

# “Responding to the Pandemic Together” Programme

## The Regulatory Climate with Covid-19

Delivered by the Social & Administrative Pharmacy Section



# Moderator(s)

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## **Professor Timothy F Chen**

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@timothychen17



## **Ms Tara Heir**

Sydney, Australia

Secretary, SAPS

# Welcome to the “Responding to the Pandemic Together” events

## *FIP’s Special Online Programme on COVID-19*

### These webinars aim to

- I. Provide relevant information and the pharmacy workforce on Coronavirus SARS-CoV-2/COVID-19
- II. Share and discuss strategies and experiences of Member Organisations – in response to the pandemic
- III. Describe sector or area-specific approaches adopted across pharmaceutical science, practice and education
- IV. Engage frontline workers of pharmaceutical organisations to know about the realities facing them around the world.
- V. Discuss the implications of the pandemic on pharmaceutical supply, shortages that have been exacerbated by COVID-19, and the impact on patients
- VI. Consider the impact of this disease on patients across age groups and with concurrent conditions.
- VII. Assess and discuss the evidence behind treatments and the process of developing therapies, vaccines and tests.



**To share ideas on webinar topics we should feature, or if you'd like to share your story on dealing with the pandemic please email**

**[lina@fip.org](mailto:lina@fip.org)**

# Important Links & Resources

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## FIP Covid-19 Information Hub

A comprehensive FIP webpage containing all of our resources and outputs relating to COVID-19, including recordings of previous webinars.

Link: <https://www.fip.org/coronavirus>

## FIP Facebook Group: “COVID-19 & pharmacy”

Link: <https://www.facebook.com/groups/covid19andpharmacy/>



# Announcements

## *FIP Digital Events House Rules*

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1. This webinar is being recorded and live streamed on Facebook
2. The recording will be **freely available** at [www.fip.org/coronavirus](http://www.fip.org/coronavirus) and on our YouTube channel
3. You may ask questions by typing them into the Q&A box
4. Your feedback is welcome ([webinars@fip.org](mailto:webinars@fip.org))

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# Learning Objectives

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1. To outline different regulatory areas which have been adjusted within the covid-19 pandemic
2. To explain how pharmacists have been involved and implemented these new regulations and changes to their practice
3. To identify the roles pharmacists can play in identifying and advocating for improved regulations and policy change
4. To understand the ethical considerations for access to medicines in times of pandemic

# Speaker/panelist 1

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Cody Midlam

Willis Towers Watson

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# Adjusting regulations to meet unprecedented challenges

Key activities from private and public sectors in the U.S. and the global pharmaceutical industry



# Families First Coronavirus Response Act

## *Waive cost sharing*

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- On March 18, U.S. Congress passed the Families First Coronavirus Response Act, which includes provisions requiring health insurers to waive cost-sharing for COVID-19 testing services.
  - The “Families First” Act applies to all health plans in the U.S., but many states have gone farther such as mandating coverage for future vaccines or drug refill requirements.
  - In the U.S. state requirements only apply to certain health plans– they do not apply to self-funded employer health plans, which is where more than 60 percent of people with employer-based coverage are insured.

<https://www.commonwealthfund.org/blog/2020/what-are-state-officials-doing-make-private-health-insurance-work-better-consumers-during>

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# Individual state requirements

## *Waive additional services beyond testing*

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- Several states have issued directives to mandate expanded coverage, including California, Colorado, Maryland, Nevada, Alaska, and New Hampshire.
  - Many of these states are requiring insurers to waive enrollee cost-sharing for COVID-19 testing services, as well as requiring coverage of other services such as a vaccine if developed, early prescription drug refills, and telehealth.
- Massachusetts and New Mexico, meanwhile, have instructed their insurers to cover COVID-19 testing *and* treatment without cost-sharing.

<https://www.commonwealthfund.org/blog/2020/what-are-state-officials-doing-make-private-health-insurance-work-better-consumers-during>

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# Insurer actions

## *Health plans*

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- Insurers waive co-pays (cost sharing for numerous health services):
  - *Diagnostic testing*
  - *Telemedicine visits (for any reason, not only COVID19)*
  - *Behavioral health services (including digital cognitive behavioral therapy apps) dCBT*
  - *In-patient admissions for COVID19 treatment or associated complications*
- Take steps to ensure adequate medicine supply:
  - *Relax refill-to-soon edits (allow members to refill their drug supply earlier than usual)*
  - *Encourage 90 day supplies of medications primarily through mail order pharmacies*
- Prior Authorizations waived for COVID19 related services and patient transfers

<https://www.ahip.org/health-insurance-providers-respond-to-coronavirus-covid-19/>

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# Insurer actions continued

## *Pharmacy benefit managers*

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- Medicines access

- *Refill to soon limits waived and 90 day supplies encouraged*
- *Prior authorizations are extended (typically require renewal at 6 months, 1 year, or 3 years)*
- *Relaxing network requirements (allow members to fill prescriptions at out of network pharmacies)*
- *Offering free delivery of medications*
- *Implement quantity limits of drugs used to treat COVID19 to prevent drug shortages*

# Food and Drug Administration (FDA)

## *Drug approval and emergency use*

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- The Emergency Use Authorization (EUA) authority allows the FDA to protect public health against chemical, biological, radiological, and nuclear (CBRN) threats by facilitating the availability and use of medical counter measures (MCMs) needed during public health emergencies.
- Under EUA, the FDA may allow the use of unapproved devices or drugs to diagnose or treat CBRN threats. To date, EUA has included diagnostic tests, personal protective equipment, ventilators and other medical devices, and these drugs:
  - Hydroxychloroquine and chloroquine (issued March 28, rescinded June 15, 2020)
  - Remdesivir for treatment of hospitalized patients with severe disease (issued May 1, 2020)

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<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#abouteuas>

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# Food and Drug Administration (FDA) continued *Manufacturer inspection and new drug approvals*

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- Effective March 10, 2020 the FDA postponed most foreign inspections through April. Inspections outside the U.S. deemed mission-critical will still be considered on a case-by-case basis.
  - In addition to safety concerns, this also impacts the market entry of new generics
- The week of July 20, 2020, the FDA will resume “prioritized” domestic manufacturing inspections
  - The agency will use their own metrics to determine which facilities are safe enough to enter and will provide advanced notice of inspection (not surprise visits)
  - Some non-U.S. based firms continue to request virtual visits

<https://www.fda.gov/news-events/press-announcements/coronavirus-disease-2019-covid-19-update-foreign-inspections>

<https://www.fiercepharma.com/manufacturing/fda-pledges-to-resume-domestic-inspections-as-u-s-experiences-troubling-uptick-new>

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# Drug Enforcement Agency (DEA)

## *Controlled substances*

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- DEA allows telemedicine practitioners to prescribe controlled substances without face-to-face patient visits – March 20
- DEA increases the aggregate production quotas allowable for controlled substances by 15% - April 7
- Exception to practitioners requiring unique licenses in each state for prescribing, including controlled substances – March 25

<https://www.dea.gov/press-releases/2020/03/20/deas-response-covid-19>

<https://www.dea.gov/press-releases/2020/04/07/dea-takes-additional-steps-allow-increased-production-controlled>

<https://www.deadiversion.usdoj.gov/coronavirus.html>

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# Impact on new drug approvals

## *Clinical trial – slow and fast*

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- More than two-thirds of trials hit by COVID-19 enrollment halts, with midstage tests the worst affected
  - *Nearly 200 companies have stopped or delayed their trials over the pandemic*
  - *Most of the impact has been from patients not being allowed into trials; repurposing investigators and focus to COVID19 has also been an impact*
- Operation Warp Speed aims to deliver 300 M doses of vaccine by 1/2021
  - *Accelerate development, manufacturing, and distribution of COVID19 countermeasures (vaccines, therapeutics, and diagnostics)*
  - *\$2B invested between March and May, 2020 with 14 promising vaccine candidates selected*

<https://www.fiercebiotech.com/biotech/more-than-two-thirds-trials-hit-by-covid-enrollment-halts-midstage-tests-worst-affected>

<https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html>

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# Looking ahead

## *Temporary changes that may become permanent*

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- Many Industry experts believe the major gains in the uptake of telemedicine and digital health care during the past 6 months will be here to stay
  - *Regulatory changes associated with reimbursement and patient adoption may prove to be irreversible trends*
- Members receiving 90 day supplies of medications through the mail may continue these practices as contagion concerns persist
- Clinical trial design and drug discovery may be changed forever
  - *Companies meet on “master trial protocols” with single points of interest, adopt virtual trials, remote monitoring and wearable technologies, and develop flexible endpoints*

<https://www.chemistryworld.com/news/covid-19-is-forcing-pharma-to-rethink-clinical-trials/4012063.article>

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## Speaker 2

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**Peter Guthrey**

Pharmaceutical Society of Australia

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@pguthreyrx



# Australia

A world map with a light gray background and white country outlines. The continent of Australia is highlighted in solid black. A horizontal blue dotted line is positioned above the text boxes on the left side of the map.

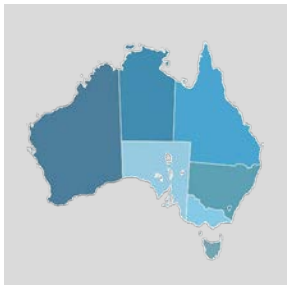
**25 million  
people**

**Island nation**

**8 states & 2 territories**

# Australia

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**States: regulate supply of medicines & fund public hospitals**

**Federal: fund most medicines & primary care**

Co-payment \$A41.50 (gen) & \$A6.60 (pension)

Regulate and fund aged care

Private hospitals mainly elective surgery



Digital image prescriptions

Continued Dispensing

Serious Supply Shortage Notices

Supply limits

Hydroxychloroquine and salbutamol restrictions

Telehealth medicine reviews

Home medicine service [delivery & post]



PSA has prepared this information using the best and most up-to-date information that we have received. This is rapidly and constantly changing. We are in constant contact with both the Australian Government and the State and Territory Governments and will update this information regularly.

Pharmacists are recommended to read this information as a guide only and in conjunction with specific laws in each jurisdiction.

#### On this page

Digital image prescriptions

Paperless transfer of prescriptions from prescribers to pharmacists to support COVID-19 telehealth consultations

Continued dispensing

A 'full supply' of an essential *Prescription Only Medicine* (S4) **without a prescription** in an emergency

Serious Shortage Substitution

Supply of alternative quantity and strength, or dose form of a medicine in shortage

Phone/fax order by prescriber

Urgent prescription ordered via phone/fax followed by hard-copy (known as 'owing prescription')

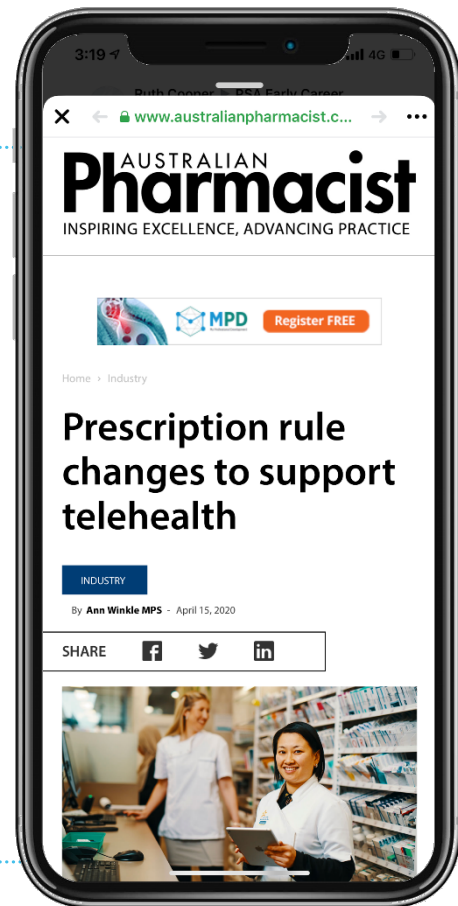
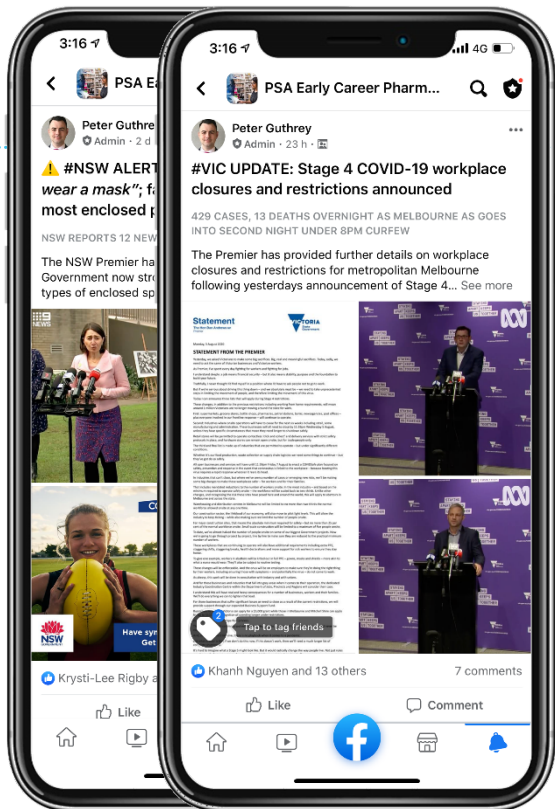
Emergency supply – 3 day rule

Supply of a small quantity of an essential medicine **without a prescription** in an emergency



	Requirement for supply under PBS – Commonwealth legislation	Legality to supply – TAS regulation
Effective to	30 September 2020	30 September 2020
Effective from	20 March 2020	15 April 2020
Prescriber	<ul style="list-style-type: none"> <li>Creates a paper prescription during telehealth consultation, signed as normal or using valid digital signature</li> <li>Provides patient's pharmacy with a digital image of the prescription via <b>fax, email or text message</b></li> <li>Must retain the (original) paper prescription (or a copy) for 2 years from date of prescription unless original prescription.</li> </ul>	<ul style="list-style-type: none"> <li>Must annotate prescription to state that it is a digital image of the prescription</li> <li>Must record (in clinical system) that prescription was issued to a pharmacist as a digital image only</li> <li>Must also record that digital image of the prescription has been sent directly to the pharmacy, noting the particulars of the pharmacy and method of transmission</li> </ul> <p>More information in the fact sheet for prescribers</p>
Pharmacist	<ul style="list-style-type: none"> <li>Can dispense and claim for the PBS item from the image</li> <li>Must print out hardcopy of digital image prescription</li> <li>Must retain the hardcopy for 2 years from date of supply</li> <li>Repeats should be held in the pharmacy</li> </ul>	<ul style="list-style-type: none"> <li>Recommended that pharmacists record in the dispensing system when they have made a supply based on the digital image of a prescription</li> <li><b>Repeats</b> must be retained and supplied at original dispensing pharmacy and may not be returned to the patient or transferred to another pharmacy</li> <li>Same requirements apply for supply of S4 medicines on a digital image of a prescription sent from a prescriber in a hospital</li> </ul> <p>Pharmacists can access additional information in the fact sheet</p>
Eligible medicines	<p><b>Excludes</b> medicines in <b>S8 and S4 + Appendix D</b> in the Poisons Standard*</p> <p><i>*Unless state and territory legislation allows supply via a digital image</i></p>	<p><b>Excludes</b> (i.e. cannot be supplied on a digital image of a prescription) <b>S8s and S4 declared restricted medicines</b> as outlined in the <a href="#">Poisons (Declared Restricted Substances) Order 2017</a></p>
Legislative instrument/s	<ul style="list-style-type: none"> <li><a href="#">National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020</a></li> <li><a href="#">National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Expansion of Telehealth and Telephone Attendances) Special Arrangement 2020</a></li> <li><a href="#">Veterans' Affairs Pharmaceutical Benefits Schemes Amendment (Special Arrangement – COVID-19 Supply of Pharmaceutical Benefits) Determination 2020</a></li> </ul>	<p>Poisons Regulations 2018</p>
Relevant resources	<ul style="list-style-type: none"> <li><a href="#">A guide for pharmacists</a></li> <li><a href="#">A guide for prescribers</a></li> <li><a href="#">A guide for patients</a></li> <li><a href="#">Prescriptions via telehealth – state and territory rules</a></li> </ul>	<ul style="list-style-type: none"> <li><a href="#">Fact sheet and FAQ for pharmacists</a></li> <li><a href="#">Fact sheet and FAQ for prescribers</a></li> </ul>





**Vaccination**

**Infection control**

**Mask and personal  
protective equipment**

**COVIDSafe plans**

**Penalties for abuse of  
health professionals**

**“Self-isolating” people / triage & referral**



## Speaker 3

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### **Carolina Oi Lam UNG**

- Assistant Professor,  
Institute of Chinese Medical Sciences, University of Macau
- Secretary General,  
Pharmaceutical Society of Macau

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# Community pharmacists in Macau: **Quick to action against COVID-19 outbreak**

# Macau and COVID-19

*One of the first areas affected by COVID-19*



 China, Macao SAR

Coronavirus Cases:

**46**  
(44 imported, 2 related)

Deaths:

**0**

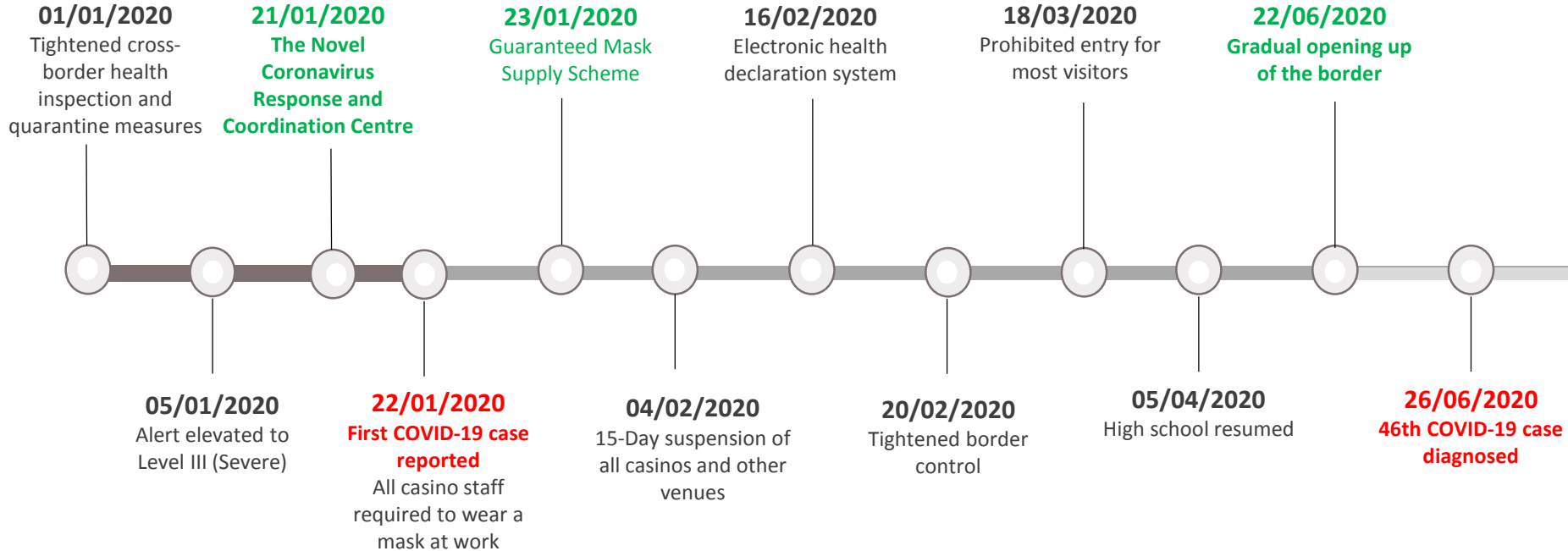
Recovered:

**46**



# Macau and COVID-19

Timeline since 01/01/2020



# Legal powers regarding disease control

## Law No. 2/2004 on the Prevention, Control and Treatment of Infectious Diseases

### Responsibilities and obligations of:

- Government
- Health Authority
- Public sector
- Private sector
- Individuals
- Infected patients

### Major areas of action:

- Keeping the public informed and educated
- Epidemiological surveillance and reporting
- Entering Macau
- Domestic control measures
- Coordinated effort
- **Exemption of diagnostic and treatment fees**
- Civil or criminal liability



The Novel Coronavirus Coordination Center



Stay home/Social distancing



Keeping public informed



COVID-19 nucleic acid test



Health Declaration QR Code



15-day suspension of casinos

# The Novel Coronavirus Response and Coordination Centre

*Established on 21/01/2020*





# Integrating community pharmacy in COVID-19 strategies

## The Guaranteed Mask Supply for Macao Residents Scheme since 23/01/2020



Government-led Top-down Approach



Sourcing/Procurement



Repacking



Central Control IT system



Public Education

- **Accessible** – more than 100 million facemasks sold since 23/01/2020 (as of 13/07/2020)
- **Affordable** – sold at < USD 0.10 each
- **Appropriate and correct use of masks** – education by pharmacists

### Special webpage against Epidemics

#### Guaranteed Mask Supply for Macao Residents Scheme

Guaranteed Mask Supply for Macao Residents Schemes  
convencionais  
Details of contracted sale locations

Update time: every 15 minutes.

Note: The public are reminded to examine the masks at time of purchase.

Contracted pharmacies	Health centers	Institution
<b>Pharmacy Name</b>		
<b>POPULAR (FONTE)</b>		
Largo do Senado n.º16-A, r/c e 1º Andar e Travessa da Misericórdia n.º3, r/c com Sobrelaja, Macau		
Tel: 28566568, 28573739		
Fax: 28517939		
2.* feira - 6.* feira : 10:00 - 19:00		
Sábado, Domingo e Feriado : 10:00 - 19:00		
Observações: Temporariamente encerrado, a partir de 20 a 27 de Fevereiro de 2020		
Stock of masks: 18988		
<b>LAP KEI</b>		
Calçada do Gaio n.º3-C, Tong Hei C, r/c com Cave, Macau		
Tel: 28590042		
Fax: 28385581		
2 afeira - 6 afeira : 9:00 - 20:00		
Sábado : 9:00- 17:00		
Descanso no Domingo		
Stock of masks: 22354		



藥房的藥房其實大部分都會休息



他們有沒有接觸過病人或密切接觸者

# Community pharmacists in action

## Other key areas

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### 1. Information Hub

- Address the public enquires with **up-to-date information** about COVID-19 and government policies.
- Build **trustful relationships** with customers/patients
- Provide assurance to **reduce panic** due to miscommunication

### 2. Continuity of medicine supply and patient care

- Secure **sustainable supply** of medicines and related health products at **reasonable prices**
- **Redirect patients from hospital setting** to fill their prescriptions at community health centers
- **Home medication delivery** and other ad hoc services

### 3. Educating about personal and environment hygiene

- **Safe and ethical care** to the public at all times
- **Infection prevention and control practices** at the pharmacy
- Education about **hand and environment hygiene**, and other preventative measures

### 4. Active surveillance of suspected cases

- Stepping up the **respiratory-disease-surveillance system**
- **Early detection** and referral of suspected cases
- Screen patients for any necessary **referral**

# Enablers for community pharmacy participation

*Important factors in the decision-making process*

## Community Pharmacy Workforce

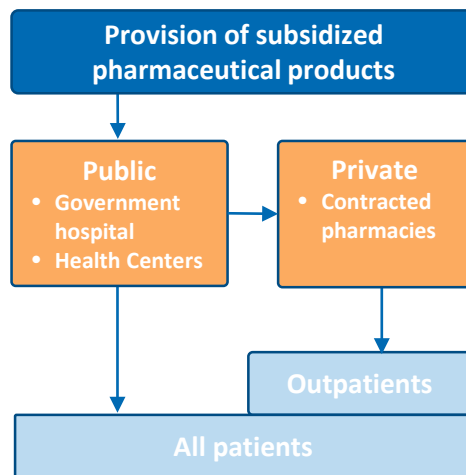
### Sufficient pharmacy workforce

- 368 of 520 practicing registered pharmacists working at 296 community pharmacies
- 82 registered pharmacist/100,000 population (OECD average 80 /100,000 population)
- 2-tiered pharmacy workforce: pharmacist and pharmacy technician

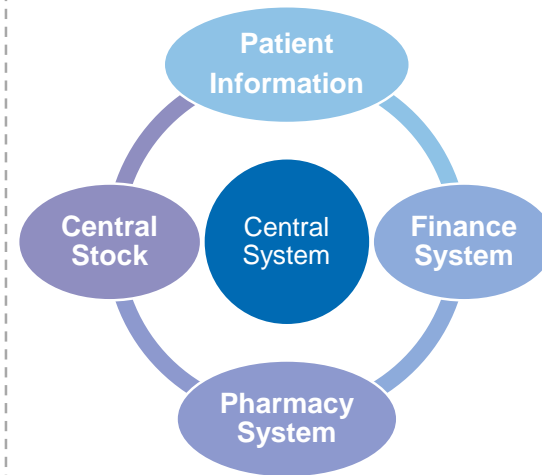
### High pharmacy/population density

- 46.9 community pharmacies/100,000 population (OECD average 25.1/100,000 population)

## Public-Private Partnership



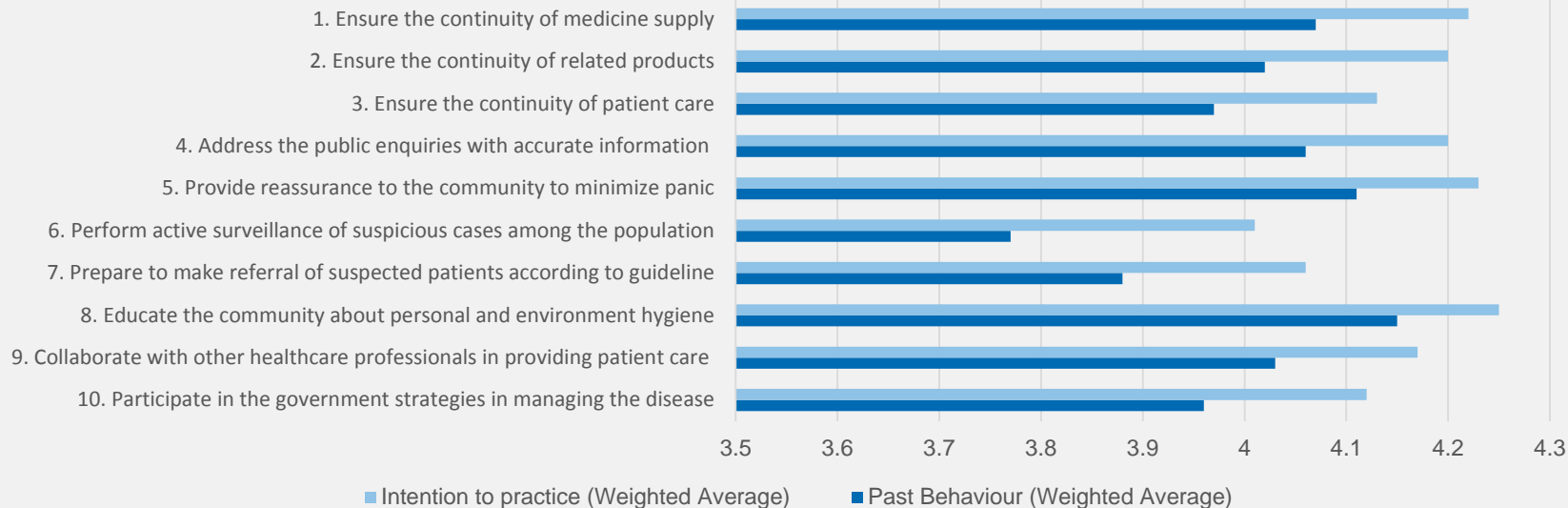
## Information Technology



# Assessing pharmacist's intention to practice

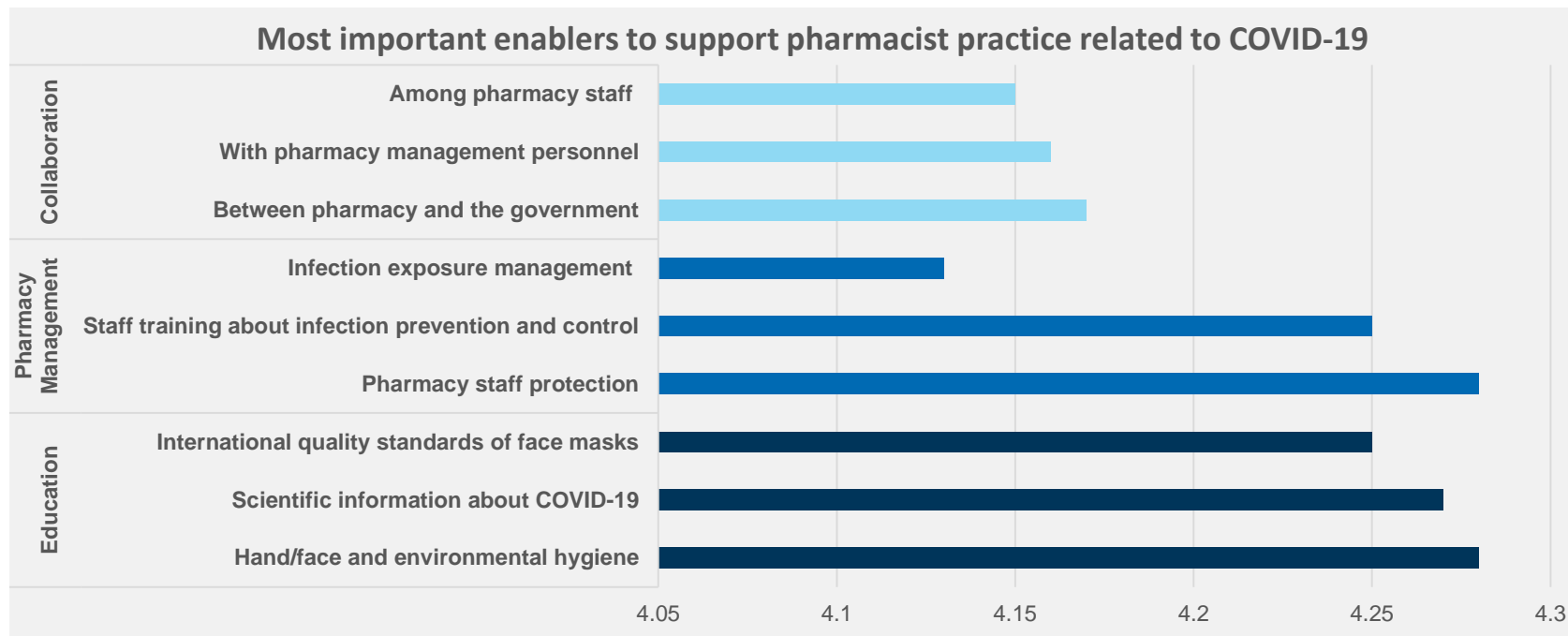
*A pharmacist survey study since May 2020 (n=260)*

## Comparison between past behavior and intention to practice related to COVID-19



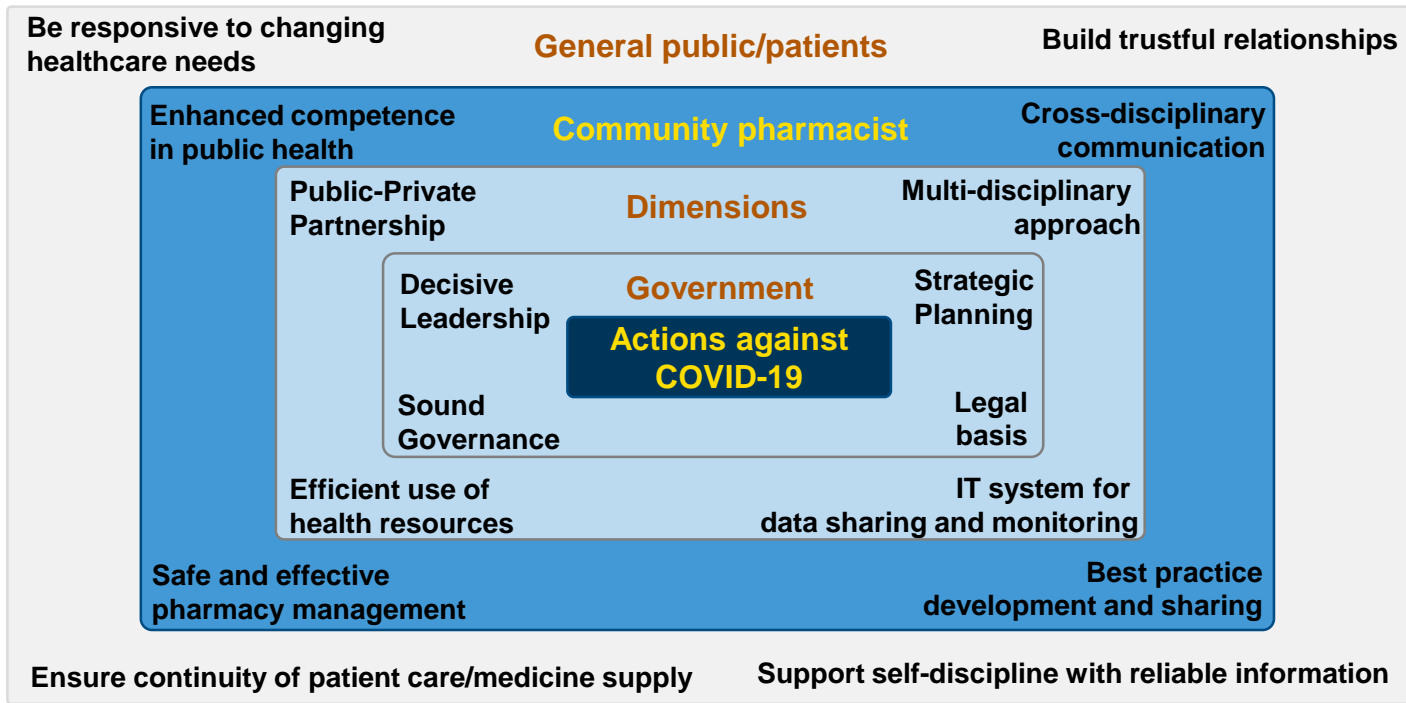
# Assessing pharmacist's intention to practice

*A pharmacist survey study since May 2020 (n=260)*



# Community pharmacist in the COVID-19 paradigm

*Well-positioned to bridge between the government and the public*



# Challenges and Opportunities in the New Norm

*The way forward for community pharmacists and policy-makers...*

**Enhanced capacity of  
public health services  
to enable emergency response**

Focus of pharmacy practice	Products → services → patients → community + visitors
Potentials of pharmacists	Being integrated → becoming more proactive
Role in disease management	Chronic disease management → public health
Mode of service delivery	Face-to-face → new technologies
Values in the community	Scattered points of care → reliable community network

# A/Professor Betty B. Chaar


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Experienced in Community Pharmacy, Hospital Pharmacy, the Pharmaceutical Industry and as an Academic Pharmacist.

*Current Chair of FIP Ethics Group and Program committee of FIP*







**Repurposing and  
access to medicines  
in COVID 19 -  
*Ethical  
Considerations***

A/Professor Betty Char  
School of Pharmacy-The University of Sydney

# FOUR PILLARS OF BIOETHICS

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RESPECT FOR AUTONOMY

TO DO GOOD  
(BENEFACTENCE)

TO DO NO HARM (NON-  
MALEFACTENCE)

JUSTICE



# Hypothetical

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**Let's imagine... a new  
medicine to treat  
Coronavirus is finally  
found and is in its Phase  
III with promising results  
so far...**

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**And let's estimate the cost .....**

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**Turns out it's just starting to be manufactured, and there's not much stock in hand.**

**This new treatment is priced at \$US1,000 per day and stocks are running out fast. The Head of State of the country announced he has placed orders for the next 6 months of all the medicines being manufactured.**

**Insurance companies not yet decided on whether to cover or not – they suggest trying Hydroxyquinine or Dexamethasone +/- a concoction of herbal products [garlic+ onion+ ginger+ ginko+ lemon) boiled and made into a 'healthy' soup**

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# *How many ethical issues are loaded in this hypothetical scenario?*

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Ethical research – *how do we know?*

What about off-label use of medicines? and alternative medicines? – is there evidence?

Medicines shortages: What if there is simply not enough to go around?

Equitable access and affordability – *who gets the treatment first?*

Universal cover – *is this the silver bullet?*

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## ***What is Ethical Research?***

- No coercion
- No pressure from Big Pharma or granting bodies or government
- Evidence based premise [based on existing literature]
- No harm inflicted on anyone
- No conflict of interest

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## ***And what about “off-label” prescribing, including complementary medicines?***

- Doctors do have the right to prescribe off-label.
- Scrutiny by pharmacists is imperative.
- Check the evidence upon which the doctor has relied on to prescribe.
- Make your own decision as a pharmacist – do not succumb to pressure or hear-say.
- Communicate clearly and meaningfully to patients
- Leave the final decision to the patient [respect autonomy].



# ***Medicines shortages: What if there is simply not enough of this new treatment to go around?***

- If supply is indeed limited, should healthcare decisions be left to politicians?
- In a pandemic, is the whole world eligible to share the findings or restrict access to the country the treatment was found and trialled in? Do patent rules still apply?
- Leaders in healthcare professions should have the moral courage to stand up and voice dissent if necessary (and safe to do so)
- How do we adapt to supply in times of shortage?
- It is important to reflect on the values which set aside the professional from the trader or even the politician.
- If prioritising is absolutely needed, clarify your process of thinking, decisions and be prepared to justify them.

Equitable access  
and affordability –  
*who gets the  
treatment first?*

- Again, should healthcare decisions be left to politicians or Big Pharma?

- Power imbalance between these powers and the consumer is huge

However....

- Moral courage and the role of healthcare providers is crucial in this pandemic.  
Universal healthcare cover should be a norm across the globe.

- At local level (in hospitals and community pharmacies)– what criteria should we use to prioritise?

- You need to specify, communicate clearly and adhere to your own criteria.

Random choices could cost you your reputation.

## ***Summary of discussion points***

- Activate your own clinical judgement in cases of off-label and complementary medicines requests in the pharmacy
- Reflect on your professional values and create your own criteria or rubric to enable fair prioritisation if there is a shortage of treatment or vaccine
- Support our professional leaders when they voice values of healthcare professions and advocate for justice of distribution and Universal healthcare cover.
- Communicate clearly with patients your justification for recommendation/s or choices in prioritising access to medicines in shortage.

....AND REMEMBER

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JUSTICE – FAIR ACCESS TO MEDICINES IS A  
HUMAN RIGHT.

THE ROLE OF HEALTHCARE PROFESSIONALS IS  
TREMENDOUS.

MAKE SURE WE ALL DO OUR PART AND NOT JUST  
BE BYSTANDERS

# Question Time

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*Please use the chat board to log your questions & comments.*

*Today's question(s):*

**1. Do you think short term policy changes to improve medical and pharmacy access will become permanent?**

# Question Time

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*Please use the chat board to log your questions & comments.*

*Today's question(s):*

- 1. What have been some of the challenges in implementing these changes?**
- 2. Which of these changes do we want to see long term?**

# Question Time

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*Please use the chat board to log your questions & comments.*

*Today's question(s):*

**1. *What would be the challenges for such a small-scale health system like Macau in the combat of COVID-19 pandemic?***

**2. *How would community pharmacists contribute to the exit strategy to cope with the long term impact of COVID-19 pandemic?***

# Question Time

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*Please use the chat board to log your questions & comments.*

*Today's question(s):*

- 1. What kind of patency laws do you anticipate would work for a pandemic? E.g. Can exclusions be enforced in a pandemic?***
  
- 2. What can we do for those who miss out for either affordability or other reasons e.g. not enough to go around?***



# FIP VIRTUAL 2020

4 - 25 September 2020

## Living and learning through the COVID-19 pandemic – Global reflections

For more information and registration: [virtual2020.fip.org](https://virtual2020.fip.org)

“One FIP” means  
trust, solidarity and action!



**FIP**  
**VIRTUAL 2020**  
SEPTEMBER





The background features a blue-toned graphic of a hand holding a pen, poised to write on a document. A magnifying glass is positioned over the document, highlighting a specific area. The entire scene is set against a blue background with a fine grid pattern and diagonal light streaks.

# Thank you for participating!

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Please provide your feedback through the 4-question survey that will appear to you at the end of the event