



# Learning from COVID-19 Pandemic The Hungarian Experience

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# Covid in Hungary

Total infected: 2M (21%)

Death toll: 47k (2% of infected)

Vaccination:

- Comirnaty (Pfizer)
- Vaxzevria (AstraZeneca)
- Spikevax (Moderna)
- *Sputnik-V (Gameleya)*
- *VeroCell (Sinopharm)*
- Jcovden (Janssen)

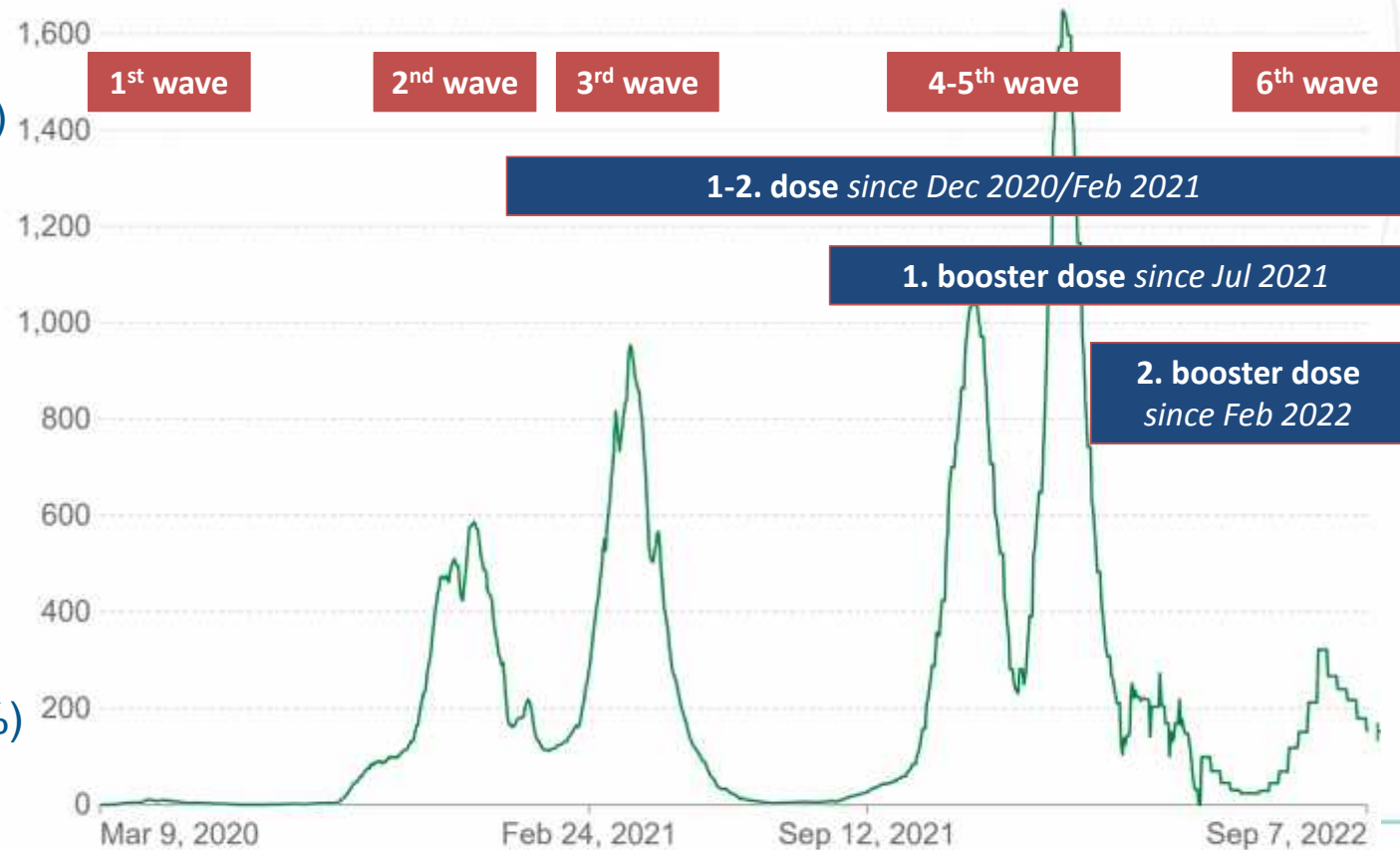
Vaccination rate:

1. dose: 6.4 M (66%)

2. dose: 6.2 M (64%)

3. dose (1.booster): 4.2 M (44%)

4. dose (2.booster): 339k (4%)



Source: Johns Hopkins University CSSE COVID-19 Data

# Emergency Use Authorisation of Vaccines (EU)

- Pfizer approval: 21 December 2020
  - Conditional marketing authorisation
  - In the interest of public health, unmet medical need
  - Favorable risk/benefit ratio (rolling review)
  - 12-16 yr old adolescents: June 2021
  - 5-11 yr old children: August 2022
- Moderna approval: 6 January 2021
- AstraZeneca approval: 29 January 2021
- Janssen approval: 11 March 2021
- Novavax approval: 20 December 2021



# Emergency Use Authorisation of Vaccines (HU)

- Sputnik-V approval: 20 January 2021
  - Provisional Market Authorisation (Import, Usage)
  - Based on a State of Emergency legislation
  - Favorable risk/benefit ratio (rolling review)
  - National Public Health Centre performed lab tests
- Sinopharm approval: 29 January 2021
  - Provisional Market Authorisation (Import, Usage)
  - Based on a State of Emergency legislation
  - More than 1M people have been vaccinated
  - EU candidate state approved it
  - National Public Health Centre performed lab tests



# Legislation changes

## Compassionate Use

- if high medical need: it can be granted for a group of patients
- can be submitted by the sponsor
- no need to provide (Investigational) Drug for free
- remdesivir, bamlanivimab

## Off-label Use

- if high medical need: it can be approved for a group of patients
- professional Cabinet should approve it
- pharmacovigilance follow-up
- favipiravir

# Legislation changes

## Drug Shortages

- Competent Authority can set up a shortage situation
- Case by case Import approval, Contingent approval can be granted
- Emergency Approval can be granted
- remdesivir, hydroxychloroquine

## Export restrictions

- Export of drugs for use in Hungary can be limited
- Parallel export stopped
- Close collaboration between Police, Customs and Drug Authority
- ICU drugs, narcotics, hydroxychloroquine

# Other tasks

## Medical Devices

- Increased amount of falsification
- Customs administration (face masks, Covid tests)
- Accelerated registration of new respiratory aids
- Proceedings against MDs claimed to have anti-Covid effect

## Laboratory investigations

- Amount and purity of active ingredients
- Mass sepctrophotometry
- Liquid chromatography
- Size and weight of tablets
- Breaking strength
- Favipiravir

## Last, but not least

- Hungary is pride: Katalin Karikó's fantastic, world famous invention: the mRNA-vaccines





# Thank you for your attention!

