



EVENTS

MMA Virtual Stakeholders Meeting 2020

Amid previous national restrictions to hold crowded events due to the novel coronavirus disease 2019 (COVID-19) predicament, the Malta Medicines Authority (MMA) organised its 2020 stakeholders meeting on Thursday 28 May 2020 in the format of a virtual discussion forum with the theme 'Addressing the COVID-19 pandemic'. Supply chain stakeholders, chamber representatives, public authority officials and healthcare organisations registered for the meeting and contributed towards a healthy exchange with the Management team of the Authority.

Several pharmaceutical areas of topical interest were discussed that include state-of-play, challenges and outlook of the COVID-19 situation, the prospect of regulating digital platforms of licensed community pharmacies for domiciliary service and the implications of e-prescribing and repeat dispensing.

MMA Virtual Staff Meeting

The Chairperson of the Authority presented and provided insights on specific thematic areas empowering members of the Authority to act as catalysts in transforming the MMA into an innovative and resilient organisation in the post-COVID era.

The following were some of the themes discussed:

- Changing resistance to initiative
- Removing insularity
- Improvisation
- Managing logistics
- Crisis management

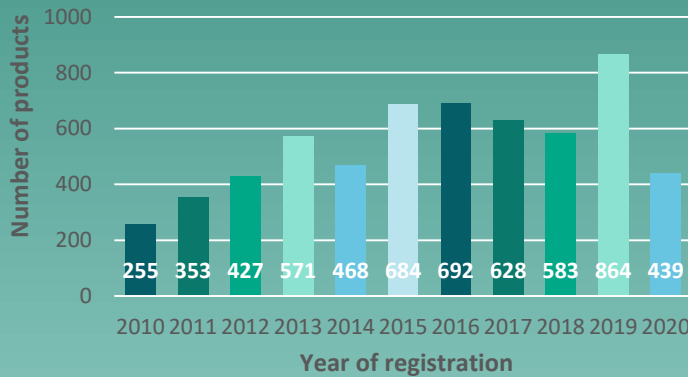
"We are in this together, and we will get through this, together!"

- UN Secretary-General, Antonio Guterres



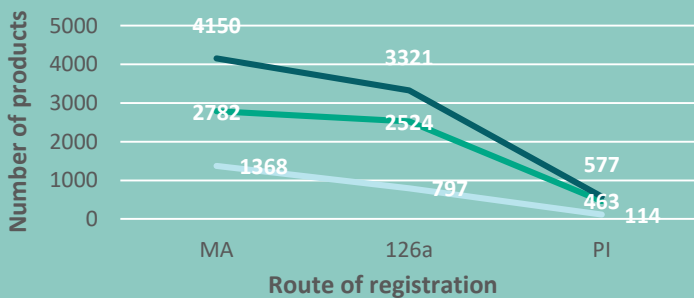
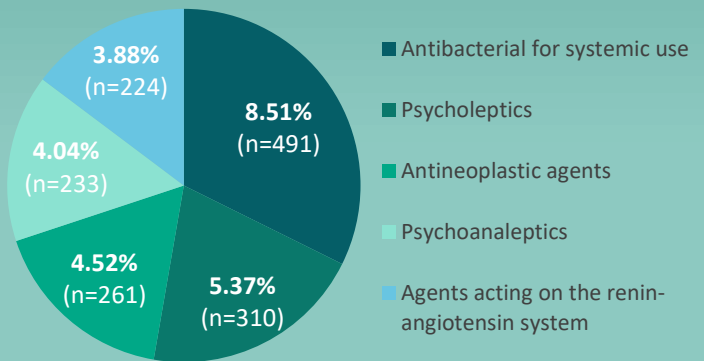
Malta Medicines Authority Licensing Directorate Key Figures

May-2020



**Medicinal products registered
January 2010 - May 2020**

**Most common ATC
classifications for
authorised/licensed medicinal
products at May 2020
(N=5,769)**



**Total number of medicinal
products authorised/licensed
(N=5,769) and
withdrawn/suspended
(N=2,279) at May 2020 by
route of registration**

— Authorised — Suspended/Withdrawn — Total processed

Health and Safety Measures Implemented at the Malta Medicines Authority to Mitigate the Risk of COVID-19 Transmission

Offices and shared spaces

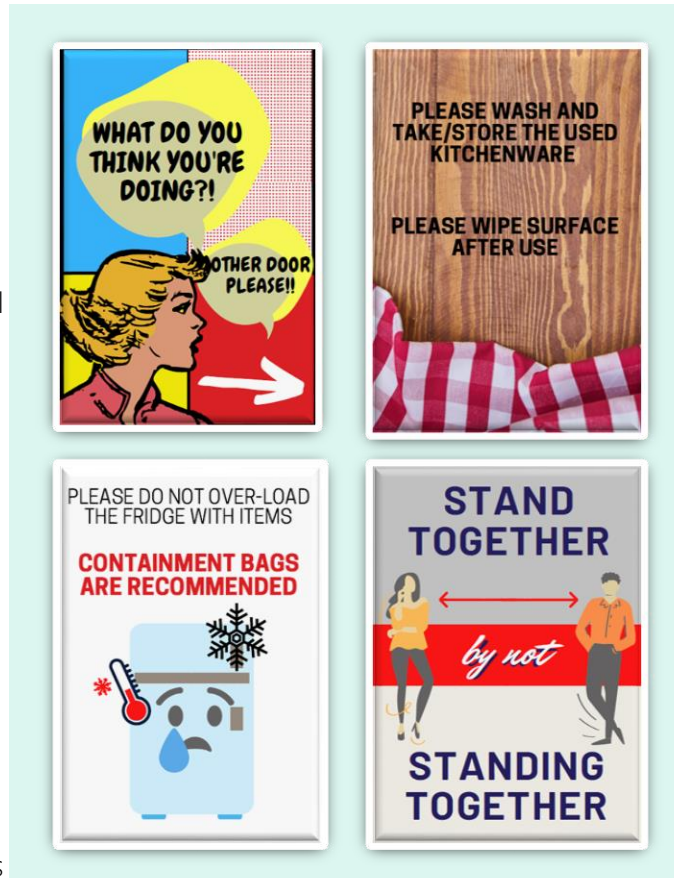
- Desk separators were installed to allow staff to work closely without the risk of cross contamination.
- Unidirectional movement in large open plan offices with 2 or more doors implemented to support social distancing in walkways and to create circulation within the workspace.
- All office doors are being kept open at all times.
- The number of staff in the office at any one time is being kept to a minimum by allowing shift patterns and part remote working.
- High traffic contact zones are being thoroughly cleaned throughout the day
- Signs and posters are used to build awareness regarding the importance of wearing masks, practising social distancing and preference for eating meals outdoors.
- Workers are encouraged to wash their hands.
- Sanitisers are provided to practice good personal hygiene with special attention to hand hygiene.
- Shared spaces, including kitchenettes and restrooms are cleaned every hour during office hours.
- Automated hand sanitiser dispensers will be installed.

Kitchenettes

- Tea towels were replaced with a disposable centrefeed roll.
- Kitchen rules were introduced: one person at a time to enter the kitchen area, surfaces are to be wiped with disinfectant spray after use and kitchenware are to be appropriately washed and stored.
- Cooler bags have been recommended to store food items.
- Disinfectant spray has been made available in kitchen to wipe surface after use.
- Kitchen sink mixers will be changed to automated.

Restrooms

- New sink mixers were installed with automated sensors to avoid unnecessary contact with surfaces.
- Sanitising liquid hand soap was provided in all restrooms to promote optimal hygiene practices and hand washing technique posters were affixed next to each sink.
- Single sheet paper dispensers replaced the previous paper rolls.
- Hand dryers were deactivated.
- Automated contactless hand towel dispensers will replace the C-fold hand towel dispensers.



Other Measures

- A Fumigation process is being carried out on a weekly basis for all areas of the MMA premises.
- Extractors are being cleaned on a weekly basis and the HVAC system is presently set on non-recirculation mode, that is, 100% fresh air.
- Cleaning logs were put up in all restrooms and kitchenettes which are cleaned every one hour.
- Vehicles have been equipped with: disinfection products, paper towels and waste bags.
- Vehicles are being cleaned and sanitised weekly.
- Recommendations were made to hold meetings via video conferencing or phone call, wherever possible.

DID YOU KNOW?

Fun Fact!

The human brain, when awake, produces enough electricity to power a 40 watt lightbulb for 24 hours.

Don't underestimate your neurons!



Image source: <https://www.ideastream.org/news/ohio-receives-limited-amount-of-promising-covid-19-drug-remdesivir>

First COVID-19 treatment in the EU

The spread of the COVID-19 affected 194 countries around the world. The COVID-19, categorised as pandemic disease by the World Health Organisation (WHO), became a prime emergency, resulting in 9,400,295 cases and 4,382,468 deaths as of 25 June 2020 (European Centre for Disease Prevention and Control, 2020)¹. The development of a vaccine for infection prevention and the discovery of a treatment have become a priority to reduce the spreading and mortality of the disease.

The European Medicines Agency (EMA) has been working to expedite development and approval processes of treatments and vaccines while maintaining the quality, safety and efficacy standards. An application for the granting of a conditional marketing authorisation (CMA) has been submitted and evaluated for the antiviral drug remdesivir, a viral RNA polymerase inhibitor.²

This follows a proactive rolling review³ of preliminary data from several clinical studies and compassionate use programmes by the EMA scientific committees and working parties. The review was triggered following promising results for remdesivir obtained in the *Adaptive COVID-19 Treatment Trial* (ACTT). The study reported improved respiratory function and reduced time for recovery in patients treated with remdesivir in comparison to placebo.

The CHMP has issued a positive opinion for a CMA for remdesivir (Veklury®) for the treatment of COVID-19 in adults and adolescents from 12 years of age with pneumonia who require supplemental oxygen.⁴ The treatment should start with a 200-mg infusion on the first day, followed by 100-mg daily for 4 to 9 days, under close patient monitoring.

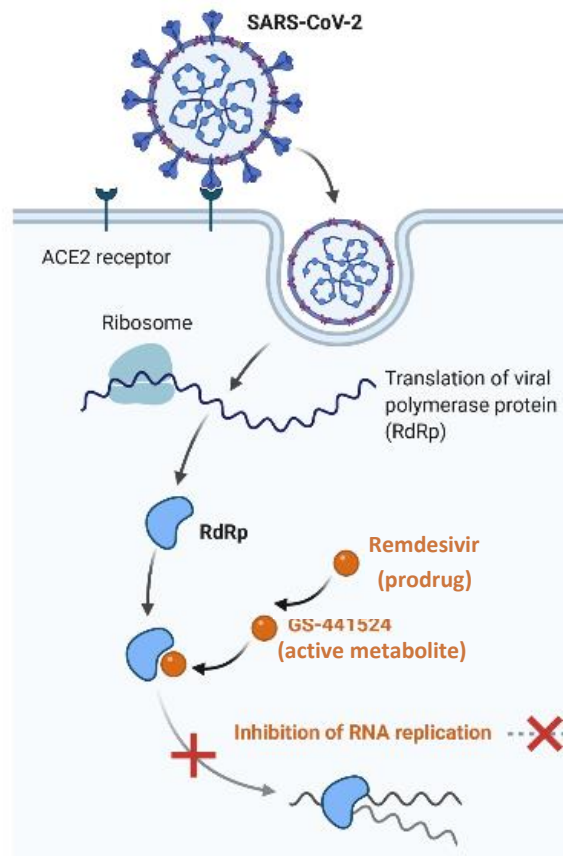


Image source: <https://microbenotes.com/remdesivir/>

Acronyms: Angiotensin-converting enzyme 2 (ACE2); RNA-dependent RNA polymerase (RdRp); Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

References:

1. Boopathi S, Pomo AB and Kolandalvel P.. Journal of Biomolecular Structure and Dynamics, Novel 2019 coronavirus structure, mechanism of action, antiviral drug promises and rule out against its treatment. 2020;1-10. PMID: 32306836.
2. European Medicines Agency. EMA receives application for conditional authorisation of first COVID-19 treatment in the EU. [cited 30 June 2020]. Available from: <https://www.ema.europa.eu/en/news/ema-receives-application-conditional-authorisation-first-covid-19-treatment-eu>
3. European Medicines Agency. EMA starts rolling review of remdesivir for COVID-19. [cited 30 June 2020]. Available from: <https://www.ema.europa.eu/en/news/ema-starts-rolling-review-remdesivir-covid-19>
4. European Medicines Agency. First COVID-19 treatment for EU authorisation. [cited 30 June 2020]. Available from: <https://www.ema.europa.eu/en/news/first-covid-19-treatment-recommended-eu-authorisation>