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Living with COVID-19: six months since the start of the pandemic

IQVIA Australia & New Zealand

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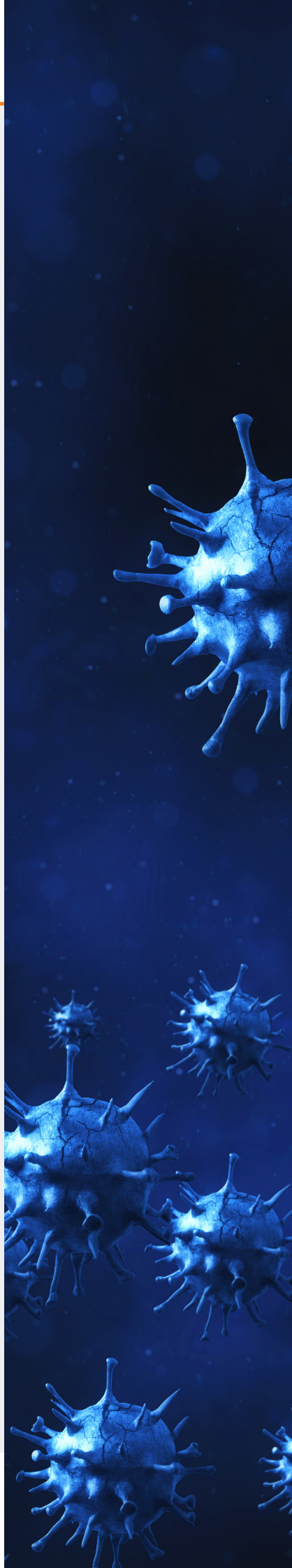
Background

Whilst Australia was initially credited for its successful response to the first outbreak of COVID-19 cases in March 2020, the surge in a second wave of infections from July, driven by alarming rates of community transmission, has highlighted the fragility of the control that had been achieved. It is clear that the pandemic will continue to dictate many aspects of daily life for the foreseeable future, until an effective treatment or vaccine can be made available on a large scale. Hence, the impacts for the healthcare system, the economy and for society as a whole, are likely to be deeper and longer lasting than initially hoped.

IQVIA's second report in a special white paper series provides a longitudinal update on the impact of COVID-19 on the Australian healthcare industry, six months since the start of the pandemic. The analysis and perspectives leverage IQVIA data assets and analytic expertise, as well as primary research with healthcare professionals and industry experts.

It provides a detailed focus on:

1. Demand for prescription medicines and the impact on critical therapeutic areas
2. Evolution in the consumption of non-prescription health products including export and e-commerce trends
3. Impact of COVID-19 on pharmaceutical promotional deployment and the evolving needs of healthcare professionals
4. Outlook for clinical development and impacts for clinical research operations and evidence generation



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- Overall demand for prescription medications remains suppressed in early August, raising the question of whether this trend can be expected to stabilise, or whether shifting dynamics triggered by the pandemic will lead to a longer-term decline.
- Demand for respiratory medications remains elevated in August, driven by an influx in asthma patients and the second wave of infections in Victoria.
- Significant increases have been reported in mental health presentations in primary care, as well as higher use of antidepressants and new initiations for antipsychotics. However, a decline in new starts to anxiolytic medications suggests some patients may be missing out on necessary treatment.
- Mounting evidence suggests significant delays to the diagnosis and treatment of cancer patients are taking place in Australia, raising concerns over longer term patient outcomes.

Consumer Health

- Since the peak in consumer health product sales in Australian retail pharmacies in March 2020, sales have been consistently below the same period in 2019. Significant sales losses have been observed between April – June, which now outweigh the higher sales which occurred in March.
- Factors which have likely contributed to this slump include extensive stockpiling of products which were not consumed, reduced transmission of traditional winter illnesses such as influenza due to social distancing, improved hygiene standards and vaccination rates, and reduced willingness to spend due to increased economic uncertainty.

Promotional Deployment

- Pharmaceutical companies have been forced to pivot rapidly to remote engagement strategies post COVID-19 lockdown, with 90% of detailing conducted remotely by April 2020.
- General practitioners indicate email as their preferred communication channel with the industry throughout the pandemic, with lower but growing interest in remote detailing technologies.
- Whilst some early feedback is positive, more time and experience are required to determine the most appropriate and effective use of remote detailing technologies.

Outlook for Clinical Development and Impacts on Operations and Evidence Generation

- Unprecedented acceleration in clinical development timelines has been achieved, with multiple vaccine candidates publishing positive phase 1/2 trial results, and two therapeutics already shown to be effective against COVID-19 in randomised controlled trials
- Virtual trial processes have proven critical to maintaining continuity in clinical research throughout the pandemic, to overcome recruitment challenges whilst also driving a shift towards a more patient-centric model for clinical research.
- The pandemic has highlighted an increased need for real-world data, both to generate timely insights to inform critical decisions, as well as to fill data gaps in randomised controlled trials caused by COVID-19 disruption.

Introduction

Global outlook

As of 11th August 2020, more than 19.9 million COVID-19 cases have been reported worldwide, with more than 732,000 deaths recorded. Global infections are now consistently above 250,000 cases per day. During March and early April, Europe accounted for the majority of new cases, however, the Americas and Asia are currently the regions reporting the highest daily cases, with the United States and Brazil the two worst-affected countries, followed by India[1].

Despite effective suppression of COVID-19 by mid-2020 in many European countries, smaller second waves of infection have begun to emerge, most acutely in France and Spain, but to a lesser degree in Germany and the United Kingdom. Likewise, some countries which successfully supressed their outbreaks of COVID-19 by May, such as Japan and Israel, are in the midst of larger second waves of infection and are reporting higher daily case numbers than in their initial outbreaks.

COVID-19 in Australia and New Zealand

Travel restrictions and social distancing imposed by the Australian and New Zealand governments in March and April achieved early success in disrupting COVID-19 transmission and eliminating community spread. In New Zealand, social distancing measures were relaxed in June[2], however, after 102 days without a case of COVID-19, a family cluster of four cases was reported in New Zealand in mid-August . With no links to overseas travel, imported refrigerated freight is being investigated as a potential conduit for transmission[3]. In response, the New Zealand government has reimposed lockdown restrictions in Auckland as well as lesser restrictions on mass gatherings in the remainder of the country[4].

Australia's COVID-19 situation remains precarious. A major outbreak in Victoria has resulted in a second wave of over 13,531 cases and 250 deaths since 15th June (Figure 1).

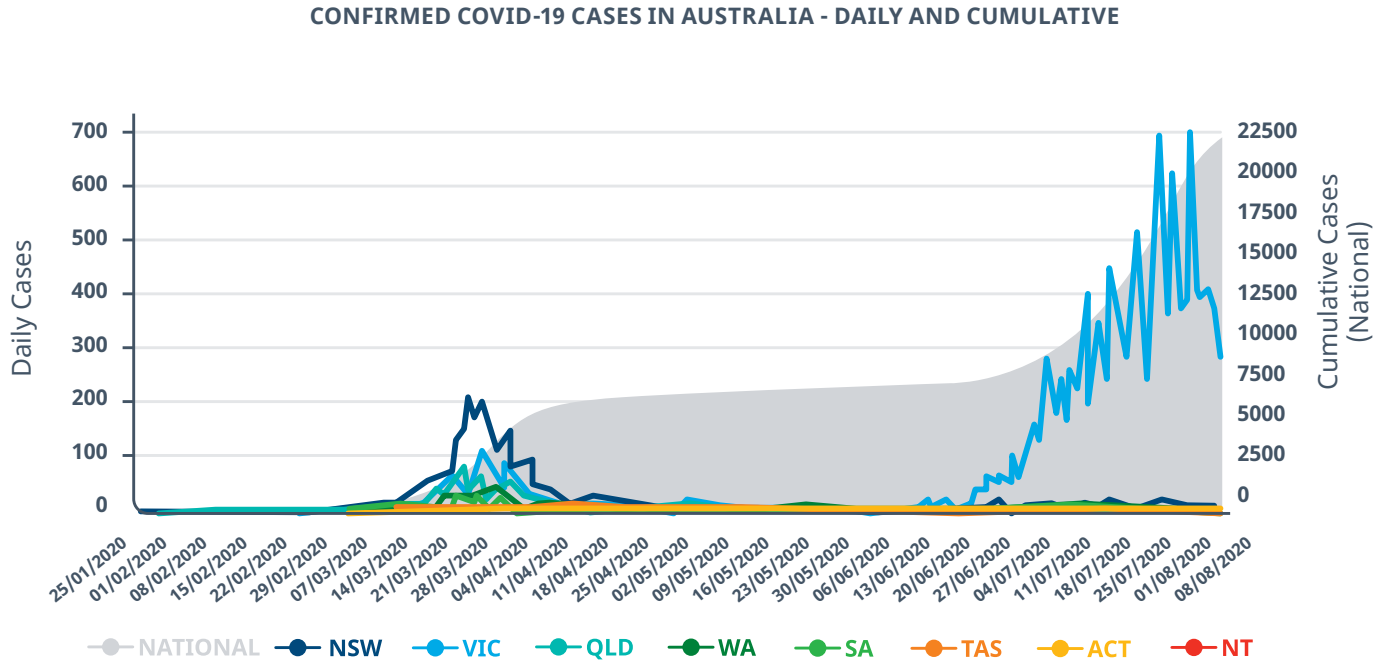
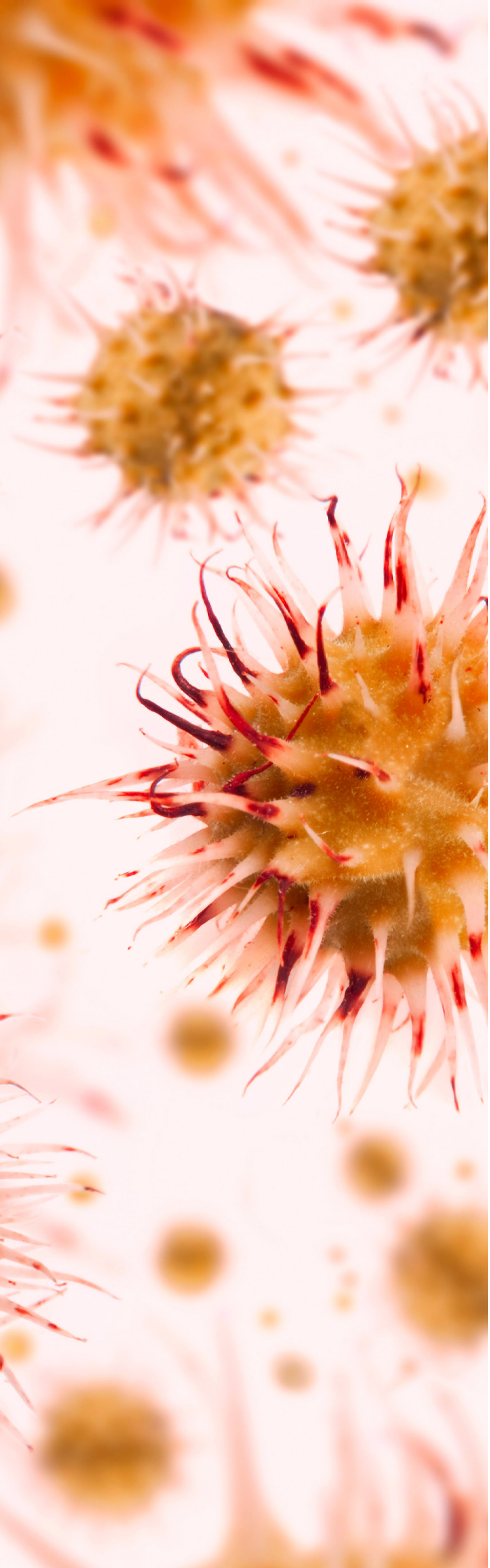


Figure 1: Daily and cumulative confirmed COVID-19 cases in Australia.

Source: NSW Health, Victoria Health, Queensland Health, WA Department of Health, SA Health, ACT Health Directorate, NT Government; 11th August, 2020.



Victoria's second wave of cases has been almost twice as many as all cases in Australia prior to 14th June (7,318). Interstate travel from Victoria has also led to clusters of COVID-19 in New South Wales[5] and Queensland[6]. This dissemination of infection has the potential to trigger a second wave of uncontrolled disease in these states. At the time of publication, the remaining states and territories do not have evidence of community-transmission of COVID-19.

While Australia's case numbers and fatalities remain low by global standards, the recent outbreak in Victoria highlights the fragility of the control which has been achieved, and the challenges which will come with easing restrictions further. The prospect of a second wave of COVID-19 spreading across the country, and the impact of the prolonged restrictions in Victoria, perhaps with other states perhaps to follow, highlights the ongoing nature of the health and economic crisis. With international borders expected to remain closed for the remainder of 2020, the extent of the economic impact on Australia, and Victoria, is becoming ever-more severe.

Impact on Prescription Demand and Clinicians' Perspectives

This section explores the ongoing impact of COVID-19 on the prescription landscape, six months on from the initial coronavirus outbreak in Australia. Insights are based on IQVIA's Longitudinal Dispensed Dataset which tracks scripts through community pharmacies across Australia, and on surveys conducted with targeted clinician groups, general practitioners (n=200), medical oncologists (n=30) and psychiatrists (n=30) in July 2020. Included is a focus on the impacts of the pandemic on treatment for respiratory conditions, cancer and mental health.

KEY INSIGHTS:

Overall demand for prescription medications remains suppressed in early August, raising the question of whether this trend can be expected to stabilise, or whether shifting dynamics triggered by the pandemic will lead to a longer-term decline.

Demand for respiratory medications remains elevated in August, driven by an influx in asthma patients and the second wave of infections in Victoria.

Significant increases have been reported in mental health presentations in primary care, as well as higher use of antidepressants and new initiations for antipsychotics. However, a decline in new starts to anxiolytic medications suggests some patients may be missing out on necessary treatment.

Mounting evidence suggests significant delays to the diagnosis and treatment of cancer patients are taking place in Australia, raising concerns over longer term patient outcomes.

Prescription Demand Overview

The initial wave of COVID-19 infection in Australia in March 2020 led to a surge in prescription demand, driven primarily by a rush to dispense chronic medications, particularly cardiovascular, respiratory and diabetes treatments, ahead of the first national lockdown. This demand surge was short-lived, in part due to dispensing restrictions introduced by the Commonwealth Department of Health, the Pharmacy Guild and Pharmacy Society of Australia on 19th March[7], which limited dispensations to a single pack or single month of supply for many prescription and selected over-the-counter medications. As illustrated in Figure 2, the initial peak was followed by a dip in dispensations in April, where demand dropped to 18% below the 2019 average, and as of early August overall weekly dispensation volume remains below 2019 levels by approximately 4%.

The resurgence of infections and the re-introduction of lockdown in Victoria has not, to date, resulted in a second spike in prescription demand. However, an upturn in dispensations was recorded in week commencing 6th July, as illustrated in Figure 3, drawing demand levels even with 2019 values, whilst a clear gap remains in other states.

Analysis of dispensed volume on a year-to-date (YTD) basis for the last two years, in Figure 4 below, reveals that during the week commencing 23rd March, prescription demand reached 9.3% above the same period in 2019. Based on the latest available data from the week commencing 3rd August, the YTD difference has declined to +0.4%, suggesting that weekly dispensed volumes may be expected to shortly return to 2019 levels, as excess medications stockpiled in March are likely to have been consumed.

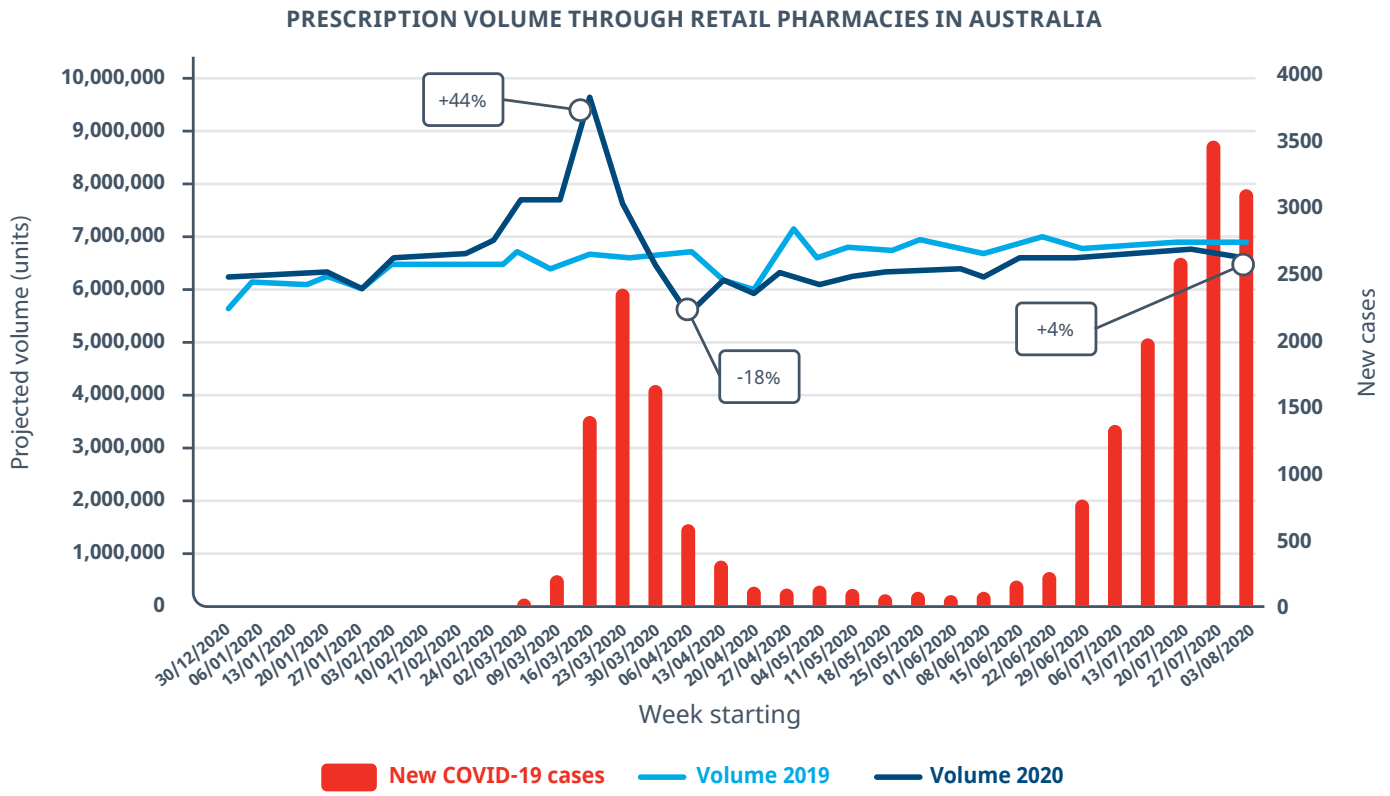


Figure 2: Prescription volume through retail pharmacies in Australia

Source: IQVIA longitudinal dispensed data.

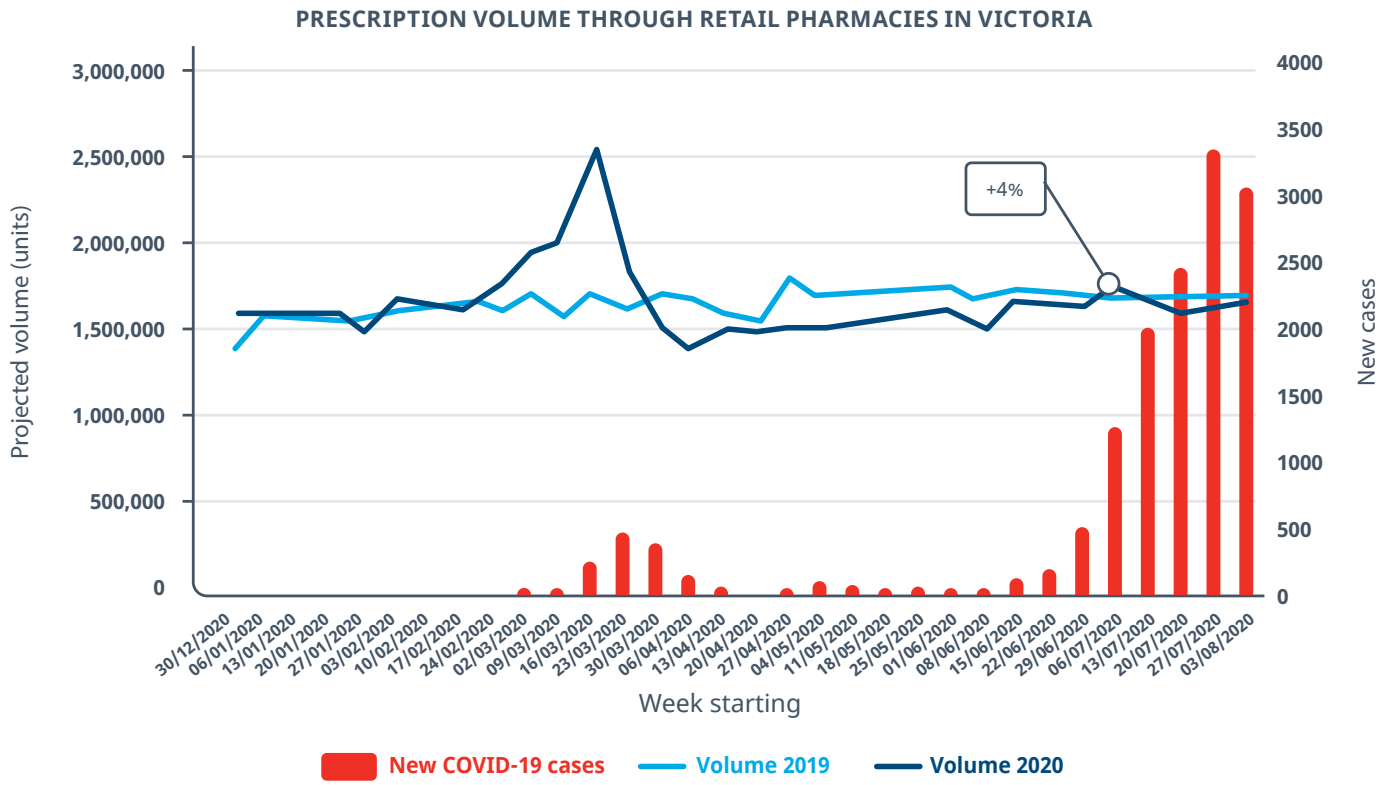


Figure 3: Prescription volume through retail pharmacies in Victoria

Source: IQVIA longitudinal dispensed data.

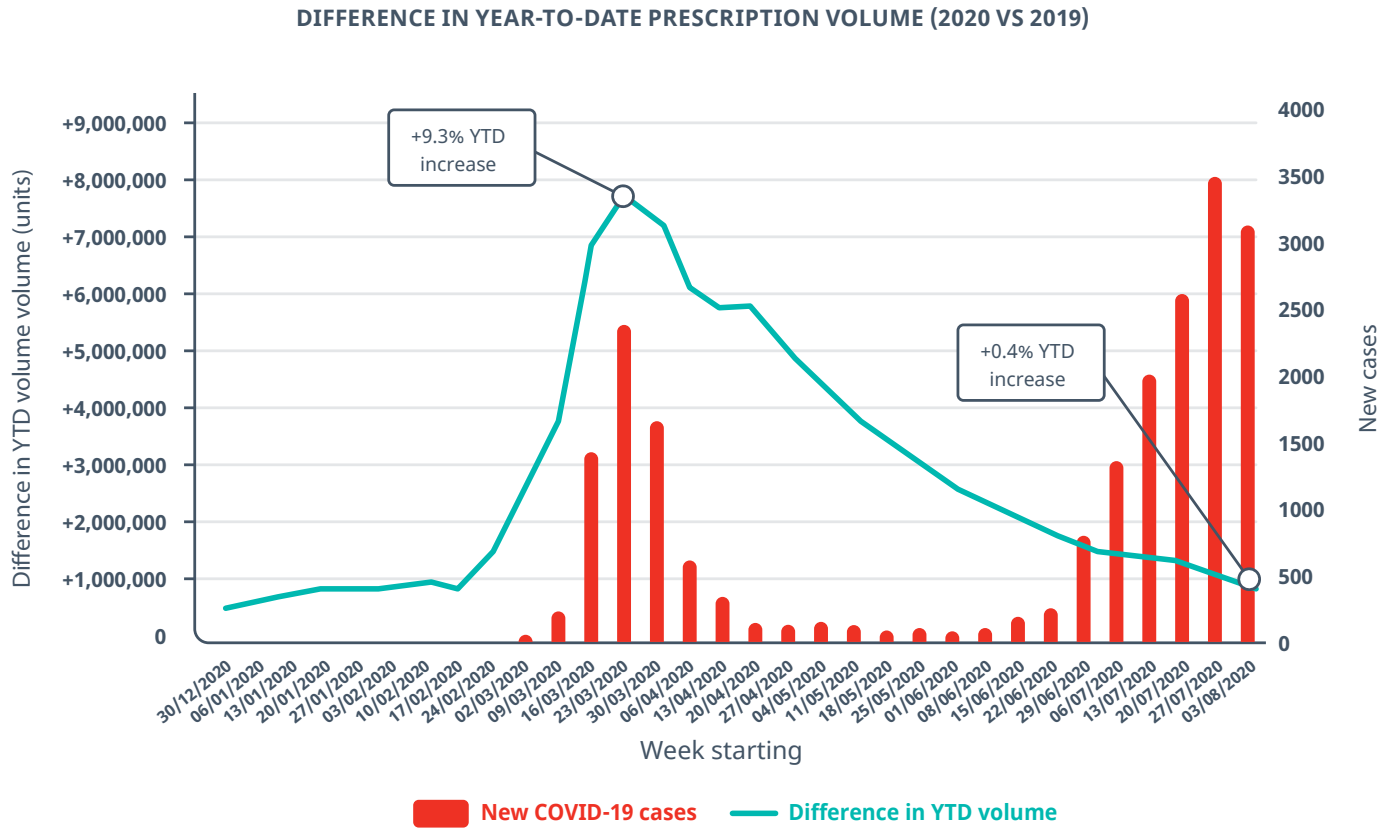


Figure 4: Difference in Year-To-Date (YTD) prescription volume (2020 vs 2019

Source: IQVIA longitudinal dispensed data.

However, behavioural change driven by lockdown, physical distancing and increased personal hygiene measures has led to reductions in many common infections, consequently lowering demand for certain medications.

Concerningly, delays in the diagnosis and treatment of certain therapeutic categories may also be contributing to suppressed dispensation volumes, and these may be indicative of risk to longer-term health outcomes.

Analysis of year-to-date (YTD) dispensed volumes by therapeutic class highlights the categories where prescription demand has been impacted on a cumulative basis, over and above the effect of stockpiling. The percentage change in YTD July for 2020 compared with 2019 is displayed in Figure 5a, with February YTD included as an indicator of the base rate of growth per category, prior to the onset of COVID-19 in Australia. The analysis highlights that the respiratory (R03) class is the category with the highest rate of growth in July YTD, with an increase of 16.4% over 2019, and 75% higher growth observed for the category in YTD February (9.4%). Considering demand across different phases of the pandemic, (Figure 5b), the current YTD growth for respiratory products is largely driven by the dramatic increase year-on-year in March of 104%. Demand remained elevated throughout April, but from May onwards has dropped below 2019 levels.

A number of other categories also show increased volume on a year-to-date basis in July. A similar pattern is observed across classes, with increased demand in March followed by a reduction in April, then demand bouncing back to meet, if not exceed 2019 levels, between May-July. However, in almost all cases the growth in YTD July is lower than that observed in February, indicating that the pace of growth has been negatively impacted by COVID-19. In particular, immunosuppressants and anti-hypertensives show declines in volume growth rates of over 1% between February – July YTD (Figure 5a).

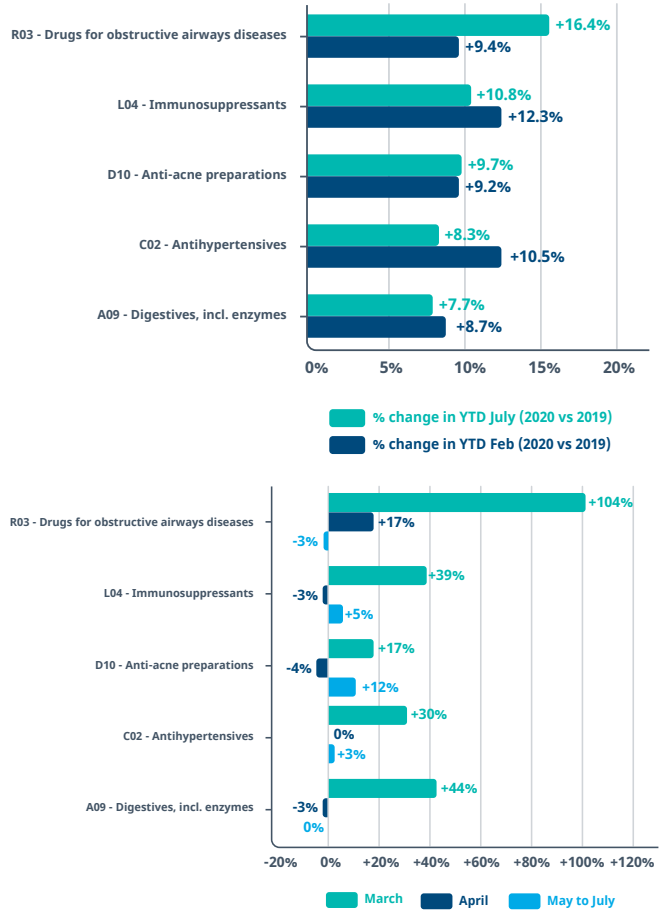


Figure 5: (a) Top 5 ATC2 categories with greatest YTD July increase in volume vs YTD Feb percentage change and (b) year-on-year percentage change in March, April and May to July

Source: IQVIA longitudinal dispensed data

A number of therapeutic categories now show a decline in year-to-date prescription demand compared with 2019, as indicated in Figure 6a, with differing explanations for the decreased usage. Antibacterials for systemic use (ATC J01) notably showed the greatest decrease of 18.1% in July YTD, from a stable position in February (0.9% growth). This decline can be attributed largely to decreased usage of the molecules amoxicillin and roxithromycin, which is likely due to both a reduction in respiratory infections, and fewer patients seeking treatment for respiratory infections through GPs.

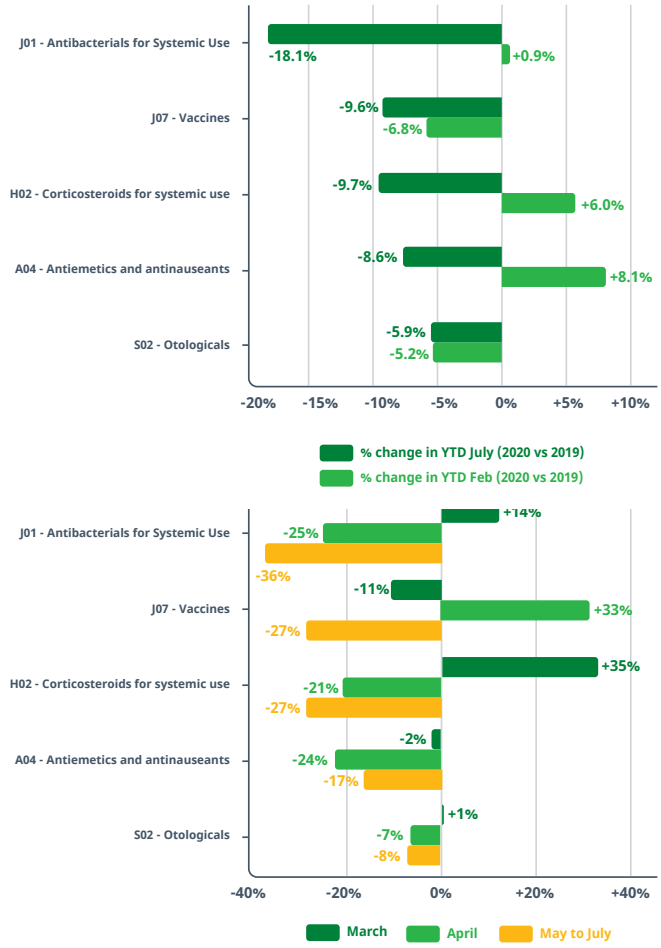


Figure 6: (a) Top 5 ATC2 categories with greatest YTD July decrease in volume vs YTD Feb percentage change and (b) year-on-year percentage change in March, April and May to July

Source: IQVIA longitudinal dispensed data

Anti-nauseants and anti-emetics are indicated for the treatment of chemotherapy induced nausea and vomiting (CINV) and are a category which was showing strong growth until February (+8.1% YTD). Consistent with a decline in the usage of cytotoxic therapies, the category recorded an 8.6% decline in July YTD. The impact of the pandemic on cancer therapies will be explored further in the subsequent section of this report.

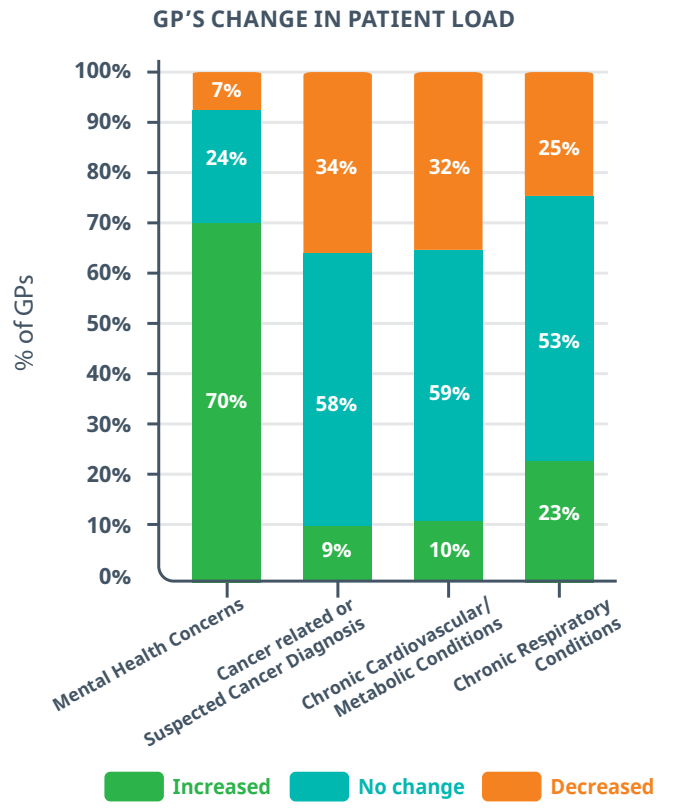
Antibacterials (J01) and corticosteroids for systemic use (H02) experienced double-digit percentage growth in March, as illustrated in Figure 9 (b). With the exception of vaccines (J07), most of the ATCs with the greatest YTD decline have been substantially below last year's level from April onwards. Strong growth in vaccines in April was driven by uptake of influenza vaccines, however the category has subsequently returned to decline, in line with the pre-pandemic trend.

Further explanation for the continued reduction in prescription demand may be offered by the trend in patient – doctor consultations, as reported by surveyed general practitioners (GPs). Over four in ten GPs (41%) reported a lower average caseload in July compared to a typical week a year ago. Whilst this figure represents some recovery in patient visits since March, when two in three (64%) GPs reported reduced caseloads, it is still indicative of a significant drop in consultations, despite efforts to promote continuity of care via telehealth services.

One in three GPs report a reduction in visits for cancer-related or suspected cancer diagnoses (34%) and for chronic cardiovascular or metabolic conditions (32%). Mental health remains the exception, with 70% of GPs reporting increased numbers of patients presenting with mental health concerns.

In addition to the changes in overall caseloads (as shown in Figure 7a), nearly half of GPs surveyed have reported reductions in the number of patients being either newly diagnosed or referred for diagnostic services and/ or specialty care (Figure 7b).

Delays in the care pathway, affecting diagnosis, and referrals, raise concerns over the longer-term impact of COVID-19 on broader health outcomes. Nearly three in four GPs believe there is a considerable pool of patients whose diagnoses of serious diseases have been delayed due to the COVID-19 lockdown, and that this will result in patients diagnosed at more advanced stages of disease in the future. Cancer patients and the elderly are considered to be the groups at highest risk, followed by those with chronic diseases.



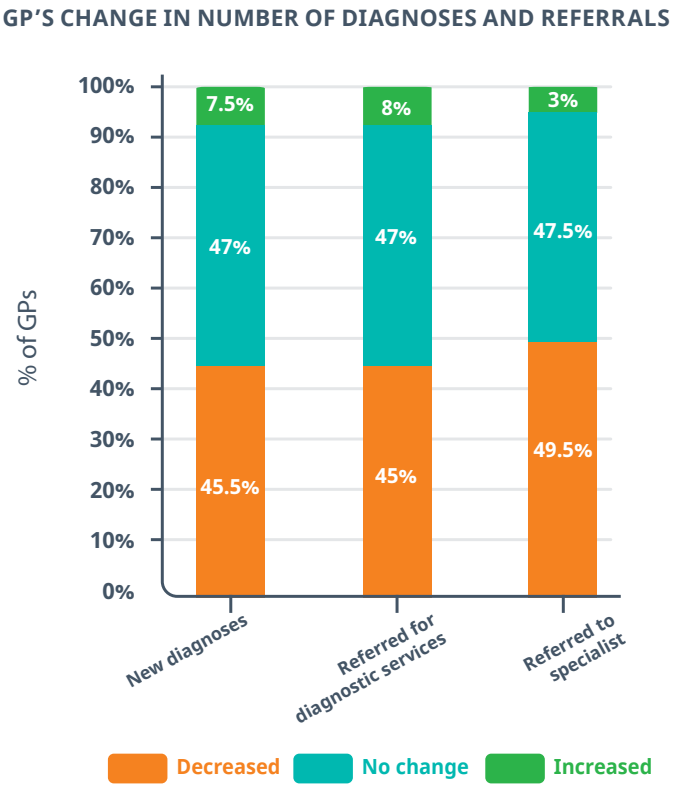


Figure 7 (a): GPs' change in patient load by condition (last 4 weeks vs 12 months ago); and (b): GPs' change in number of diagnoses and referrals (last 4 weeks vs 12 months ago)

Source: IQVIA Medibus, July 2020, n = 200 GPs.

Impact on Treatment for Respiratory Conditions

In the week commencing 16th March 2020, the surge in demand for respiratory treatments (ATC R03) saw volume increased by +193% year-on-year (YOY), mainly driven by a surge in the number of patients (+171% YoY) filling R03 dispensations, as shown in Figure 8 below. Both the volume and the number of patients subsequently dropped from April onwards, and now mostly aligns with last year's levels. The second wave of the pandemic in July has not introduced a substantial surge in demand, with a marginal increase of +4% and +4% in volume and the number of patients respectively.

The increase in demand was driven by both repeat and relapse patients, with 82% and 195% increases in volume in March, respectively. Relapse patients increased as a proportion of total patients to account for 18% of volume in the week commencing 16th March, as compared to 11% before the first wave. Demand has been driven more by the usage of asthma medications than those used to treat chronic obstructive pulmonary disease (COPD). The volume received by asthma patients increased by 134% during March (Figure 9a), contributing to 72% of the total R03 class volume dispensed, whereas asthma medications were responsible for 57% of the total R03 volume before the first wave. The volume dispensed for COPD increased to a lesser extent, growing by 46% during the first wave (Figure 9b).

Since the start of the second wave of the pandemic in Victoria in July, the demand for respiratory medications in this state has increased and is largely responsible for driving the uplift at a national level, illustrated in Figure 10. From week commencing 6th July, both the volume and the number of patients filling respiratory dispensations in Victoria have consistently reached, or exceeded, 13% above 2019 levels (Figure 10).

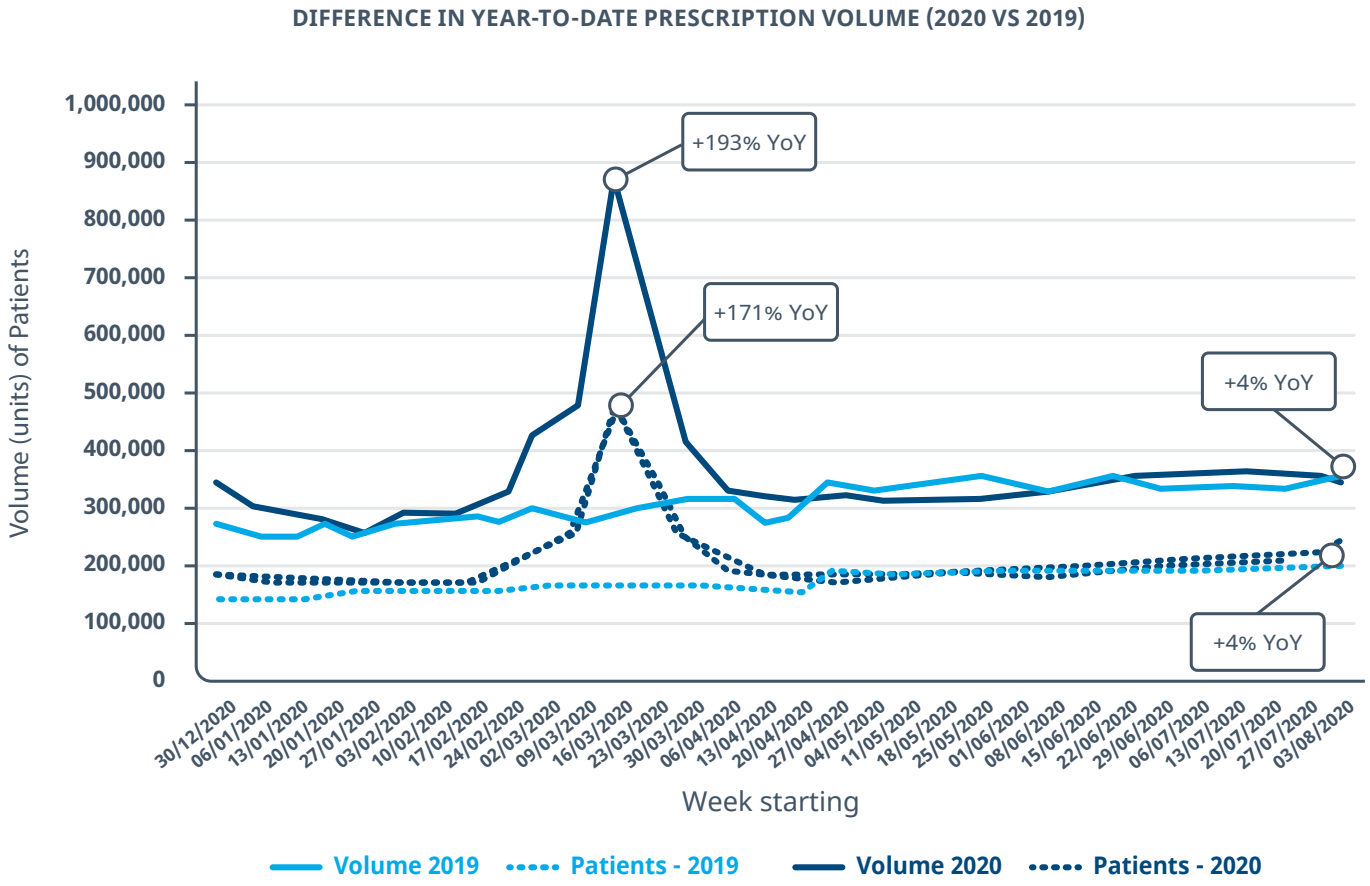


Figure 8: Weekly prescription volume and patients for respiratory treatments (R03 category)

Source: IQVIA longitudinal dispensed data.

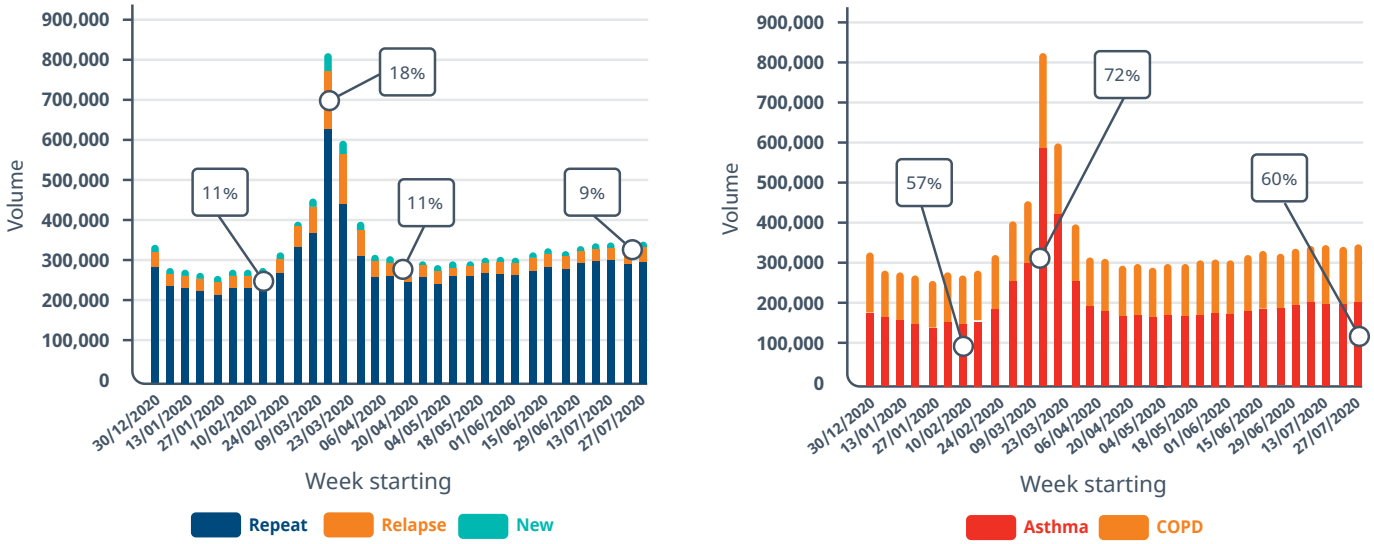


Figure 9: (a) Prescription volume by New/ Relapse/ Repeat patient type, and (b) by asthma and COPD treatments for the R03 category

Source: IQVIA longitudinal dispensed data.

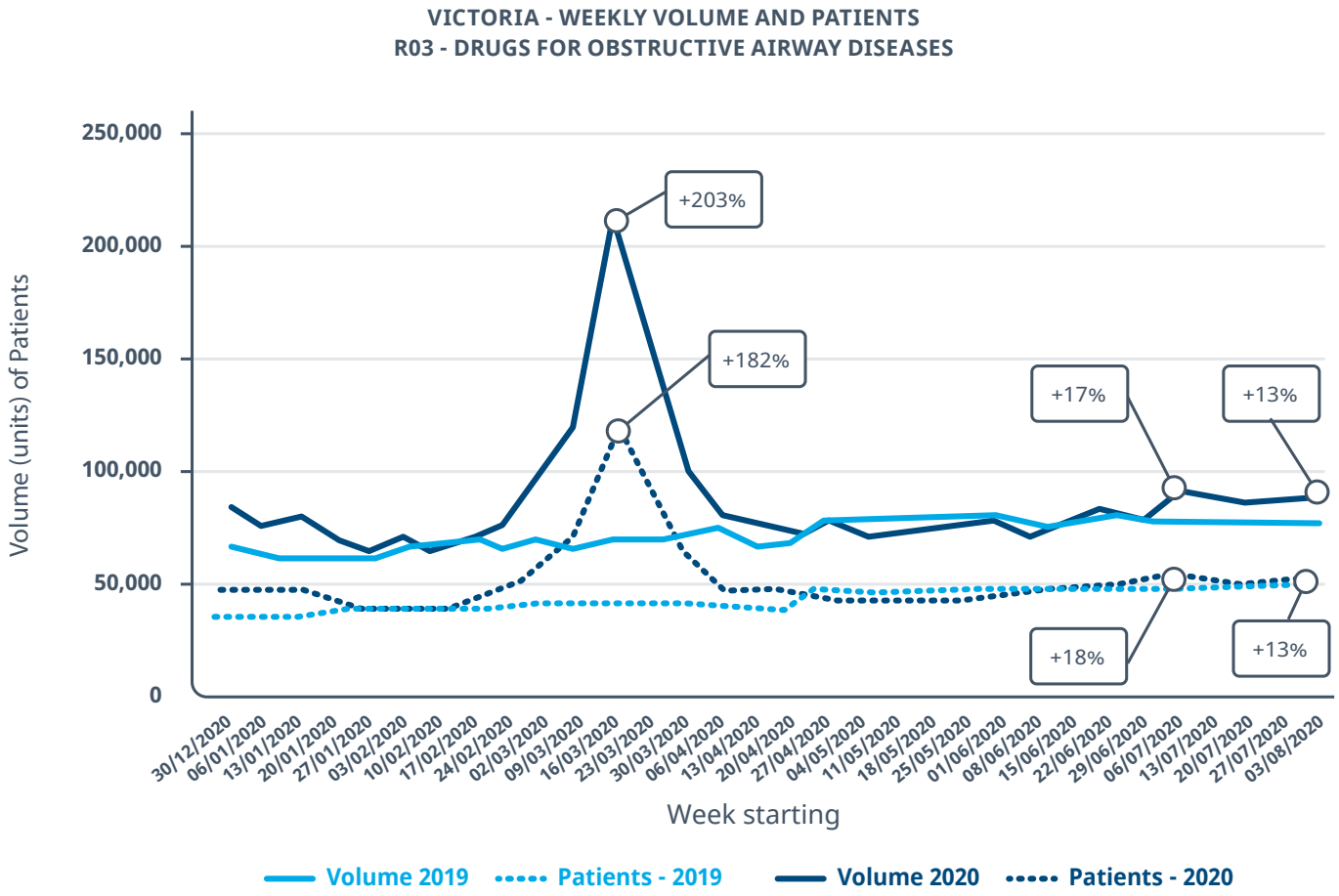


Figure 10: Weekly prescription volume and patients in Victoria for the R03 category

Source: IQVIA longitudinal dispensed data.

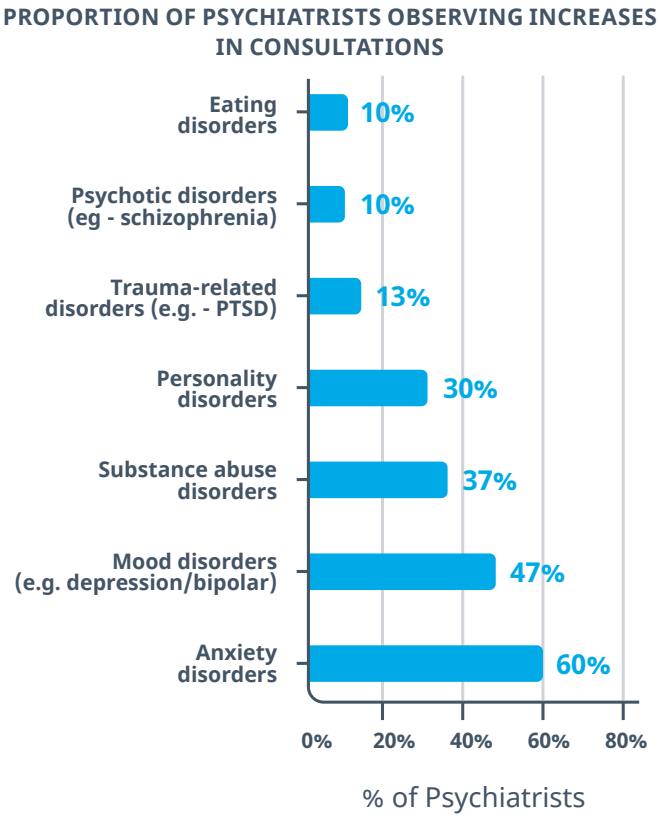
It could be expected that the large influx of patients filling respiratory dispensations would continue to drive demand for these medications in subsequent weeks or months. However, as discussed earlier, the volume since May has been largely aligned with last year, ranging between 5% below and 4% above 2019 levels. This would suggest that a significant proportion of the patients filling dispensations during the first wave were temporary or transient patients who picked up a script in March but have not continued treatment with these medications on an ongoing basis.

Impact on Mental Health

The impact of the coronavirus pandemic on mental health, including the consequences of lockdown and physical distancing, financial hardship and economic uncertainty, has been extensively discussed.

In March, the non-profit mental health charity Beyond Blue reported a 30% increase in calls to their support service, with one in three of these linked to coronavirus[8]. On 29th March, the government announced a $1.1 billion support package, aimed to support more Medicare, mental health, and domestic violence services[9], to help deal with the secondary effects of the health and economic crisis caused by the coronavirus. With metropolitan Melbourne now under the strictest level of lockdown yet, following the announcement of stage four restrictions on 2nd August, concern over the mental health, particularly of Victorians, remains elevated.

Over half (53%) of psychiatrists surveyed indicated that they experienced a decline in patient visits during the initial wave of infections in March and April. However, as of July, four in ten report an increase in the number of referrals or appointment enquiries, with an average increase in caseload of 23%.



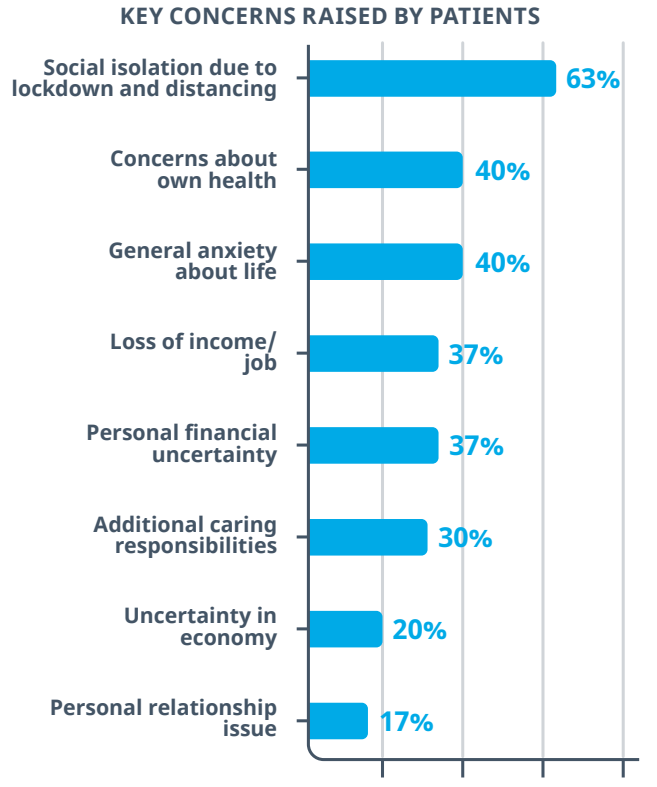


Figure 11 (a): Proportion of psychiatrists observing increases in consultations; and (b): Key concerns raised by patients visiting psychiatrists

Source: IQVIA Medibus, July 2020, n = 30 Psychiatrists

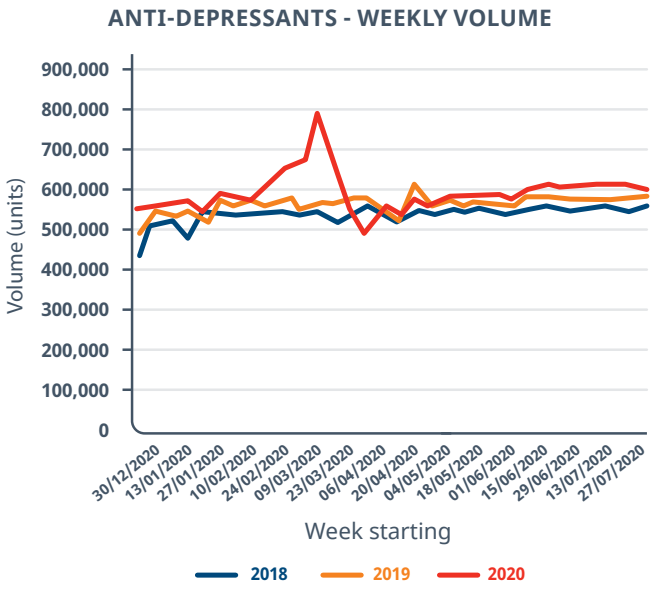
Anxiety disorders have increased the most (60%), ahead of mood disorders (e.g. depression/ bipolar – 47%) and substance abuse disorders (37%).

A slightly higher proportion of psychiatrists have observed increases in female patients compared with male patients. Most psychiatrists see social isolation due to lockdown and distancing as the key concern most commonly raised by patients (63%), while four in ten mention general anxiety or concerns over health and catching COVID-19 (Figure 11b). Personal financial uncertainty, including the loss of a job or income, and economic uncertainty also represent significant concerns, in addition to coping with additional caring responsibilities, such as home-schooling.

Demand for anti-depressants prescriptions

The usage of anti-depressant medications has been on the rise in Australia for several years.

Since the initial outbreak of the virus in March, more Australians have turned to anti-depressant medications to deal with the increased mental health burden. A clear spike in prescriptions for the anti-depressant (N06A) class was observed in March, and unlike other chronic medication categories where stockpiling occurred followed by subsequent reduced demand, the demand for anti-depressants has remained high.



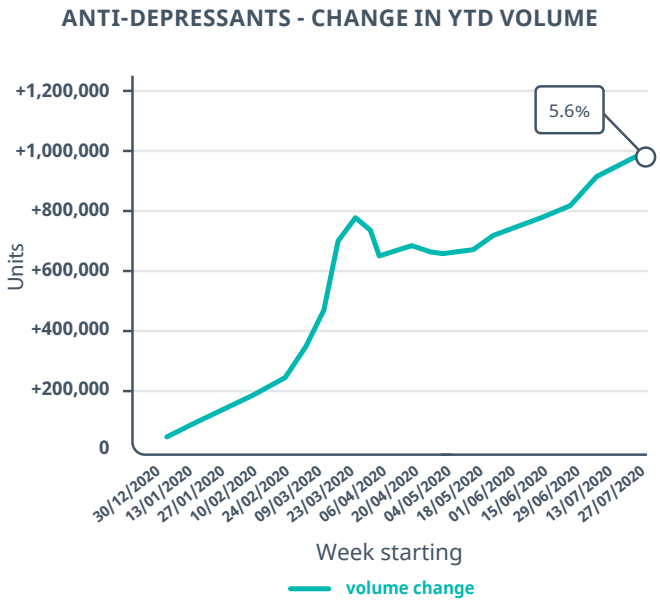


Figure 12 (a): Weekly prescription volume, and (b) change in YTD volume (2020 vs 2019), anti-depressants;

Source: IQVIA longitudinal dispensed data.

So far, the rise in demand (Figure 12a) has been driven by the combined factors of existing treated patients dispensing a higher volume of scripts, as well as, to a lesser extent, by relapse patients, who may have seen symptoms of depressive illness return alongside the increased stress of the pandemic. Together, these contribute an increase of 5.6% in anti-depressant dispensed volume on a year-to-date basis over 2019 (Figure 12b).

The number of patients initiating anti-depressant therapies for the first time dropped during March and April 2020, potentially linked to a reduction in patients visiting their doctor during lockdown. However, by June the number of new patient initiations had recovered to historical average levels.

Demand in anxiolytics prescriptions

Prior to the outbreak of COVID-19, the usage of anti-anxiety (anxiolytic) medications had been declining in Australia in recent years. This declining trend was briefly reversed during the initial COVID-19 wave in March, following a surge in both repeat and relapse patients filling scripts. However, from April onwards, demand has considerably reduced compared with previous years and remains substantially lower than the last two years' averages. The number of new patients initiating anxiolytic therapies for the first time has declined steeply since March (Figure 13 (a)).

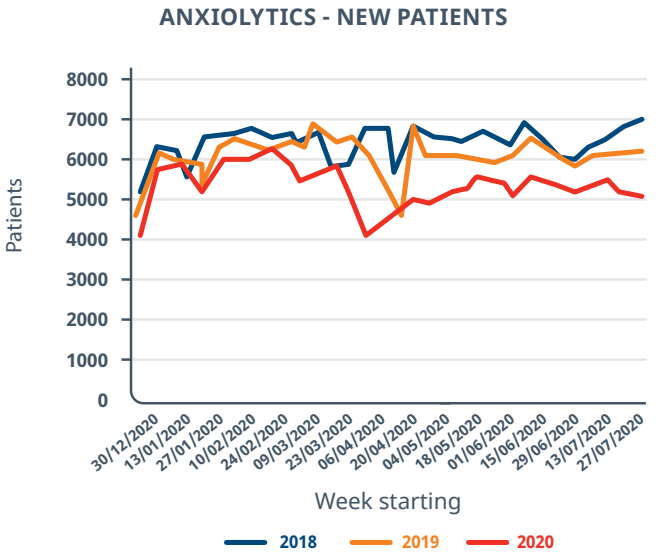


Figure 13 (a) Weekly New patients

Source: IQVIA longitudinal dispensed data.

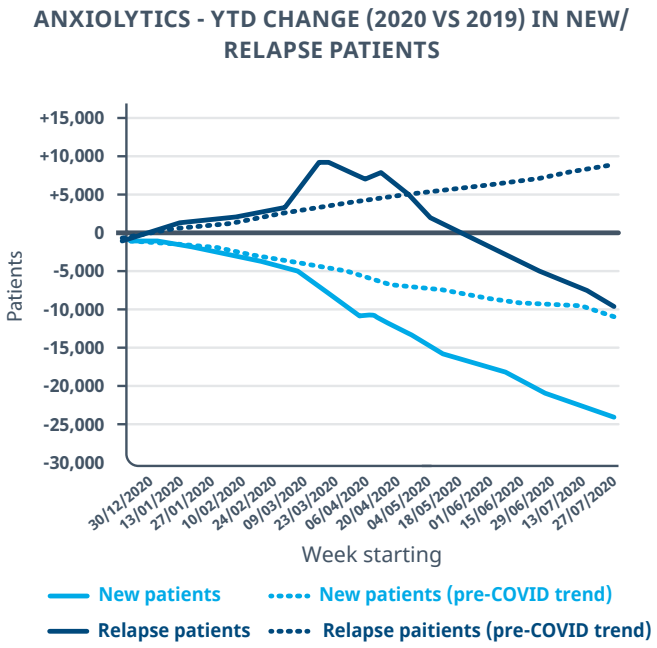


Figure 13 (b) YTD change in New/ Relapse patients (2020 vs 2019) for Anxiolytics

Source: IQVIA longitudinal dispensed data.

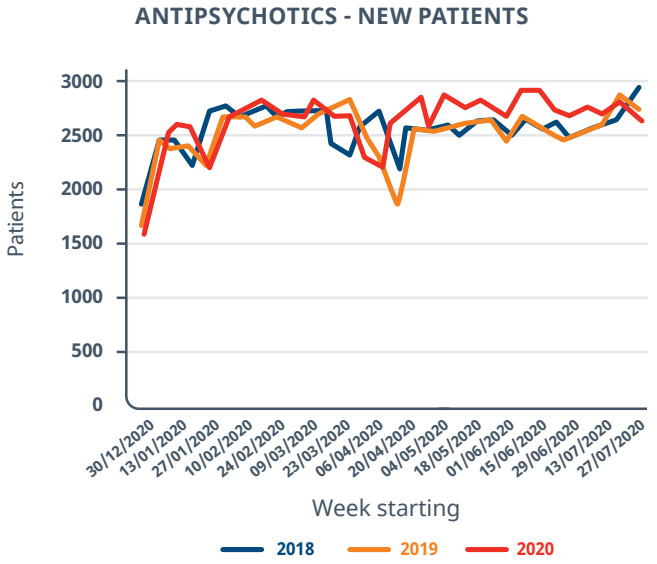
As demonstrated in Figure 13 (b), the trend in both new initiations and relapses has significantly diverged from March onwards compared with the pre-COVID-19 trend. The drop in new initiations from 2019 to 2020 is markedly greater than the decline from 2018 to 2019 and suggests that while existing treated patients increased consumption of anxiolytic medications during the pandemic, there may be a significant pool of patients who are not receiving the treatment they require.

Given the increased risk factors for anxiety-related disorders in the current environment, and the data from other sources which suggest increased diagnosis rates, it seems unlikely that there is a genuine decline in the number of patients requiring first line anxiolytics. Therefore, we suggest that the decline is more likely to be due to reduced patient willingness to present to their doctor during the lockdown period, or to delays in the referral process between primary and specialty care. A further hypothesis is that the telehealth model for consultation may incur more challenges in the area of mental health, particularly with regards to new diagnoses and treatment initiations.

Demand in antipsychotics prescriptions

Similar to the antidepressant and anxiolytic classes, a temporary surge in demand for antipsychotics was observed in late March. However, the number of new patients initiating on antipsychotics from April onwards has been greater than in the same period in the two preceding years (Figure 14a and 14b).

The data suggests that the pandemic has triggered an increase in both new and relapse cases. New cases may be linked to stress and situational factors increasing the onset of psychiatric disorders, while relapses may reflect individuals stocking up on medication in case of relapse, as well as those who have already relapsed. Relapses may be explained by adjustments to care paradigms, including reduced face-to-face social support, including community outreach and in-home visits, due to social distancing and isolation[10].



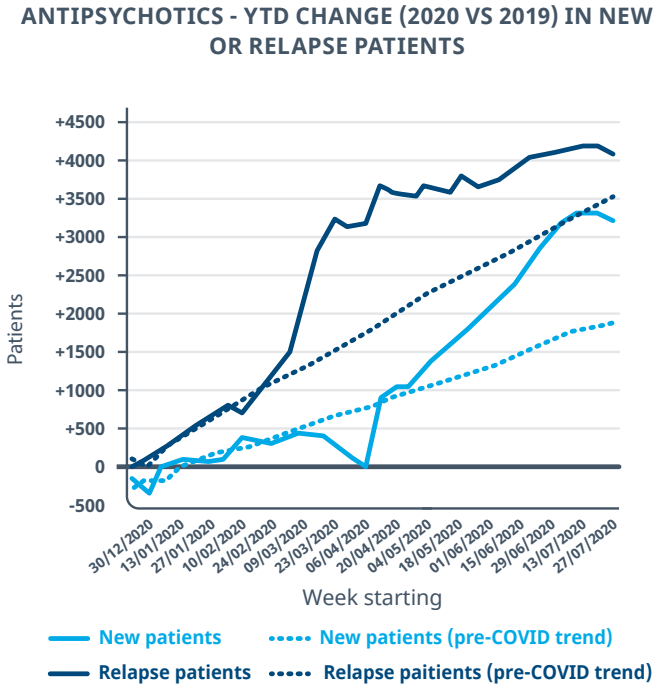


Figure 14 (a): Weekly New patients; and (b): YTD change in New/ Relapse patients (2020 vs 2019) for antipsychotics

Source: IQVIA longitudinal dispensed data.

Delays in Treatment for Cancer Patients

The impact of COVID-19 on cancer patients raises significant concerns, as timely diagnosis and the prompt initiation of treatment can be critical for ensuring optimal outcomes.

An IQVIA report on the impact of COVID-19 on cancer treatment across European countries based on a survey among oncology specialists, indicates that declines in patient presentations, delays to referrals and diagnoses, and modifications to treatment schedules have been widespread[11].

A national, population-based modelling study, funded by the UK Research and Innovation Economic Social Research Council, and published in the journal Lancet Oncology found that substantial increases in avoidable cancer deaths are to be expected in England as a result of diagnostic delays due to the COVID-19 pandemic[12].

Whilst the period of national lockdown in Australia has been shorter, and the extent of disruption to healthcare delivery has been less when compared to the UK, delays in treatment for cancer patients are also a concern for local clinicians. Based on IQVIA's Medibus survey of 30 medical oncologists in July 2020, during the initial wave in March, 70% of oncologists surveyed reported a decrease in patient referrals from primary care, with caseloads dropping on average by more than one quarter (27.4%). Whilst there has been some recovery in recent weeks, in July nearly four in ten (37%) oncologists continue to receive fewer referrals, with these clinicians seeing nearly one-third (30.5%) fewer patients. At the same time, referrals at Australia's leading cancer centres including the Peter MacCallum Cancer Centre in Melbourne, and Sydney's Chris O'Brien Lifehouse, are reported to have dropped by up to 30%[13], raising concerns that seriously ill people are going undiagnosed, amidst fears of contracting coronavirus or not wanting to burden health services.

Hence, the vast majority (80%) of oncologists surveyed believe there is a significant pool of patients whose diagnosis of serious disease has been delayed due to the COVID-19 lockdown, and that this will lead to

patients being diagnosed at later stages of disease. Almost all (90%) are concerned about delays in diagnosis leading to poorer outcomes for patients.

Over half (60%) of surveyed oncologists report that their rates of new treatment initiations have been impacted by the pandemic, and this modification to treatment schedules is evident in patient dispensation behaviours. As anti-emetic and anti-nauseant medications are indicated for the treatment of nausea and vomiting induced by chemotherapy and radiotherapy, dispensations of these products can be compared to the sales of chemotherapy drugs. Patient numbers for anti-emetic and anti-nausea medications showed a significant decline March 2020 onwards, with new or re-initiating patients dropping to approximately half of pre-COVID-19 levels (Figure 15). This correlates with a similar decrease in the sales of cytotoxic chemotherapy medications between March – mid April.

Avoiding the risk of immunosuppression associated with chemotherapy, as well as the need for frequent hospital visits for intra-venous (IV) therapies, are reported to be the main challenges limiting treatment initiation, alongside patients' fear and anxiety surrounding the risks of contracting COVID-19. Visiting the treatment centre has become an inherently stressful experience for many patients, particularly with caregivers unable to attend in many centres leaving patients to receive diagnoses and make challenging decisions alone. These factors have altered the already fine balance between the potential benefits of undergoing chemotherapy compared with the risks, within the pandemic environment.

Most oncologists report delaying treatment for older, frailer patients who may be considered borderline fit for treatment, or those with co-morbidities which may place them at higher risk for severe COVID-19. Many have opted to delay palliative treatments, where the required visit frequency is high, and the risks are seen to outweigh the potentially small benefits. Aggressive chemotherapy regimens, including intravenous therapies and multi-agent combinations, have been avoided, and in some cases, treatment for less aggressive, slow progressing cancers has been delayed.

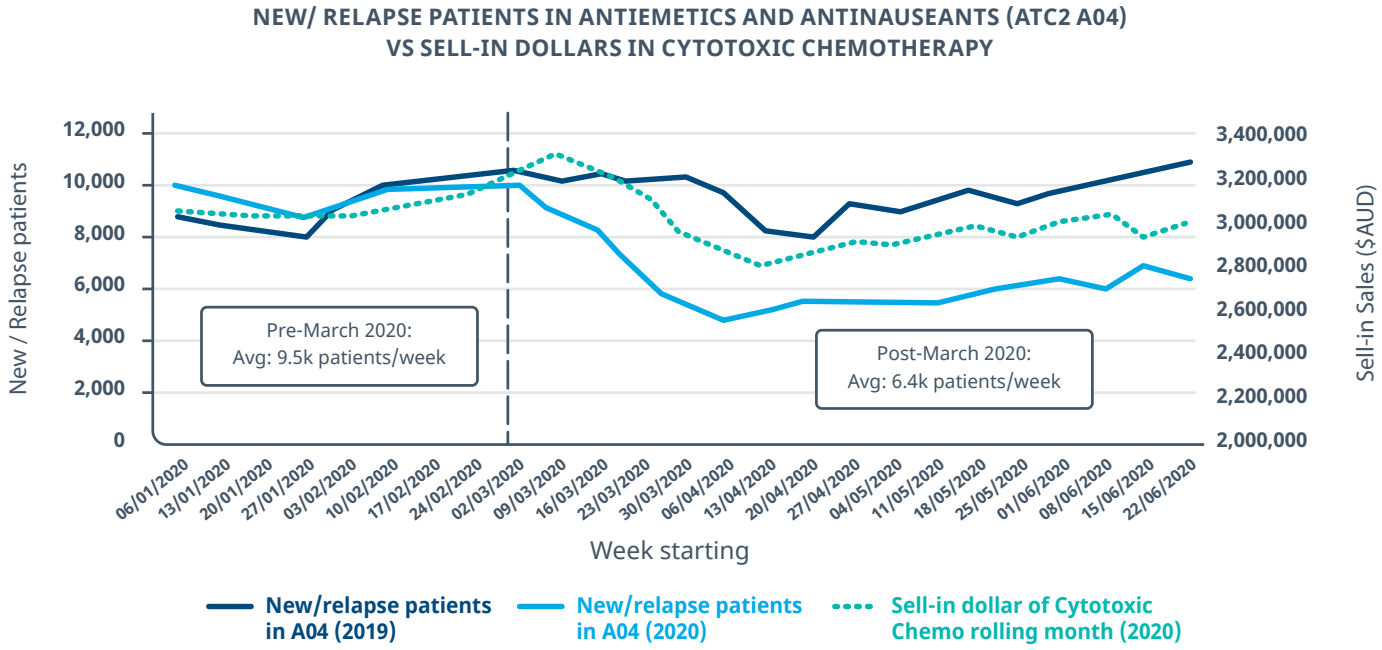


Figure 15: New/ Relapse patients in antiemetics and antinauseants (ATC2 A04) vs Sell-in dollars in Cytotoxic Chemotherapy

Source: IQVIA longitudinal dispensed data and IQVIA DDD sell-in data

In addition, many oncologists report that they have chosen to prescribe modified or alternative treatment protocols. This is visible in the dispensing trends for cancer therapy classes in Figure 16. Initiations for hormonal and non-IV cytotoxic therapies increased throughout the initial wave of the pandemic, reaching peaks of +16% and +28% growth in new patients over 2019 respectively.

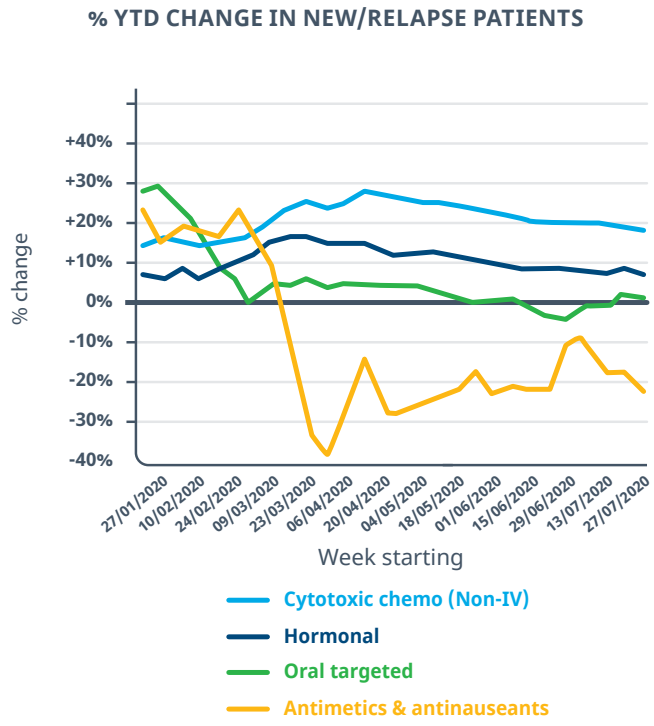


Figure 16: YTD percentage change in New/ Relapse patients for cytotoxic chemotherapy (Non-IV), hormonal, oral targeted, antiemetics & antinauseants classes

Source: IQVIA longitudinal dispensed data.

According to oncologists' feedback, oral capecitabine is being chosen over intravenous fluorouracil, abiraterone or enzalutamide in preference to docetaxel for castration resistant prostate cancer, immunotherapies over chemotherapies, and more single agent therapies, including single agent immunotherapy over immunotherapy plus chemotherapy combinations.

Hospital in the Home – Enabling Treatment Continuity & Minimising COVID-19 Infection Risk

In light of concerns over susceptibility to the virus in already vulnerable populations, and the risks of frequent hospital visits required for many chemotherapy schedules, the pandemic has highlighted the need for hospitals, funders and manufacturers to improve access to hospital in the home and hospital substitution services, which enable patients to receive treatments such as infusions and intravenous chemotherapies in their own home. These services, where clinically appropriate, could enable clinicians to continue their preferred treatment schedules as planned, whilst both minimising risk and increasing comfort for patients.

If more broadly accessible, home infusion services could form part of the solution to reduce the delays and modifications to treatment currently taking place as a result of COVID-19, hence ensuring that cancer patients are able to receive the timely treatment they need. An increase in the need for these services is reflected in a shift in attitudes among oncologists, who are increasingly open to referring patients to home infusion services.

Over nine in ten oncologists surveyed in July stated that they have considered home infusion services, whilst only 7% reported that they would not consider referring patients. The proportion of oncologists who would not refer patients has dropped from 33% in a survey conducted in February 2020, prior to the COVID-19 outbreak.

Given the known risks to vulnerable patients in the current environment, home infusion services offer critical benefits for patients and healthcare providers alike. Lowering the risk of infection is now perceived as a key advantage, in addition to benefits for patients of increased comfort and reduced travel burden, and reduced pressure on hospital wards and clinics (Figure 17).

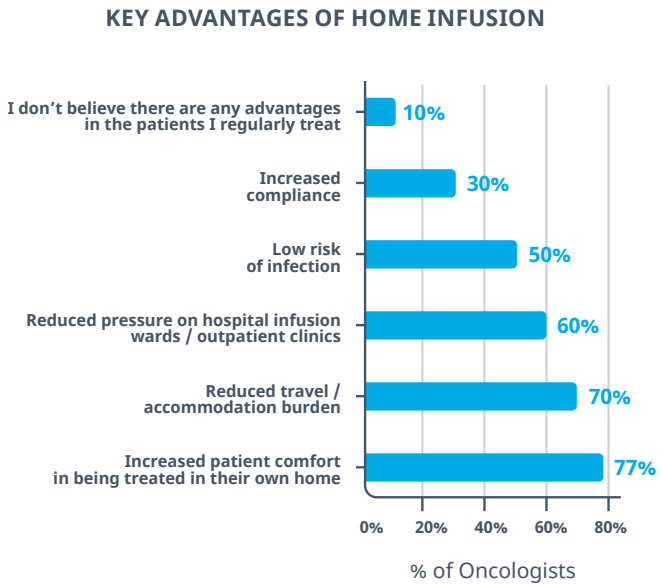


Figure 17: Key advantages of home infusion reported by Medical Oncologists

Source: IQVIA Medibus, July 2020, n = 30 Medical Oncologists.

Impact on Consumer Health Sales in Pharmacy

KEY INSIGHTS:

Since the peak in consumer health product sales in Australian retail pharmacies in March 2020, sales have been consistently below the same period in 2019. Significant sales losses have been observed between April – June, which now outweigh the higher sales which occurred in March.

Factors which have likely contributed to this slump include extensive stockpiling of products which were not consumed, reduced transmission of traditional winter illnesses such as influenza due to social distancing, improved hygiene standards and vaccination rates, and reduced willingness to spend due to increased economic uncertainty.

Consumer Health Sales Overview

Consumer health product sales in Australian retail pharmacies been consistently below the weekly sales achieved over the same period in 2019 (Figure 18) since the peak which occurred in mid-late March.

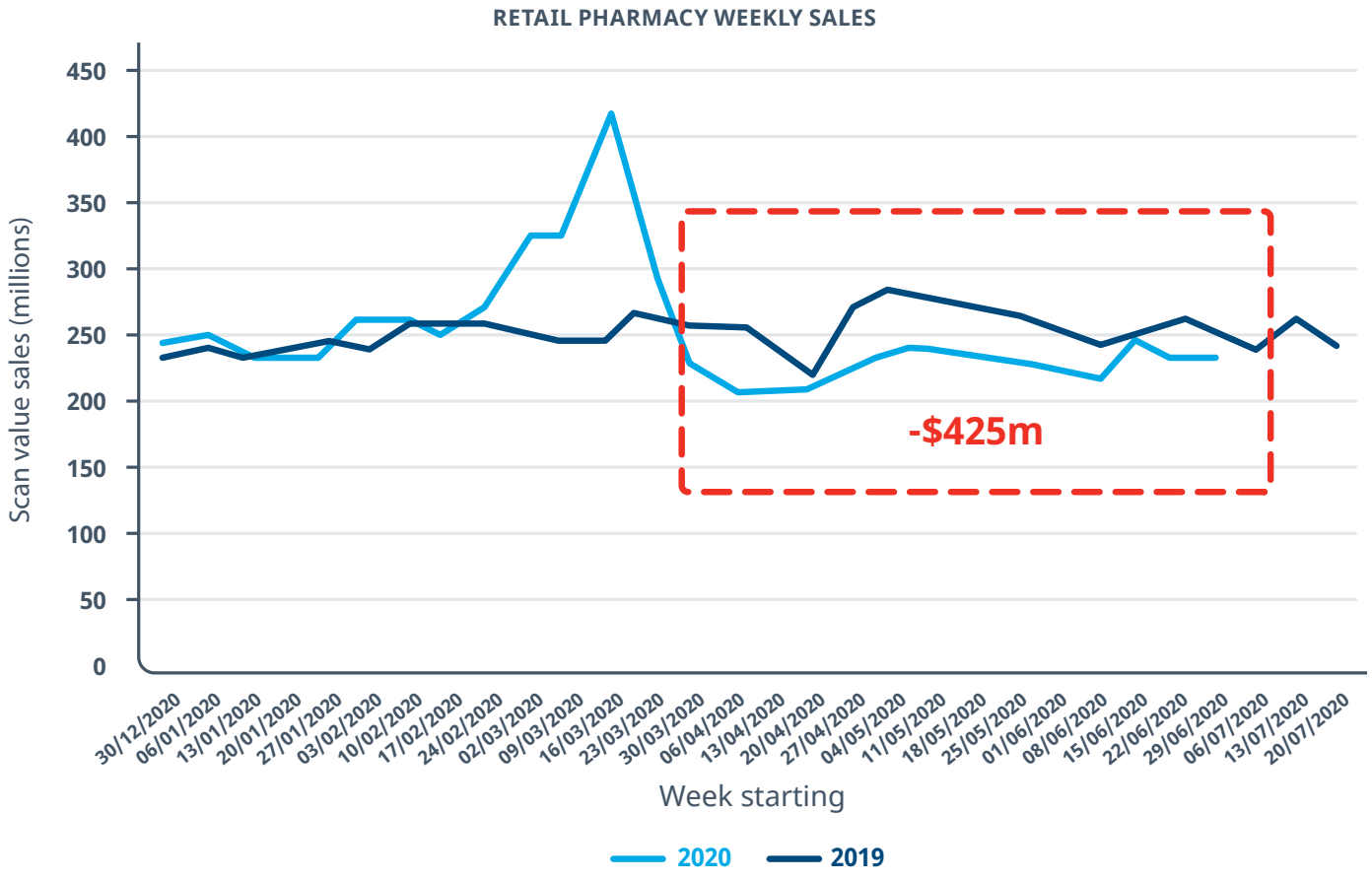


Figure 18: Retail pharmacy weekly sales

Source: IQVIA Pharmacy Scan data

Sales losses totalling $425 million over a 14-week period relative to 2019 have been noted. Thus, all the first quarter sales gains across Australian retail pharmacies were effectively wiped out by losses that largely accumulated in the second quarter of 2020.

Growth of retail pharmacy sales destined for consumers based in China spiked on week commencing 15th June, indicating that the sales uplift observed was a result of increased export consumption (Figure 19) coincided with the end of the China Mid-Year Shopping Festival. Domestic sales did not experience an uptick over the same period, with weekly demand still below 2019 levels. Other than this brief increase in demand, export sales growth remains in decline relative to 2019, more so than domestic sales.

Export sales highlight the extent to which COVID-19 has exacerbated the drop off in retail pharmacy exports sales that began in January 2019 (Figure 20) due to the introduction of the Cross-Border E-commerce (CBEC) tax.

It was anticipated that export sales would begin to rebound this year but the COVID-19 impact on a wide range of export market essentials such as logistics, travel and migration, and consumer willingness to spend, could delay the onset of this expected recovery.

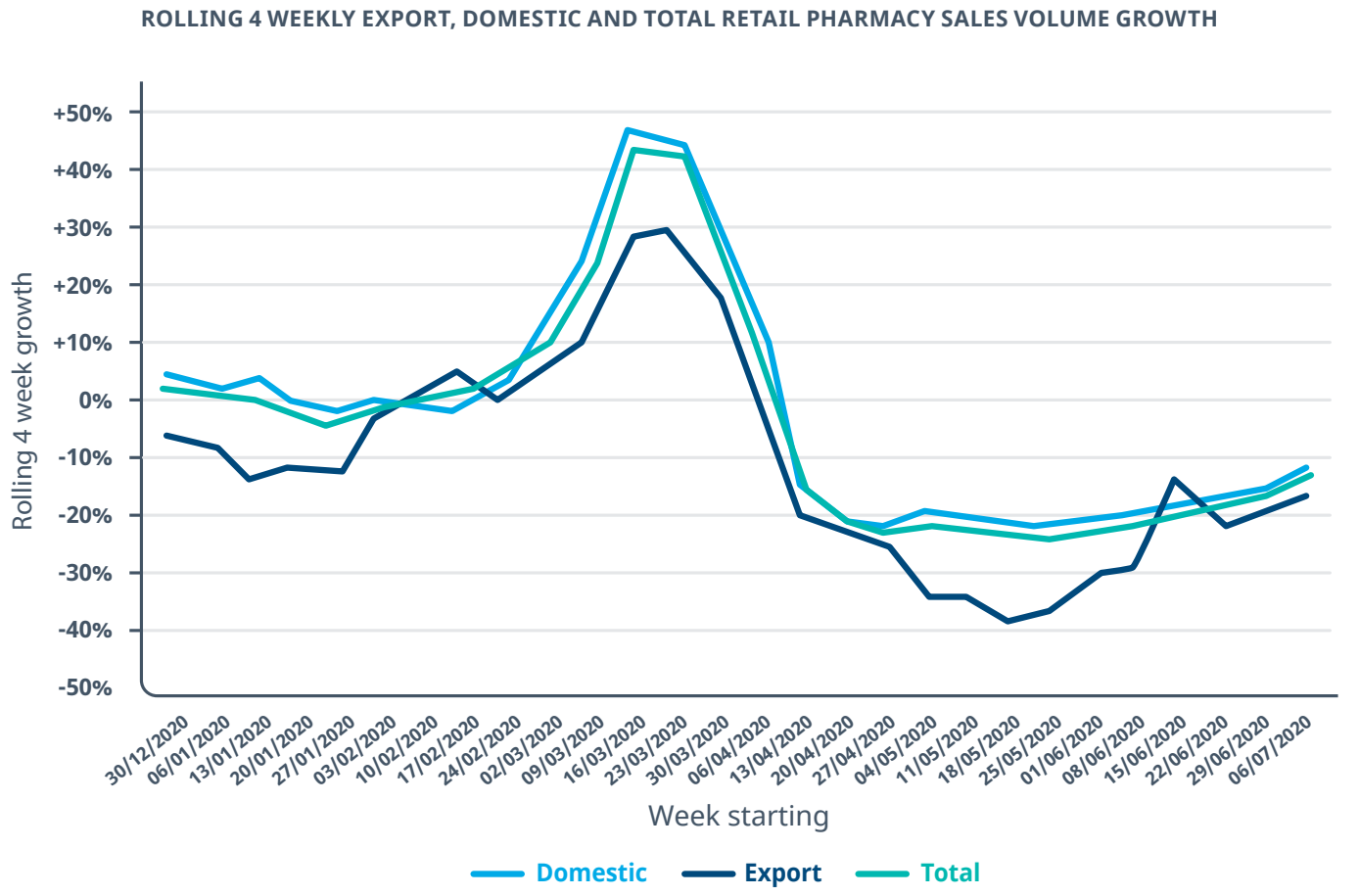


Figure 19: Rolling 4 weekly export, domestic and total retail pharmacy sales volume growth

Source: IQVIA Pharmacy Scan data and Xport Dynamics

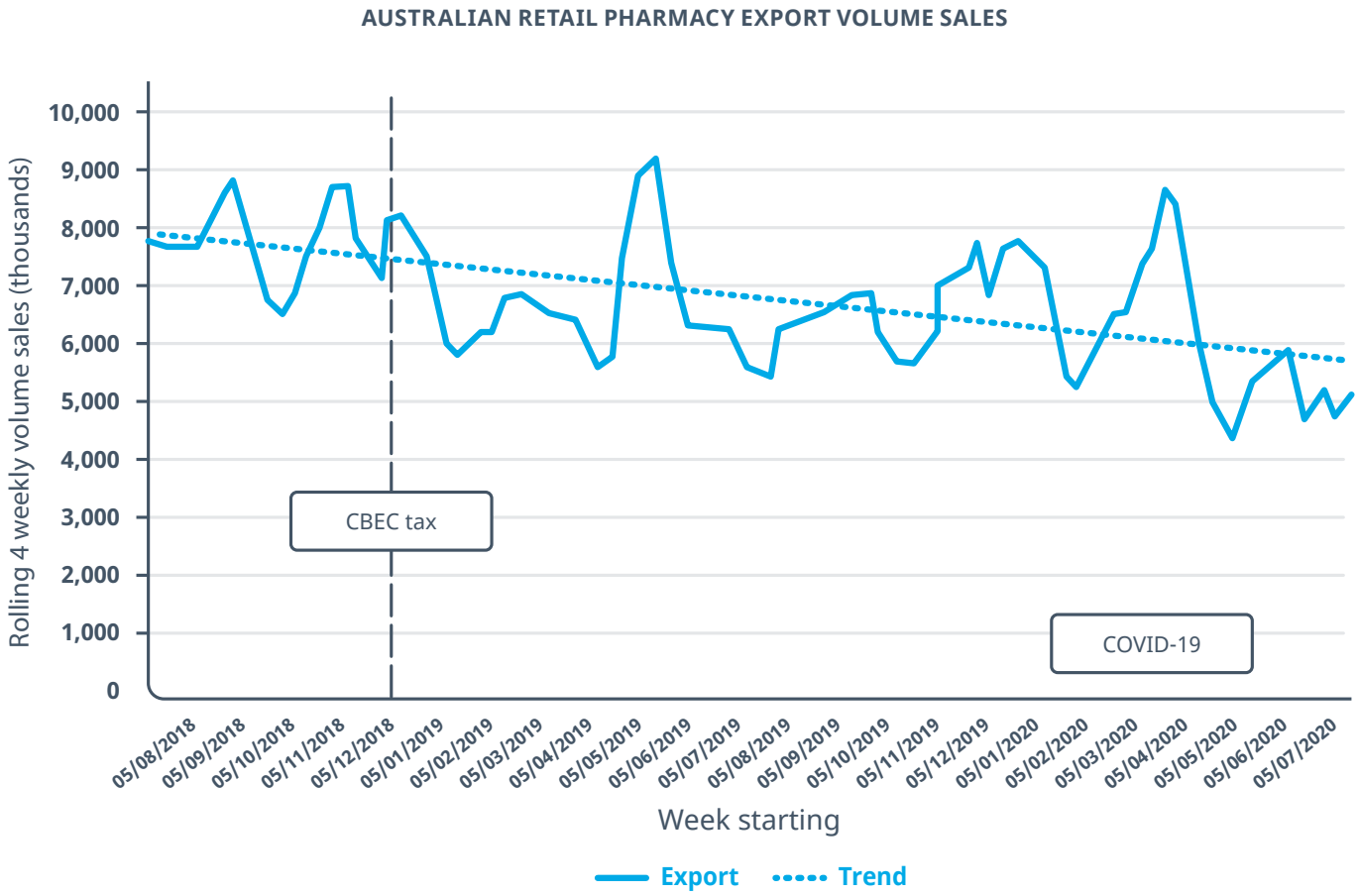


Figure 20: Rolling 4 weekly total Australian retail pharmacy export volume sales

Source: IQVIA Pharmacy Scan data and Xport Dynamics

Category performance

Despite the decline in total sales across the retail pharmacy sector, several categories have been able to achieve continued growth. Unsurprisingly, the single largest category in absolute sales value growth between Q2 2019 and Q2 2020 is hand sanitiser, with almost $14 million in sales value growth (Figure 21); soaps also feature in the top 10. Given the widely reported greater predisposition for hypertension sufferers to have significant morbidity or mortality if infected with COVID-19, the growing sales of blood pressure devices could indicate a greater desire to detect and manage this or related conditions. Vitamin uptake could be linked to an increased desire to boost health and vitality whereas increased vitamin D consumption could be a result of reduced exposure to sunlight during lockdown. Thus, the underlying cause for the sales growth observed in 5 of the top 10 categories could be related to the on-going impact COVID-19 has on consumer behaviour. In other categories, growth could be indicative of the return to a certain level of normalcy in day-to-day behaviour post lockdown, triggering a need for daily essentials like depilatories or facial moisturisers.

Categories most impacted by sales decline were those that were heavily stockpiled in March, including cold or flu remedies, pain relief, sore throat remedies and chesty cough products (Figure 22). Three export categories also feature in this list, normal milks, omega-3 and joint care products, which primarily contain the ingredient glucosamine. This is explained by the continued declines within the export market (Figure 26). Finally, both make-up categories remain in decline presumably as a result of reduced demand due to social distancing and working from home.

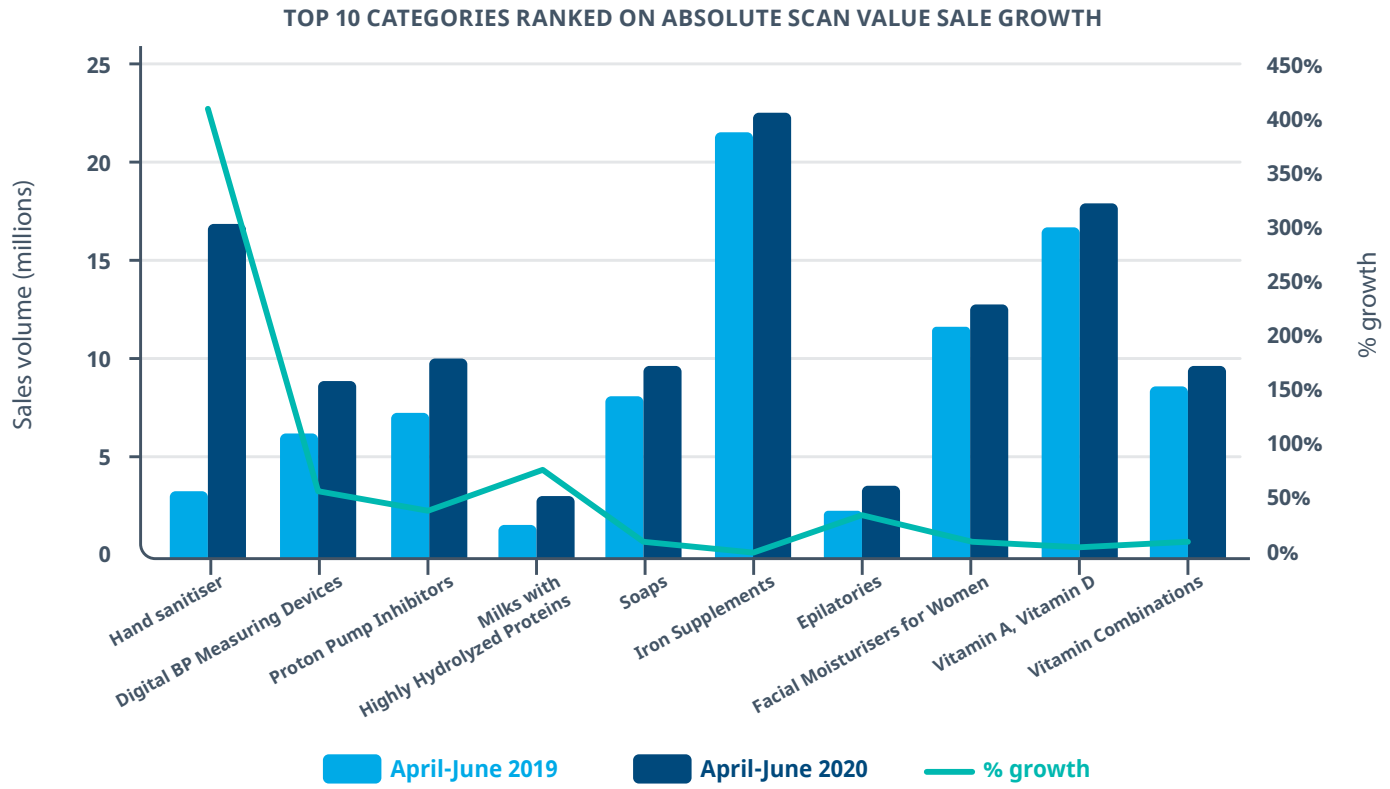


Figure 21: Top 10 categories ranked on absolute sales value growth (Q2 2020 vs Q2 2019)

Source: IQVIA Pharmacy Scan data.

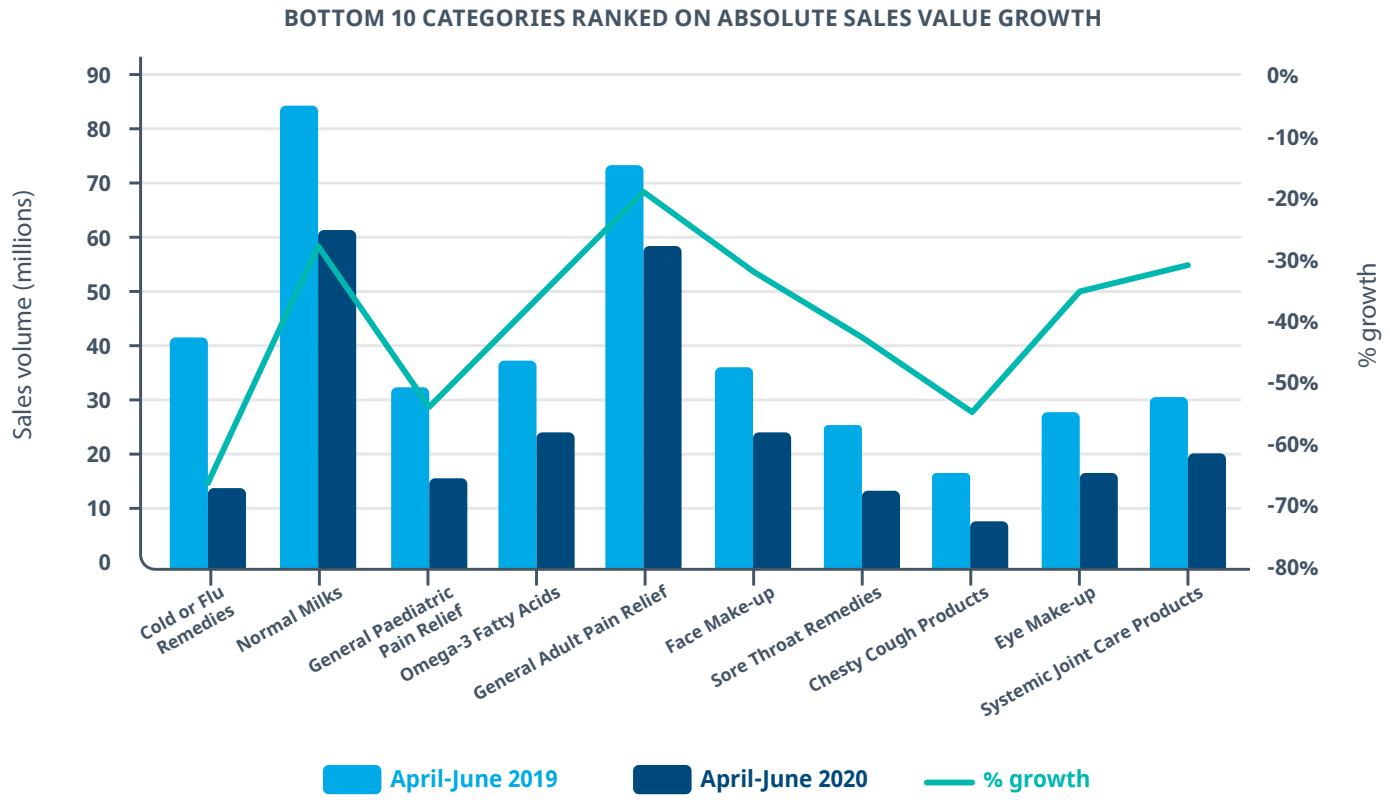


Figure 22: Bottom 10 categories ranked on absolute sales value growth (Q2 2020 vs Q2 2019)

Source: IQVIA Pharmacy Scan data.

Demand for consumer health goods that typically occur in the winter months has also changed as a result of new consumer behaviours triggered by COVID-19. Social distancing and working from home, along with improved hygiene standards and the increased uptake of influenza vaccines have resulted in fewer cases of influenza detected this year.

As well as the reduction in influenza cases (Figure 23), social distancing measures will also reduce the transmission of other respiratory infections. Hence, it is likely that fewer consumers will need to purchase cough and cold or pain relief products this flu season, especially those who have stockpiled, thus contributing to category and total retail sales decline. A concern for suppliers should be the extent that stockpiling, and these new behaviours may carry over into 2021, affecting forecast sales and performance.

Willingness to spend

After over a quarter of a century of sustained economic growth, Australia is in a recession brought about rapidly by COVID-19. As a result, consumer confidence is low and has marked fluctuations, according to the Westpac Consumer Sentiment report[15]. Consumers are likely to be more conservative with their spending behaviour and there is evidence of this in consumer health sales patterns. In the vitamins category for example, more affordable private label product volume sales grew by 45% in the YTD period ending 27th July 2020 (Figure 24), whereas non-private label product volume sales declined by 9% in the same period. In the last 4 weeks of Q2, private label volume continued to expand relative to 2019, whereas non-private label products declined further. This shift towards private label is an indicator of a continued desire to consume vitamins, but with a reduced willingness to spend more on premium items.

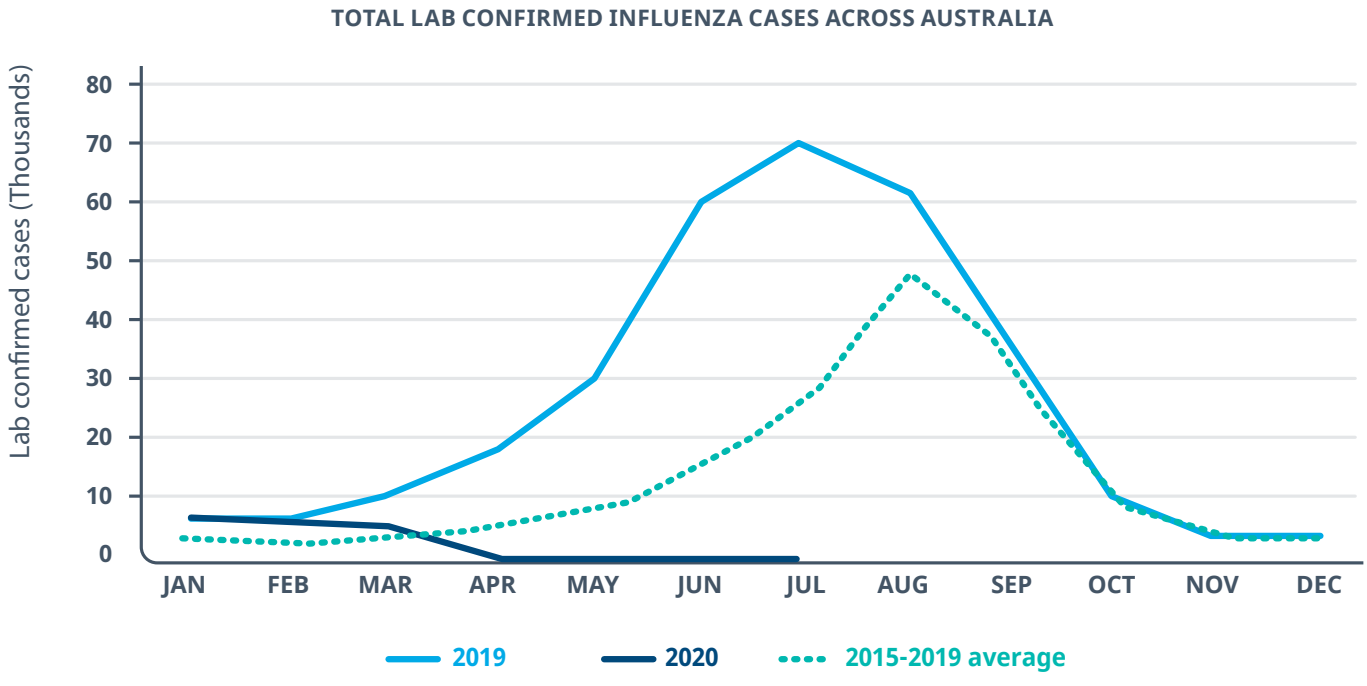


Figure 23: Total lab confirmed influenza cases across Australia

Source: Australian Government Department of Health National Notifiable Diseases Surveillance System[14]

PRIVATE LABEL VERSUS NON-PRIVATE LABEL SALES VOLUME GROWTH

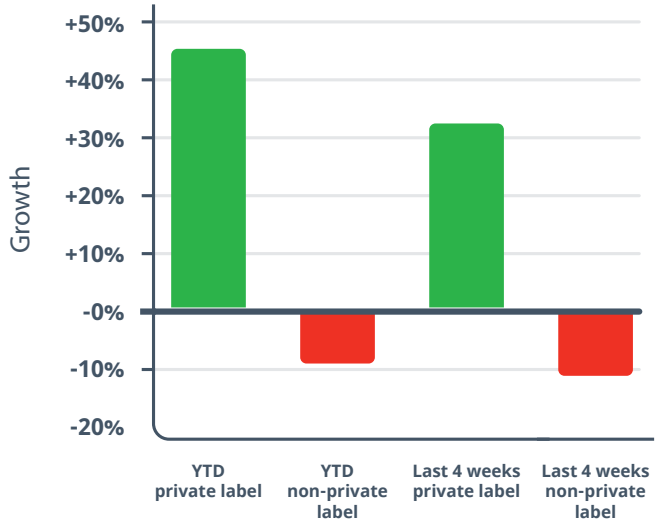


Figure 24: Private label vs non-private label sales volume growth

Source: IQVIA Pharmacy Scan data

Certain ingredients such as propolis, celery and valerian are also in decline, and these ingredients are not heavily exported nor were they stockpiled. Hence, this indicates that these items may be perceived to be less essential to wellbeing in times of economic uncertainty. In light of this, suppliers should exercise caution when planning new launches, forecasting and assessing growth opportunities, especially when considering items or ingredients that experienced sustained growth immediately prior to COVID-19, and should potentially reconsider marketing and promotional plans to account for changes in spending behaviour that the economic downturn is likely to create.

An Online Shift - eCommerce Trends in Consumer Health

Online over the counter (OTC) pharmacy sales have been significantly impacted by COVID-19, increasing by 50% in units and 59% in value in April - June 2020 compared to April - June 2019.

The pandemic has had a significant effect on the way people are shopping for consumer health products, as many consumers seek to avoid shopping centres and turn to online purchasing.

This shift comes on top of an already solid growth trend for online pharmacy sales, which were increasing at 15% based on MAT January 2020. These two factors combined led Australia to reach its predicted 2030 ecommerce forecast, with online sales volumes hitting peaks which were 20% higher than 2019 Black Friday and Cyber Monday sales.

Between March to June 2020, almost 9 million items were sold online through tracked Australian pharmacy e-commerce platforms. This equates to a 56% increase on 2019, with March alone (+65%) recording the highest monthly units ever sold in online pharmacy (Figure 25). The proportion of pharmacy sales purchased online, compared with in bricks and mortar stores, more than doubled in April 2020, with a jump from 2.3% to 4.9%.

AUSTRALIAN ECOMMERCE PHARMACY SALES GROWTH JANUARY TO JUNE 2020 V 2019

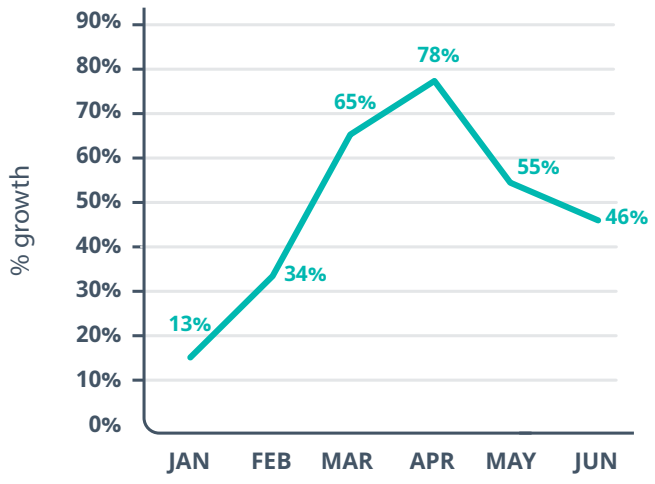


Figure 25: Growth of pharmacy eCommerce

Source: IQVIA Pharmacy Scan data

Nine out of ten categories are in growth when comparing current online pharmacy sales to June 2019. In general, a higher proportion of online sales are observed for categories that have a high convenience factor, such as nappies for busy parents, categories with high export sales, such as vitamins, and categories that have a sensitive element to purchase, such as hair loss or weight management. During COVID-19, other categories have shown higher growth, including items that shoppers considered essential and felt the need to stockpile or purchase online rather than in store.

The categories that have been most impacted by online sales align largely with the most impacted categories in bricks and mortar pharmacies, although the ranking is different, and the percentage increases are generally larger online (Figure 26). Within the preventative categories, increased consumption of vitamin C, immune supplements, masks, disinfection, mouthwash, and wipes was observed. Growth for some categories, for example hand sanitiser, was restricted due to availability and limits on the number of units that could be purchased online.

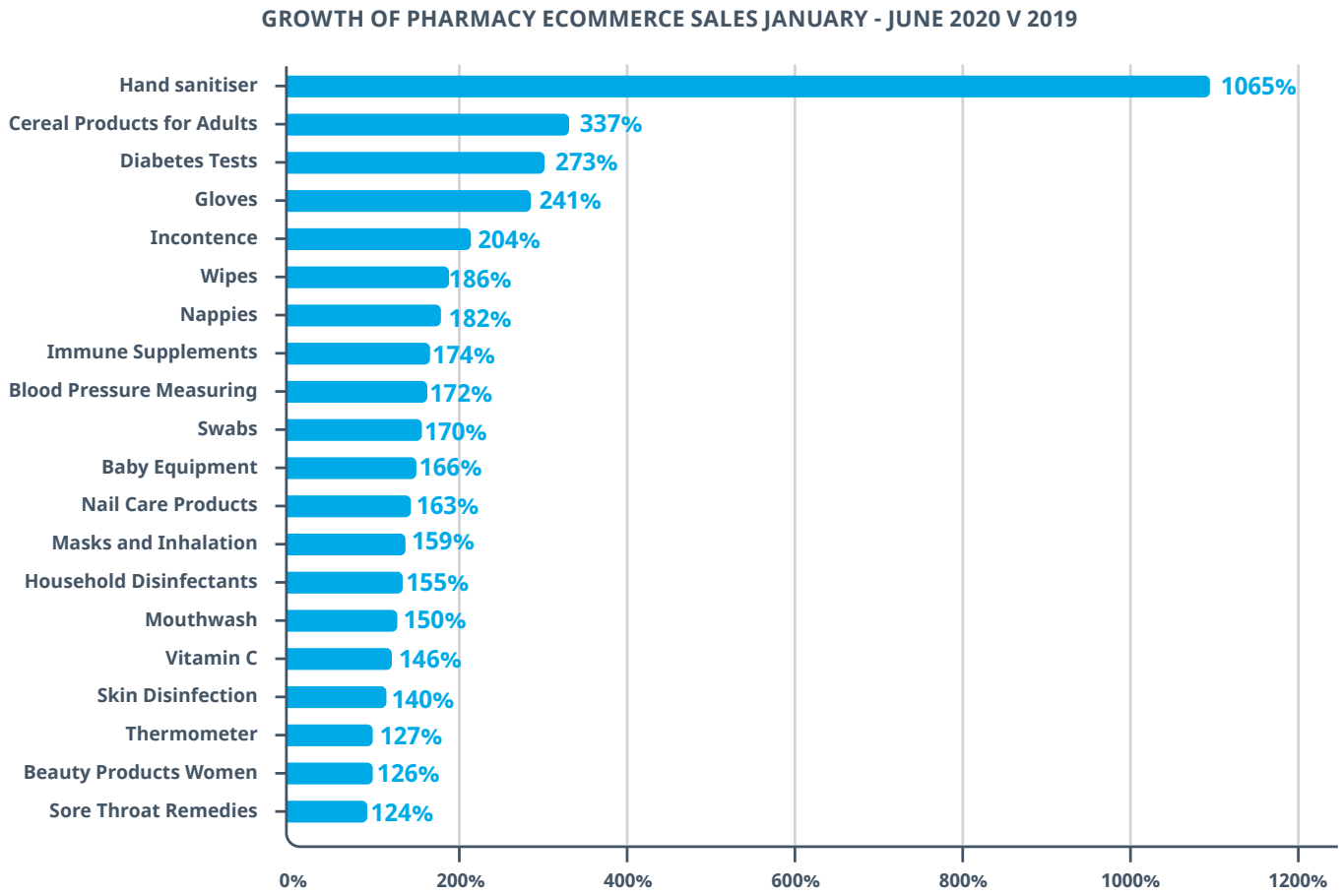


Figure 26: Growth % of Pharmacy eCommerce by Category (Rank by Growth %)

Source: IQVIA Pharmacy Scan data

A significant shift towards the purchasing of consumer health items online has taken place this year, with the total share of online sales reaching almost 5%. Most categories have doubled, or even tripled, their proportion of online sales, and three categories now have more than 10% of their total sales purchased online, including fragrances, hair loss and family planning (Table 1).

COVID-19 can be expected to have a long-lasting impact on e-commerce pharmacy sales, with changes in consumer shopping behaviour likely to continue to drive increased online purchasing growth.

RANK	CATEGORY	% OF CATEGORY SALES ONLINE APRIL 2019	% OF CATEGORY SALES ONLINE APRIL 2020
1	Fragrances	5.0%	17.3%
2	Hair Loss	11.0%	15.5%
3	Family Planning	4.7%	10.6%
4	Insect	3.8%	9.7%
5	Baby	5.3%	9.3%
6	Cosmetic Skin Care	3.2%	8.7%
7	Weight Management	4.9%	8.5%
8	Talcs	2.9%	7.3%
9	Vitamins & Supplements	4.1%	7.0%
10	Deodorants	2.4%	6.9%

Table 1: Proportion of OTC Pharmacy Sales Purchased Online April 2019 vs April 2020)

Source: IQVIA Pharmacy Scan data

Promotional Deployment During COVID-19

KEY INSIGHTS:

Pharmaceutical companies have been forced to pivot rapidly to remote engagement strategies post COVID-19 lockdown, with 90% of detailing conducted remotely by April 2020.

General practitioners indicate email as their preferred communication channel with the industry throughout the pandemic, with lower but growing interest in remote detailing technologies

Whilst some early feedback is positive, more time and experience are required to determine the most appropriate and effective use of remote detailing technologies.

The past six months have seen significant and unplanned upheaval for the pharmaceutical industry in the area of promotional deployment, as COVID-19 lockdown restrictions have prohibited face-to-face interactions. Pharmaceutical companies have been forced to pivot rapidly to remote engagement strategies to ensure that healthcare professionals and patients continue to receive the information and services they need. This shift has been required across all deployed resources, including sales representatives, medical science liaisons, and clinical nurse educators.

Feedback from Australian general practitioners and specialists captured through IQVIA's ChannelDynamics survey on promotional activities, indicates that before the pandemic pharmaceutical companies continued to invest heavily in traditional face-to-face channels. Those with a digital presence primarily utilised emails, and e-detailing was very limited. Consequently, March and April saw an immediate reduction in interactions between the pharmaceutical industry and healthcare professionals (Figure 27).

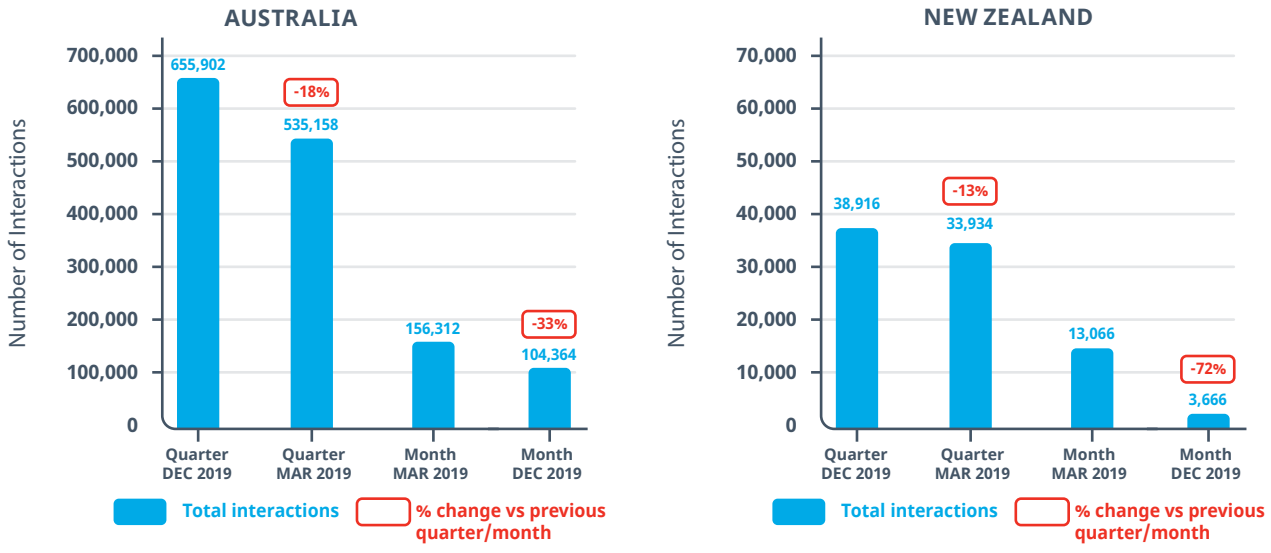


Figure 27: Total Interactions (All Channels)

Source: IQVIA ChannelDynamics ANZ

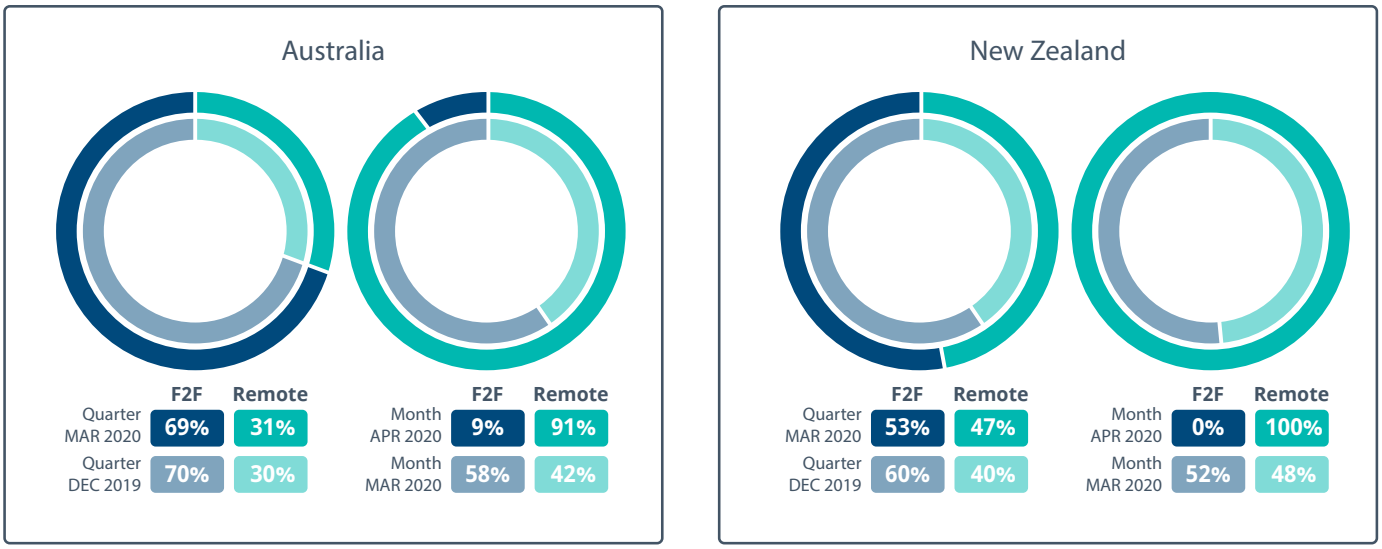


Figure 28: Face-to-Face versus Remote Interactions

Source: IQVIA ChannelDynamics ANZ

At the early onset of the pandemic in March, promotional trends for general practitioners were similar across Australia and New Zealand, however by April a far greater impact was observed in New Zealand, with a -72% drop in total interactions as the country entered a strict level four lockdown. By comparison, the drop in Australia was -33% compared with previous month.

Companies' ability to shift promotional efforts from live to virtual channels has become critical to enabling sales team interactions with healthcare professionals to continue. From a starting position of heavy reliance on face-to-face detailing prior to the pandemic, by April 2020, over 90% of details in Australia were remote, and activity in New Zealand was fully remote (Figure 28).

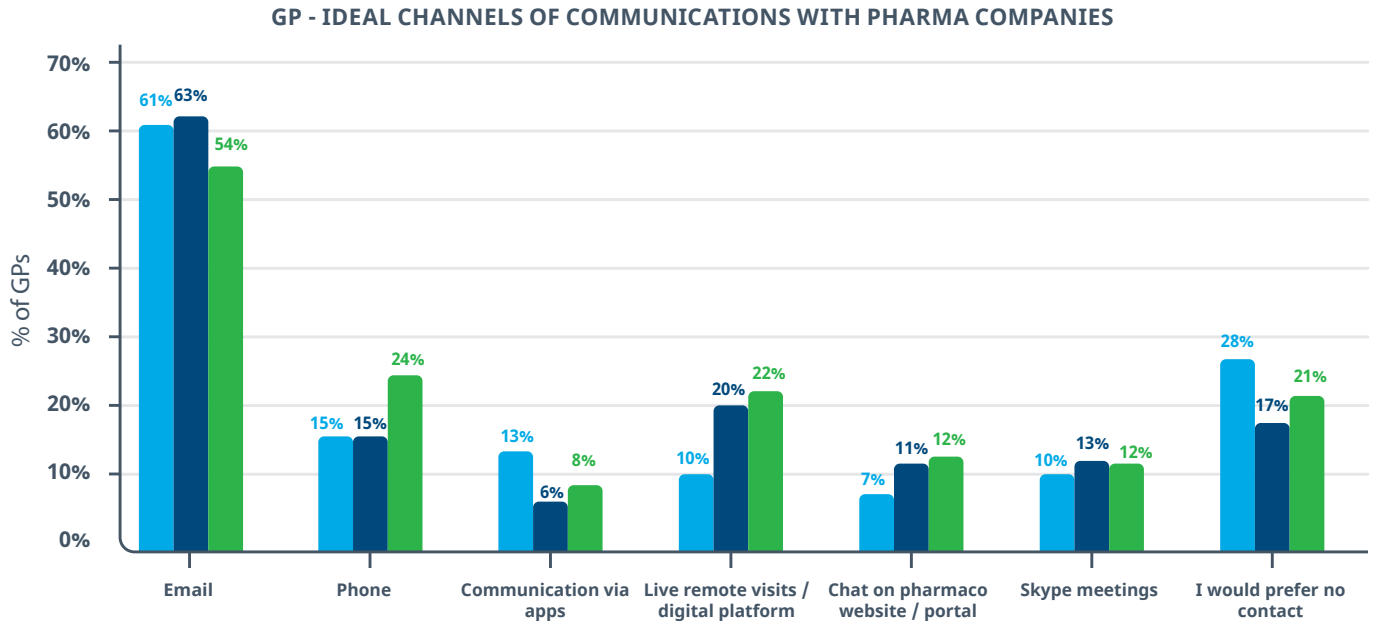


Figure 29: GPs' Reported Ideal Communications Channels with Pharma Companies

Source: IQVIA Medibus AU July 2020

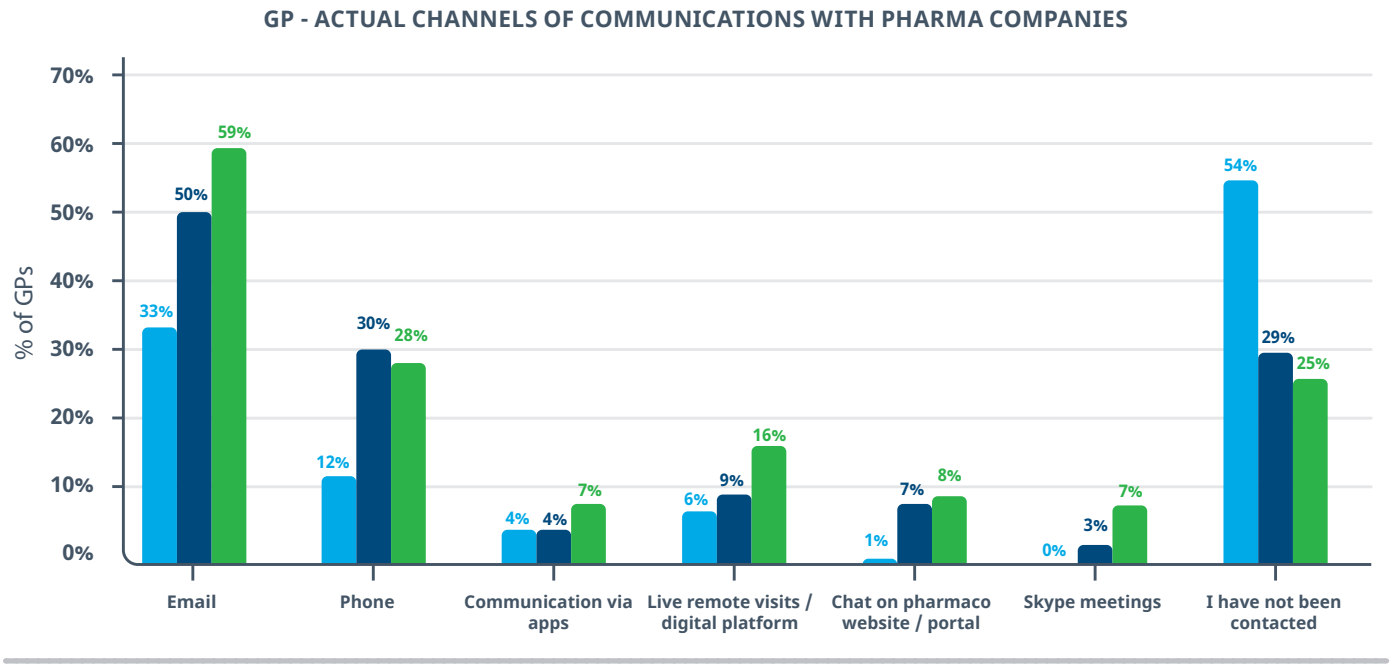


Figure 30: GPs' Reported Actual Communication Channels with Pharma Companies

Source: IQVIA Medibus AU July 2020

IQVIA has surveyed healthcare professionals to understand their evolving preferences regarding communication channels with the pharmaceutical industry throughout the course of the pandemic. In April, surveyed general practitioners initially indicated a clear preference for email as their ideal communication channel, whilst over one-in-four (28%) stated they would prefer no contact with the industry at this time. Preferences have evolved as of the latest survey conducted in July, with increasing preference for phone and live remote detailing, with four-in-five GPs indicating that it is important for them to maintain contact with the pharmaceutical industry during this period (Figure 29).

Analysis of the actual communication channels received by the same surveyed GPs throughout the pandemic (Figure 30) suggests that the industry has been able to respond appropriately to the evolving preferences expressed. The use of email detailing has increased and now aligns with the reported ideal in July, and the use of live remote detailing has steadily increased between April to July. GPs have also reported a recovery in the overall level of communication received from the industry from April onwards. Whilst over half of GPs received no contact in April, this has dropped to 25% in July, which aligns with the proportion of GPs who prefer not to be contacted.

As the broader mix of channels has continued to evolve over subsequent months, varying perceptions towards remote detailing amongst specialists and general practitioners are emerging (Figure 31). Feedback suggests a higher acceptance of remote detailing among specialists, who report four-in-ten interactions via phone or web-enabled platform (e-detail). Oncologists, rheumatologists and neurologists report a higher share of e-detailing, whilst amongst general practitioners, usage remains very limited, albeit gradually increasing month-on-month.

With the use of remote detailing slowly increasing, the technology is emerging as a potentially suitable tool for engagement as both the industry and healthcare professionals gain experience in using it effectively. Whilst adoption remains slow at this stage, surveyed GPs acknowledge that remote detailing is useful if used in the right circumstances, and that it can be associated with potentially greater impact than face-to-face or phone detailing.

	F2F DETAIL	F2F MEETING	E-DETAIL	PHONE DETAIL	E-MEETING	EMAIL	POSTAL MAIL
General Practice	22%	-	7%	16%	5%	23%	26%
General Practice	13%	13%	20%	16%	5%	21%	12%
Rheumatology (RA)	12%	2%	27%	27%	5%	20%	7%
Neurology (MS)	7%	6%	31%	33%	-	17%	6%

Figure 31: Share of Interactions by Channel

Source: IQVIA ChannelDynamics AU

Overall, the feedback provided by clinicians highlights the challenges involved in changing established behaviours, as well as the potential for greater use of remote technologies in the future. The preference for face-to-face interactions with sales representatives, particularly among general practitioners, is heavily entrenched, and e-detailing will take some time to become established. Flexibility is more important than ever in the COVID-19 environment, and representatives still need to tailor their interactions to ensure that they meet the needs of their individual customers. As healthcare professionals work through the challenges of managing evolving patient needs, it will be critical for the industry to offer flexible engagement strategies, striking an appropriate balance between face-to-face and remote calls, as well as patient-centric tools, training and support solutions, whilst demonstrating sensitivity to new safety and compliance procedures necessitated by the pandemic.

Outlook for Clinical Development and Evidence Generation

Six months on from the start of the global coronavirus pandemic in Wuhan, China, scientists around the world are working at breakneck speed to find a solution to halt the virus that has placed so many aspects of global daily life on hold[16]. Much hope hangs on finding an effective vaccine to prevent transmission of the virus, a solution that will enable a sense of normalcy to return. Therapeutic interventions that treat the symptoms of the virus and reduce the severity and mortality of the disease are also being pursued. Several key players in the biopharmaceutical industry have joined forces with biotech companies, universities and government agencies in the hope of developing solutions to treat or prevent COVID-19[17].

KEY INSIGHTS:

Unprecedented acceleration in clinical development timelines has been achieved, with multiple vaccine candidates publishing positive phase 1/2 trial results, and two therapeutics already shown to be effective against COVID-19 in randomised controlled trials.

Virtual trial processes have proven critical to maintaining continuity in clinical research throughout the pandemic, to overcome recruitment challenges whilst also driving a shift towards a more patient-centric model for clinical research.

The pandemic has highlighted an increased need for real-world data, both to generate timely insights to inform critical decisions, as well as to fill data gaps in randomised controlled trials caused by COVID-19 disruption.

COVID-19 Clinical Trials Update

It is widely accepted that SARS-CoV-2 will only be effectively contained with mass vaccination. As of early August 2020, there are currently at least 25 vaccine candidates under clinical evaluation[18], and more than 130 in preclinical evaluation , according to a WHO landscape assessment. A wide variety of approaches are under investigation, including adapting technologies from licensed vaccines, as well as new technologies, such as mRNA and DNA vaccines.

Key vaccine candidates are outlined in Table 2 below. At this stage, it not known which approach will work best. However, there is a need for vaccines to be efficacious in different populations, including children, young healthy adults, the elderly, and special populations, such as those who are immunocompromised, and consequently, having multiple options is likely to be essential for ensuring sufficiently broad vaccine efficacy as well as supply.

VACCINE TECHNOLOGY	TIMELINES	DEVELOPER
Molecular clamp	Phase 1 commenced 13 Jul 20	Uni Q / CSL
Recombinant (with adjuvant)	Phase 1 reporting Aug	Clover / GSK
	Phase 1 launched May 20, human results report 4th Aug	Novavax/Takeda
	Phase 1 completed Jul, phase 2 planned Sep 20.	Vaxine
	Phase 1 start Sep	Sanofi/GSK
mRNA	Phase 1 published NEJM, phase 3 launched 27 Jul 20	Moderna
	Phase 1 commenced 29 Apr 20, lead candidate selected and global phase 2/3 study started	Pfizer/BioNtech
	Phase 1 Planned late Q3	Sanofi/Translate
DNA	Interim phase 1 reported, not yet published. Phase 2/3 trial planned to start later Q3	Inovio
Viral vectors	Phase 1 published NEJM 20 Jul 20, phase 2/3 trials underway	AstraZeneca/Vaccitech/Oxford
	Phase 1 results published May 20, reported 20 Jul 20 that phase 2 results demonstrated immune response (Lancet)	CanSino
	Phase 1/2 trials launched Jul, phase 3 planned to start in Sept	Johnson & Johnson
Whole cell / inactivated	Phase 1 results announced Jun, phase 3 trial launched in Brazil	Sinovac Biotech

Table 2: Key vaccines in development

Source: Source: New England Journal of Medicine, Vaccine Platforms, Attributes and Status of Candidates[19]

Some of the biggest challenges to the success of a vaccine against COVID-19 are likely to occur in the manufacturing and distribution of sufficient vaccine doses. To inoculate the global population upon approval of a vaccine will require manufacturers and distributors to ramp up rapidly to unprecedented volumes of supply. A complicated supply chain of unparalleled scale will be required, involving securing raw materials and factory capacity to manufacture in large volumes, and the equipment to transport millions of doses subject to stringent security and temperature controls.

Due to the urgency of the current crisis, governments and manufacturers have already started to plan for manufacturing at risk, prior to the demonstration of suitable efficacy and safety. The US government has allocated $10 billion for Operation Warp Speed, an initiative that aims to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021[20].

The Australian government has confirmed an agreement with AstraZeneca to secure at least 25 million doses of leading vaccine candidate, ChAdOx1 nCoV-19 or AZD1222, co-developed by Oxford university and AstraZeneca, if trials are judged to be successful, safe and effective. The deal will ensure a guaranteed supply of the vaccine to be provided free to every Australian[21]. IQVIA is partnering with AstraZeneca to accelerate development of the vaccine, with the aim of driving faster delivery of clinical studies in the U.S. aimed at demonstrating efficacy of AZD1222. The initiative includes an expansive subject study and will leverage IQVIA's virtual trial solutions[22].

In parallel with efforts to develop a safe and effective vaccine against COVID-19, research is also underway to identify treatments to reduce the severity and associated mortality of the disease.

Several other areas are also under investigation, including anti-viral therapies, anti-malarials, and convalescent plasma.

The pace of development in the area of therapeutics has also been striking, with two repurposed therapeutics already confirmed in randomised controlled trials as being effective against COVID-19 infection, including the anti-viral remdesivir[23] and the corticosteroid dexamethasone[24].

Challenge of Pre-Peer Review Data Dissemination

Since the start of the pandemic there has been a remarkably rapid growth in the number of research papers generated relating to COVID-19 (Figure 32). A significant proportion of these papers have been released to pre-print sites without undergoing the usual peer review process. The adaptive approach has been justified in the context of a global health crisis and the need for expedited dissemination and sharing of data to inform clinical decision-making. However, there is legitimate concern over the risks posed to patients by the potentially premature adoption of therapies based on incomplete or flawed trial results released into the public domain without the scrutiny of peer-review.

The most serious challenge, however, has arisen following the retraction by the New England Journal of Medicine (NEJM) and Lancet in June 2020 of two published registry studies utilising the patient database of Surgisphere, a US-based healthcare analytics company. In each case, concerns were raised about the veracity, methodology and integrity of the database and published analyses. When Surgisphere declined to cooperate with an independent third-party audit, both papers were retracted by the academic co-authors.

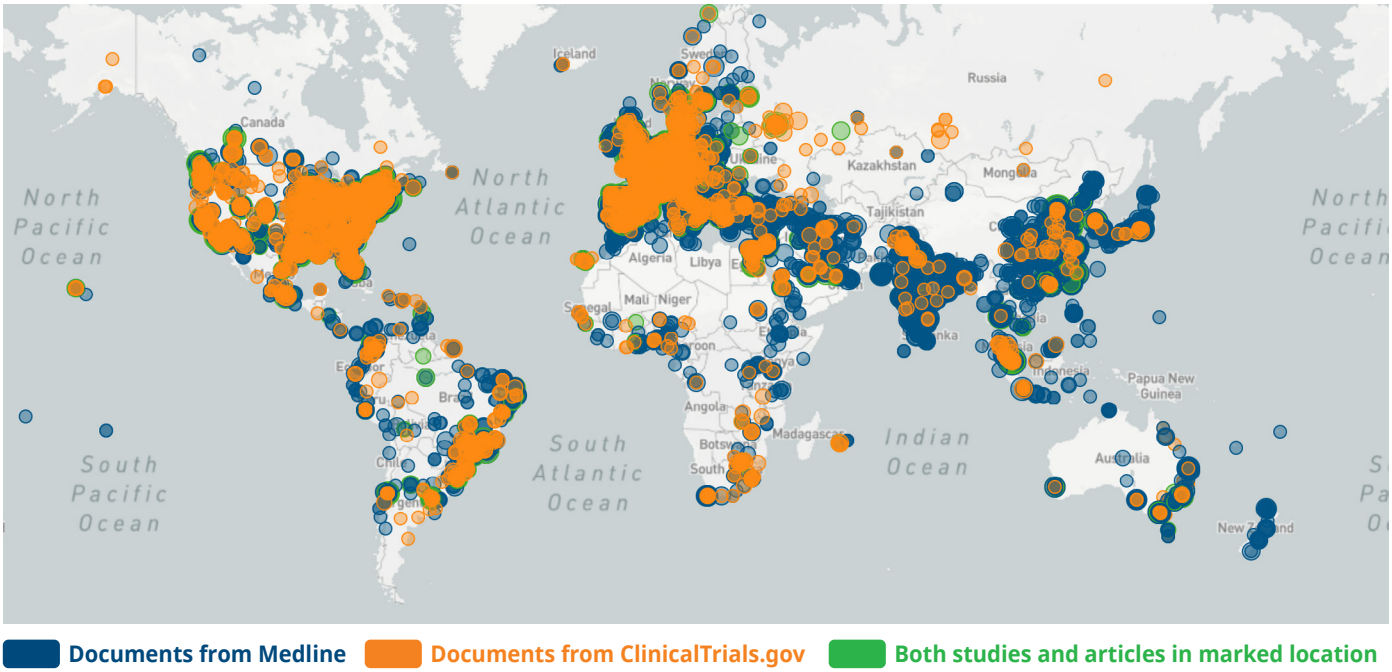


Figure 32: Locations around the world where COVID-19 studies are being run and COVID-19 scientific abstracts are being written

Source: IQVIA Linguamatics Natural Language Processing[25]

This had a direct impact on trials such as SOLIDARITY, where the HCQ treatment arm was immediately stopped, only to be restarted following the retraction of these articles. The WHO subsequently discontinued the HCQ arm, as well as the lopinavir/ritonavir arm, from the SOLIDARITY randomised trial after concluding no evidence of a reduction in mortality in hospitalised COVID-19 patients.

Virtual Trials and a Shift to a Patient-Centric Approach

Australia's clinical trial industry recognises that until an effective vaccine or treatment is developed, clinical trial activities will continue to be conducted in a highly constrained environment limited by the continuation of many lockdown measures[26]. The recruitment of patients to clinical trials has been significantly impacted during the pandemic. Trials involving immunocompromised patients or investigational products that may modulate the immune system have been put on hold. Additional factors, including limitations on global investigational product supply and distribution, the location of clinical research monitors, and a reduced patient willingness to attend trial sites and undergo trial interventions, have further limited recruitment. Such a trend has been observed globally and presents a challenge to the clinical trial industry.

The ability to maintain continuity in clinical research throughout the pandemic is critically important. IQVIA has investigated globally how sites and clinical research organisations are utilising a variety of approaches in order to allow research activities to continue[27].

One important pillar of the industry response has been the accelerated adoption of virtual processes, which enable standard clinical trial procedures normally conducted face-to-face, such as consenting, drug administration, patient consultation and data monitoring, to be completed remotely[28].

These virtual processes help to maintain trial continuity during restricted travel periods and reduce opportunities for COVID-19 exposure. There are further benefits for sites in reducing requirements for personal protective equipment (PPE) and associated safety and compliance procedures, as well as for patients in improving convenience.

Remote monitoring solutions have evolved, with an increasing number of sites now establishing solutions that enable remote access to patient medical records for the purpose of source data verification (SDV). Each site solution is unique and requires careful consideration to assess the extent of source data that is remotely available, while weighing potential risks relating to patient privacy, confidentiality and IT security. Trial sponsors are being increasingly challenged to develop and support flexible monitoring solutions that may include partial SDV and a combination of remote and on-site visit activities.

Many of these steps were adopted for immediate use during the early phases of the pandemic. To ensure consistency in application, these processes should now be standardised nationally and embedded as best practice for future clinical research. It will also be critical to ensure that new virtual processes can be accepted by study patients.

Future trials must be designed to be adaptable to patients, whilst still adhering to site and country regulations. The most effective solutions to manage the challenges related to patient recruitment, trial management, monitoring and delivery will be patient-centric and virtual in nature. The evolution of trial technology and patient-centric services such as tele-health and in-home treatment has enabled more decentralised trial designs.

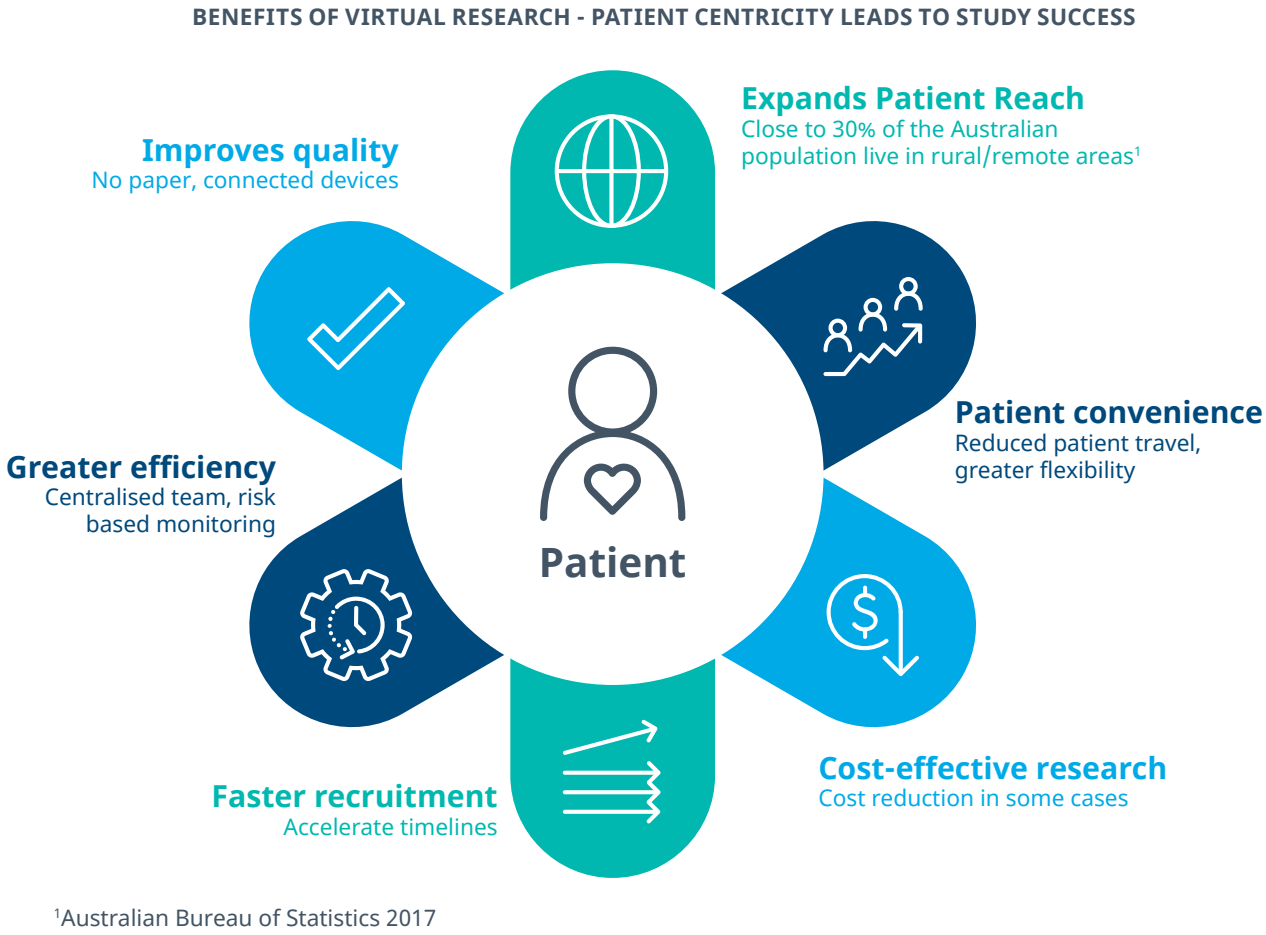


Figure 33: Benefits of Virtual Research

Source: IQVIA Thought Leadership

Future trials are likely to involve both traditional and virtual elements. Patient-centric studies have the potential to significantly increase patient recruitment and retention while enabling participation from more diverse patient populations.

Virtual trial designs can utilise connected smart devices for collecting and monitoring data, that can be harmonised through advanced analytics to support patient safety and data quality monitoring (Figure 33)[29].

A Growing Role for Real-World Data

The pandemic has served as a wake-up call for healthcare systems, which have been unprepared for the speed and scale of the outbreak. Traditional methods of generating evidence through randomised control trials have been challenged, and research papers have been published and subsequently retracted. Yet, at the same time, these lessons may also serve as a catalyst for positive change. The need for a coordinated, more interdisciplinary approach to the prevention, detection and action against major infectious disease outbreaks has been highlighted.

The experience of the first six months of the pandemic has highlighted the importance of timely access to data for research purposes -to understand the virus, its spread, and treatment responses.

Whilst randomised control trials unquestionably remain the gold standard in evidence generation, throughout the pandemic they have shown their limitations, particularly in relation to lengthy timelines. Meanwhile, real-world data has emerged as a critically important complementary tool for generating timely insights to inform critical decisions.

The pandemic has taught us important lessons about the quality of the data we rely on, and the importance of ensuring that data is appropriately interpreted. It has highlighted the challenges of data gaps and inconsistencies between and across countries and healthcare systems.

Consequently, it is interesting to consider whether the pandemic may have played out differently had a fit-for-purpose real-world data ecosystem been in place. Plausibly, the right real-world data technologies could have enabled more efficient management of community spread, outbreak clusters and contract tracing. . Timely access to high quality and interoperable data could have facilitated improved decision-making surrounding patient treatment and management to support public health strategies.

Furthermore, there may be an increased need for real-world data and evidence to address data gaps caused by disruption to clinical trials as a result of the pandemic, according to IQVIA research conducted with European payers in May 2020. Whilst it is not expected that COVID-19 will lead to a relaxation of existing evidence requirements, post-launch real-world data collection may be considered as an option to address data uncertainties, and/or to substantiate efficacy and safety claims in certain cases, particularly for highly innovative products where initial available data suggests a high clinical benefit or cost saving. Examples may include leveraging digitised healthcare data, such as claims or electronic medical records, in enriched studies, or using real-world cohorts to generate comparator data or contextualise trial information. These approaches are more likely to be appropriate in borderline cases when near-complete data is available, or when there is strong justification for not repeating trials, for example, when no other therapeutic options are available. There is also strong evidence that real-world evidence can be used as a strategic differentiator which contributes to commercially successful launches[30].

Looking ahead

Five months since the declaration of the global pandemic, as Australia and New Zealand battle to contain second waves of COVID-19 infections, the broader and longer-term impacts on the healthcare system are starting to be felt.

Uncertainly remains in the global outlook for COVID-19 clinical development. Notwithstanding the unprecedented progress to date, it is not yet known whether or when a vaccine will be proved successful and made widely available worldwide. The completion of phase 3 clinical trials demonstrating safety and efficacy is required before any timeline for availability can be confirmed. January 2021 represents a key milestone, as the timeframe within which Operation Warp Speed aims to make vaccine doses broadly available.

In Australia, the demand for prescription medicines currently remains suppressed following the peak in demand in March. Whilst rates of treatment for many chronic conditions have stabilised, there is increasing evidence to suggest that delays in the diagnosis and treatment of certain conditions, in particular cancer patients, is taking place, which raises concerns over longer term health outcomes. At the same time, the rising trend in presentations and initiations to treatment for several mental health disorders reflects the strain of the pandemic and prolonged lockdown restrictions.

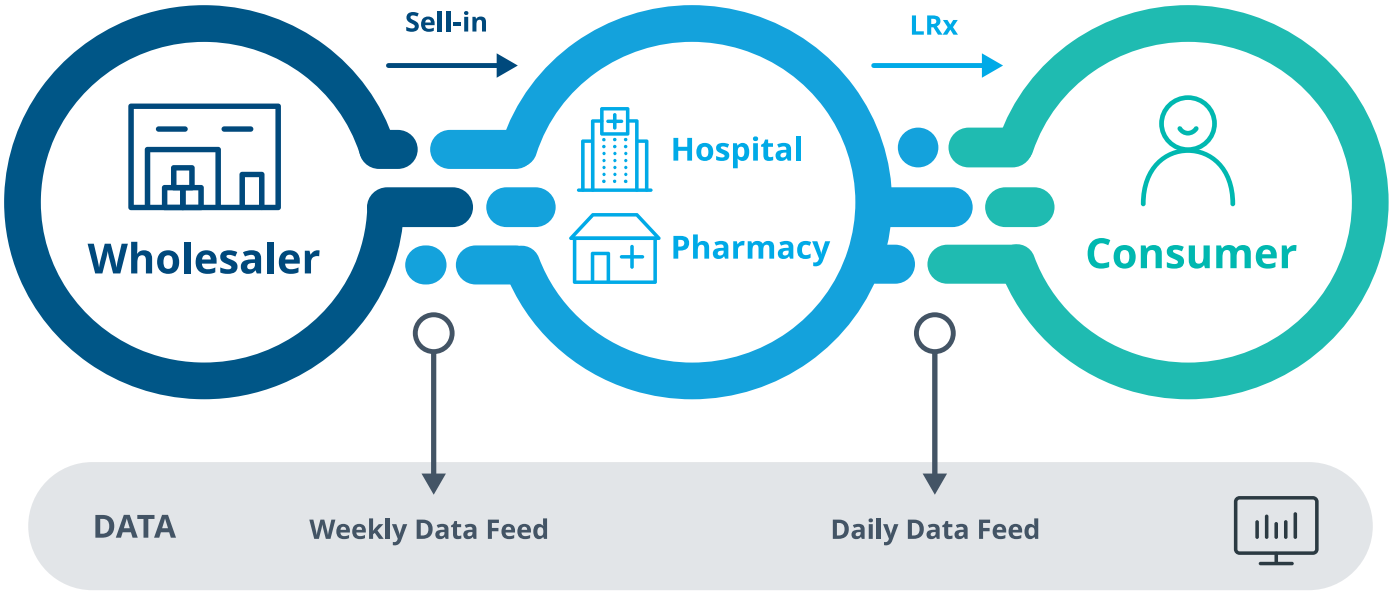
Purchasing patterns for consumer health products have been volatile since the outbreak of the pandemic, with losses in recent months now offsetting high purchasing observed during the initial stockpiling in March. Behavioural changes and reduced willingness to spend have further dampened demand and can be expected to persist throughout the economic downturn.

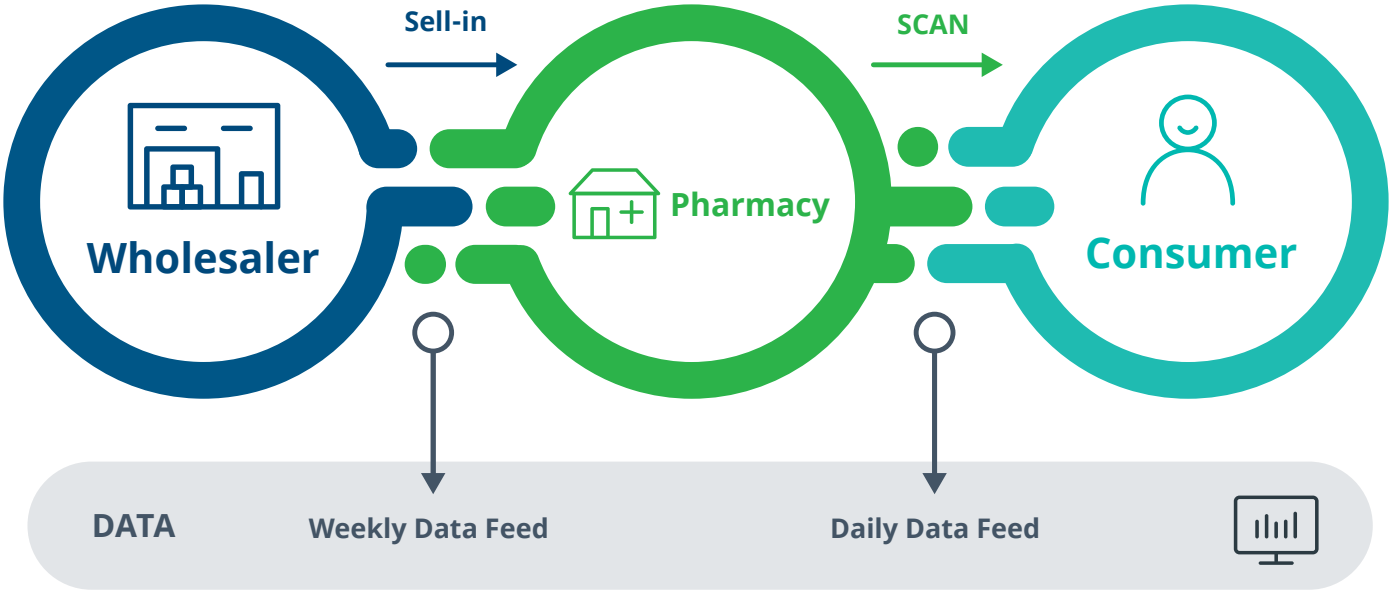
The effects on clinical research have been widespread, due both to the re-prioritisation of research efforts towards COVID-19 treatment and vaccine trials, as well as the disruption in recruitment and everyday trial activities caused by lockdown restrictions. However, the subsequent shift to a virtual trial model offers benefits for all stakeholders and can be leveraged as a move to greater patient-centricity in clinical research.

Key challenges for the industry will be to listen to the evolving needs of patients, consumers, clinicians, and healthcare providers, and to demonstrate the ability to adapt accordingly. The COVID-19 environment requires a shift from traditional approaches, in the methods we use to generate evidence, how we offer health services and how we interact with patients and healthcare professionals. Innovative technologies and virtual solutions that facilitate remote communications will be critical to enabling continuity in all of these fields, and ultimately to developing patient-centric solutions and services that lead to improved health outcomes. Timely access to robust and interoperable data will be essential to support improved decision-making surrounding patient treatment and public health strategies.

IQVIA data assets

IQVIA's proprietary data assets cover all stages of the supply chain in Australia:





IQVIA Longitudinal Prescription (LRx) Dispensed Data [Sell-out]

- Longitudinal prescription data captured from panel of over >4,500 retail pharmacies across Australia and coverage of approximately 75% of script volume dispensed through retail pharmacy
- National, state, and sub-state levels of reporting available
- Data available with daily frequency
- De-identified patient ID allows for longitudinal tracking at patient level

IQVIA Wholesaler Prescription and Non-prescription Supply Data [Sell-In]:

- Manufacturers ex-factory data received from more than 80 suppliers containing direct sales to pharmacies, hospitals and other outlets such as medical centres, prisons, ambulance services, aged care facilities, dentists and others
- Distribution data received from all major wholesalers and other distributors (e.g. DHL)
- Data from compounding houses
- Data from pharmacy chains, such as the Chemist Warehouse Group
- Coverage of 97% of all consumer health sales into Australian pharmacies

IQVIA-Nielsen SCAN Data – Non-prescription Dispensed Data [Sell-Out]

- Over-the-counter, nutrition, patient care and personal care products from 3,964 pharmacies
- Coverage of 90% of all consumer health sales in Australian pharmacies
- National, state, and sub-state (SA3) levels of reporting available
- Data is available with daily frequency

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