With respect to the North American heroin market, the US Drug Enforcement Administration has acknowledged this problem, saying: 'Mexico emerged as a prominent source of heroin to the United States in 1974, when growers stepped up production to fill the void left by the suppression of heroin supplies from Turkey in 1972.' As early as 1975, Mexico was supplying 89% of the heroin consumed in the United

States.

This is a classic example of the 'balloon effect', which describes how enforcement, rather than eliminating the drug problem, often merely displaces it to new locations – like air moving around in a squeezed balloon. Given this dynamic, it is unrealistic to think that transitioning Mexico's traditional/illegal opium producers into a legal market will eliminate illegal production and related cartel activity. While the demand remains in the USA and Canada, the likely outcome is that Mexico's illegal production will be displaced; existing farmers may merely extend their land under cultivation to produce for legal and illegal markets, or new actors may enter the market to exploit the new opportunity, in existing production regions or potentially elsewhere in Mexico or further afield (for example in Colombia or Guatemala where smaller scale opium production also occurs). For organised crime groups this will represent an inconvenience and marginal expense, rather than a serious challenge to their business.

So while legal opium production in Mexico can bring many benefits - caution is needed for claims that it can significantly impact on organised crime, at least in the short term. That said, if Mexico's shift could be aligned with new thinking in responses to the opioid crisis gripping the USA and Canada, then there are certainly opportunities to meaningfully reduce the scale of regional illegal opium production in the longer term.

This new thinking would need to address illegal demand in North America at least in part through more effective treatment and harm reduction provision. This can involve scaling up availability of more established opioid substitution therapy, such as methadone and buprenorphine, as well as exploring the possibilities for heroin assisted treatment (HAT). It is on this last option that some triangulation with Mexican reforms could be possible

HAT is a well established legal medical intervention that has a long history, including in the UK, Switzerland, Germany, the Netherlands, and more recently, in Canada. It has positive local impacts, successfully reduced fatal overdoses (including the growing menace of

heroin contaminated with the potent synthetic opioid fentanyl) and needle sharing that can lead to infections, including HIV and hepatitis; high risk street injecting; fundraising driven acquisitive crime and street sex-work; and discarded needles, while increasing take-up and retention in treatment.

More significantly for this discussion it has been shown that the 10-15% of heaviest problematic heroin users - the population specifically targeted by HAT - consume 50% of the total heroin. If, therefore, such HAT provision could be rolled out to support a wider upscaling of treatment and harm reduction in North America, it is not unrealistic to suggest that more than half of current illegal demand could be met through regulated supply. Less well explored proposals to utilise opium tincture and hydromorphone as possible lower threshold substitute treatments could help undermine illegal still further.

The long established international drug policy principle of 'shared responsibility' could be brought to bear here. There would be a mutually beneficial symmetry to seeing North America rolling out innovative opioid substitution treatments, using opioids from Mexico's emerging opium industry. While the current US administration has pivoted away from pragmatic harm reduction to more traditionally hawkish enforcement-led drug war rhetoric, the gravity of the growing opioid epidemic - with more than 50,000 opioid deaths in 2017¹⁵ - may yet force a rethink. Indeed, much needed pragmatism has appeared in Canada - with HAT pilot projects starting in a number of provinces, alongside innovative experiments with opium and hydromorphone based treatment. It may be that this is an idea that could be developed with Canada first and when demonstrated to be effective - expanded to the US in the future under a more receptive, pragmatic administration.

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