Delays in receiving scripts and biologic medication – A national survey

Report

June 2022

1. Introduction

Musculoskeletal Australia (MSK) and Arthritis Australia conducted a survey of consumers regarding delays in receiving biologic and targeted synthetic disease-modifying anti-rheumatic drugs (b/tsDMARDs) scripts and medications. The survey was prompted by anecdotal reports from consumers about delays and the impacts on their health.

Biologic DMARDs (also called 'bDMARDs' or biologics') are a class of disease-modifying anti-rheumatic drugs used to treat inflammatory musculoskeletal conditions. They are grown from biologically sourced cells. These medications are given as an injection under the skin or infusion. A biosimilar is almost an identical copy of an original product that is manufactured by a different company once the patent of the originator biologic expires (similar to a generic drug). A biosimilar works in the same way as the reference biologic. Targeted synthetic DMARDs (tsDMARDs) are medicines with similar cost, the same eligibility criteria and approval process.

b/tsDMARDs are in the authority-required category of the Pharmaceutical Benefits Scheme (PBS). These medications can only be prescribed by rheumatologists and clinical immunologists for patients who meet strict criteria including trial and failure of conventional DMARDs. The application to initiate b/tsDMARD treatment on the PBS must be submitted to Services Australia (Medicare) for prior approval. Continuation with b/tsDMARD therapy through the PBS also needs to be pre-approved by Services Australia based on a positive response to the b/tsDMARD as measured by improvements in blood chemistry levels and reduction in the number of affected joints.

We strongly welcome the Pharmaceutical Benefits Advisory Committee's (PBAC) recommendations in March 2022 to change the 'authority required' arrangements governing the use of some of the b/tsDMARDs and biosimilars. We urge the government to swiftly accept and implement these changes, which should improve the timeliness of access to medications for some patients. However, the recommended changes exclude all patients on b/tsDMARDs for psoriatic arthritis and people with ankylosing spondylitis prescribed originator biologics, as well as those taking a biologic or targeted synthetic DMARD without a corresponding biosimilar available. Hence the current challenges will remain for those consumers. In addition, the findings of this survey identify other possible barriers to timely access and also reveal the serious impacts of delays.

2. How we developed the survey and interpreted the results

The survey was developed with input from MSK's Consumer Advisory Committee and Arthritis Australia's Consumer Advisory Panel. The survey was made available online and open for four weeks in early 2022 and was promoted regularly via social media and other electronic means with the assistance of other organisations including the Australian Rheumatology Association, Dragon Claw, Creaky Joints Australia and some of the other Arthritis Foundations in other states.

To assist in the interpretation of the results we also spoke with the Australian Rheumatology Association to get an understanding of the process and systems used in prescribing b/tsDMARDs.

3. Things to consider when reading this report

People responding to the survey were self-selected, and we specifically targeted those who had experienced delays in receiving b/tsDMARDs. Although they do not necessarily reflect the perspectives of all people on b/tsDMARDs, they provide important insights into the impacts of these delays and potential reasons as to why they occur.

From July 2021 there have been shortages in supply of tocilizumab (Actemra®) and abatacept (Orencia®) in Australia due to global demand. We explored whether shortages in these medications may have explained the delays. However, when we removed the data of those that were taking tocilizumab (Actemra®) and abatacept (Orencia®), there was no major difference in the overall results for any of the survey questions.

4. Who responded to the survey

Responses to the survey were received from 290 people. The majority of these were aged between 55–64 years (29%) followed by people aged 65–74 years (25%) and 45-54 years (18%). Some parents of children with juvenile idiopathic arthritis (JIA) also responded (3%).

People living in large metropolitan cities were the largest group of survey respondents (51%) with most others indicating that they lived in either a large regional city, town or area (48%). Three respondents lived in remote areas.

Rheumatoid arthritis was reported as the main condition for which respondents were prescribed a b/tsDMARD (71%) followed by psoriatic arthritis (17%), ankylosing spondylitis (13%), JIA (4%), non-radiographic axial spondyloarthritis and giant cell arteritis.

Seventy-seven per cent of people saw their rheumatologist privately with only 15% seeing a rheumatologist in the public sector and 5% indicating they saw a rheumatologist in both private and public settings.

The b/tsDMARDs most commonly used by survey respondents are listed in Table 1.

Table 1: b/tsDMARD most commonly prescribed to survey respondents

Active ingredient	Brand name	Percentage of survey respondents
adalimumab	Humira	19%
abatacept	Orencia	18%
tocilizumab	Actemra	15%
upadacitinib	Rinvoq	11%
etanercept	Enbrel	8%
tofacitinib	Xeljanz	6%
certolizumab pegol	Cimzia	5%
golimumab	Simponi	5%

The majority of survey respondents had been first prescribed b/tsDMARDs more than two years ago (60%) and 19% had been on b/tsDMARDs for the last 1-2 years. Eleven per cent indicated that they had been prescribed b/tsDMARDs within the last six months.

5. Reporting of delays

These results explore the extent to which delays were experienced. As part of the reporting, we also considered whether these results were due to the supply shortages of tocilizumab (Actemra®) and abatacept (Orencia®) arising during the COVID-19 pandemic. The results were similar even after the responses of people using these medications were removed.

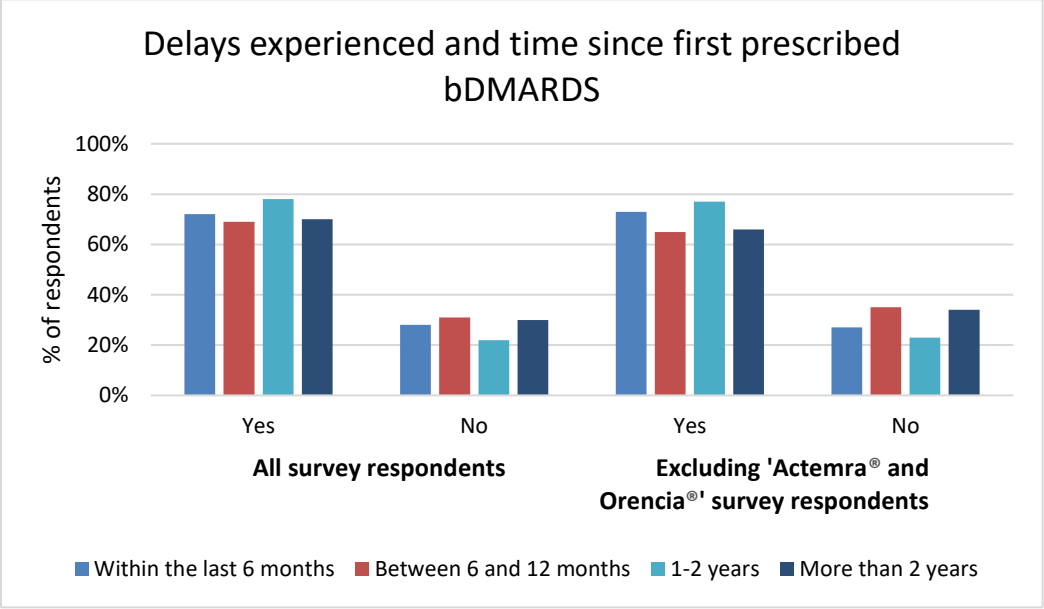
Seventy-one percent of all respondents indicated they had experienced delays in obtaining their b/tsDMARDs after seeing their rheumatologist or specialist in the last two years. Sixty-nine percent of respondents still indicated that they had experienced delays, even after those taking tocilizumab (Actemra®) and abatacept (Orencia®) were removed.

In relation to the number of times people had experienced delays, 48% indicated delays twice in the last two years and 19% indicated that they had experienced delays three times or more. After, removing the respondents taking tocilizumab (Actemra®) and abatacept (Orencia®), 51% indicated they had experienced delays twice in the last two years and 17% indicated that they had experienced delays three times or more.

With regards to the length of the delay, 39% percent stated that it was more than four weeks and 32% indicated it was for 3-4 weeks. After removing tocilizumab (Actemra®) and abatacept (Orencia®) responses, 41% stated delays of more than four weeks and 31% reported delays of 3-4 weeks.

Also, the length of time that people had been using b/tsDMARDs didn't seem to provide a different experience of delays see Chart 1 below.

Chart 1: Length of time using b/tsDMARDs and the experience of delays



6. Consumers' understanding of administrative arrangements for accessing b/tsDMARDs

Survey respondents were asked if they knew how their rheumatologist submitted the request for their b/tsDMARD to Services Australia. The majority of people did not know how this was done (76%), but 22% indicated that it was submitted online or via email.

7. Consumer's understanding of reasons for delays in receiving scripts

The majority of survey respondents were not told the reason for the delays in receiving their script (55%). However, for those who were told, the following reasons were reported.

For people using tocilizumab (Actemra®) and abatacept (Orencia®), they were told that their medication was delayed due to the international shortage of these drugs.

For those not using tocilizumab (Actemra®) or abatacept (Orencia®), delays were reportedly due to the 'workload in the government department and postal delays', as typified by the following:

> *'Script not processed in time and delays with post. Not sure why cannot be emailed to chemist. Happens due to long closure at place who approves, mine is always dec (sic) delays, left 2 weeks before processing after arrival, so do not get back until 2nd week in jan (sic).'*

> *'Rheumatologist has to send script for approval then it gets sent back to them and they forward to me. Told to expect delays due to timing of approval and mail.'*

'The prescription was delayed in the mail to my address at Christmas time. My rheumatologist provided me with the medication from his practice.'

'My prescription approval was sent by post and approvals are now taking more than 5 weeks.'

'My specialist posts the application and it is returned to me via post. The last one took 7 weeks to arrive so I was without any injection for 3 weeks which affected my skin and joints.'

Other respondents expressed their frustration at what they saw as an approval process that was too lengthy and not utilising more current and efficient methods of communication.

'Just the stress of it. I have always wondered why they could not do everything electronically like they do with Medadviser, but with a step for Medicare approval.'

'Worrying about delays causing flare-ups. Script sent to home & post always delayed and reduced deliveries … would love it if sent by email to pharmacist.'

8. Impact of delays

Survey respondents were asked to detail the impact of delays on their quality of life and a large number of responses were received.

Given b/tsDMARDs are designed to reduce disease activity, many people reported that they experienced flares, pain and fatigue as a result of medication delays. As a consequence of increased pain and fatigue, mobility, sleep and physical functioning were affected.

'I suffer badly, can't sleep, joints stiffen and I just feel terrible.'

'It took 7 weeks for my script to be sent to me. I had 4 weeks of sample medication then had to stop till I received my script. This delayed any benefit I was getting and my joints continued to be inflamed.'

Major impacts on family life, caring responsibilities, work and activities of daily living were reported.

'The whole Xmas period I was feeling dreadful and without medication. Impacted ability to care and engage with young child. Distressing after long periods of lockdown.'

'Delayed medication. Increased pain. Inability to sleep. Increased brain fog. Affected ability to parent.'

'I am unable to enjoy physical activities with my family. I've had to get my support worker to work longer hours as I am unable to care for my kids alone. I have become isolated. Unable to drive long distances. My pain is uncontrolled.'

'Increased pain and stiffness. Reduced interaction and capacity to perform daily activities.'

'Pain and fatigue increased to a point of being unable to walk well at all. I had terrible joint swelling and had to take leave from work. I took myself to ED and from that point things turned around. Slowly but surely.'

Delays also interrupted the ongoing management of people's conditions. This was a major concern both for the adverse health impacts, and due to the risk that if treatment is interrupted, re-initiation of medication may not achieve the same level of disease control.

'My 12 yr old experienced significant pain again during the break in medication coverage (8 days). After restarting the med, she seems to not be getting the same amount of coverage since (9 days).'

'Every time there is a delay it causes a break in the treatment. So any side effects that you experience when you first take it come back when you start again. So for me, it is taking 6 weeks to get the script so I am always short at least 2 weeks.'

'Having to go without treatment lead to increased pain and decreased function. Also took longer to come back to baseline when the script did come through because it had gotten so bad.'

'I have developed autoantibodies to multiple biologic medications when delays have occurred in treatment and I am running out of options.'

'My DMARD requires a consistent, regulated once-monthly dosage schedule: script delays ruin this schedule and reduce the DMARD's efficacy – a cause for profound distress when this core aspect of my treatment regimen is so regularly compromised.'

Also, several people had to use steroids due to a flare, which potentially increased their immunosuppression, putting them at greater risk of a severe COVID-19, if infected.

'When there is a lapse in medicine there is increase in pain and then the medication is less effective. Often leading to needing to take steroids or change medication.'

'Went into a flare and had to start steroids to control til I received my script.'

Mental/emotional distress was also commonly reported as a major impact of medication delays as highlighted by the following comments:

'Creates anxiety waiting for the scripts, constant need to follow up with doctor to see if scripts are lost. Delays in taking medicine and therefore impacts pain levels.'

'Stress, worry about how delay of biologic will affect my condition and my day to day standard of life.'

A loss of control over personal circumstances and a sense of helplessness was also cited by several respondents.

'It is the biggest source of my anxiety related to my disease. I do not know for over a month if I'm approved for my DMARD the next 6 months. I always check the mail every day waiting. Then it repeats every time I see the rheumatologist every 6 months.'

'I was literally sitting in the chair at the clinic awaiting my IV infusion when told that my script hadn't been approved. They spent the morning chasing it up. The time before I had to chase and chase via phone and email the rheumatologist and the head nurse to get my script approved. More than anything it was stressful as I've already developed antibodies to Humira so I can no longer self-administer and that drug is no longer available to me and I have to use a different DMARD. My concern is if the delay causes worsening illness or prevents the medicine from working and then my treatment options become even more limited.'

9. Impacts on consumers with psoriatic arthritis and ankylosing spondylitis

Given that people with psoriatic arthritis and some people with ankylosing spondylitis are not covered by the changes within the recent PBAC recommendations, we specifically reviewed these responses to our survey to highlight the impacts, which are likely to be ongoing if there are no changes to the process for them to access their medicines.

48 respondents (17%) had psoriatic arthritis, of whom 65% (31) had experienced a delay, only three of whom appeared to have been affected by the medicine shortages. 27% (13) experienced a delay of more than four weeks, and 21% (10) experienced a delay of three to four weeks.

38 respondents (13%) had ankylosing spondylitis, of whom 70% (26) had experienced a delay, only two of whom appeared to have been affected by the medicine shortages. 52% (13) experienced a delay of more than four weeks, and 32% (8) experienced a delay of three to four weeks.

The impacts described were similar to those set out in the section above, including serious health impacts, stress and anxiety, and impacts on their ability to fulfil work and caring responsibilities:

'I suffered a regression of my disease, resulting in increased pain and extreme fatigue. The symptoms alone made me feel incredibly anxious and depressed, and now the ongoing effect is that I feel my life is completely at the mercy of health administrative processes. Someone has to "care" enough to process my request promptly so that I have no gaps in my treatment, and that distance from that person, and the lack of control I feel, scares me.'

'Having to go without treatment lead to increased pain and decreased function. Also took longer

to come back to baseline when the script did come through because it had gotten so bad.'

'My specialist posts the application and it is returned to me via post. The last one took 7 weeks to arrive so I was without any injection for 3 weeks which affected my skin and joints'

'I wasn't able to walk and was in a lot of pain. Couldn't go to work.'

One consumer described the difficulties in getting the script approved despite clear medical advice:

'Blood results showed inflammation and repeating tests were required despite rheumatologist explaining I had experienced a severe infection requiring extended hospitalisation'

10. Discussion

The findings of the survey support previous anecdotal reports that people prescribed b/tsDMARDs experience delays in receiving their scripts. Responses provided evidence of the serious impact of these delays on people's quality of life and the physical, mental, financial and social disruption and distress caused by medication delays. Notwithstanding the limitations of the survey discussed above, the respondents included a broad range of geographic locations, ages, musculoskeletal conditions and b/tsDMARDs prescribed.

The processes for authorising prescribing of b/tsDMARDs and providing scripts to consumers are complex, difficult for consumers to understand and navigate, and still greatly reliant on hard copy mailing of documents and scripts. Our broad understanding of the steps involved as follows:

- Appointment with a rheumatologist
- Rheumatologist applies for an authority (initial or ongoing) either by mail or via the online PRODA system. We understand that many rheumatologists find the PRODA system time consuming and inefficient, and its use does not actually expedite the application
- Processing by Services Australia - we understand that the processing time varies significantly from a few hours to several weeks
- Assuming there are no errors and the application is approved, the script is mailed to either the rheumatologist or the patient depending on what the rheumatologist has indicated on the prescription
- If the script comes to the rheumatologist, it must then either be mailed to the patient or they need to pick it up.

In summary, applications must be received, processed, approved and the script sent to the patient or prescriber. Delays can arise from factors including errors, postal delays and incidents such as the loss of an application or a script. Factors affecting Services Australia's processing times also appear to be a source of delays, e.g. staffing availability and rostering changes due to COVID and during holiday periods, with some participants commenting that they experienced delays around the Christmas/Summer holiday period. Rheumatologists report that they can spend up to 20 minutes on hold on the telephone waiting to discuss an application. It is clear that there is a significant administrative burden incurred by Services Australia (as well as rheumatologists) in processing these requests, which was stated by the PBAC as a reason for changing the approval process for some b/tsDMARDs.

Due to the approval process of b/tsDMARDs being authority required, eScripts are not available for these medications. This is despite the Australian Government's website stating that 'electronic prescribing aims to provide convenience and choice to patients while improving PBS efficiency, compliance and drug safety.' The Australian Government website further states that, '…While paper prescriptions are still available, prescribers and patients can choose an electronic prescription to be issued instead.'

With regards to the factors that may have contributed to delays, drug shortages during the last two years did not have a significant impact of on the results with little to no effect on the results when these respondents were removed from the analysis. In addition, delays did not appear to be influenced by where people lived or whether they saw their rheumatologist privately or in a public setting.

11. Recommendations

Given the serious impacts on consumers' health and wellbeing and their ability to undertake daily activities when they are unable to access their medicines in a timely way, we are calling on the Commonwealth government to:

- Swiftly implement PBAC's March 2022 recommendations, which will make access to these vital medicines quicker and easier for many consumers
- Ask the PBAC to consider the discriminatory impact of not including patients with psoriatic arthritis, ankylosing spondylitis and those taking a biologic or targeted synthetic DMARD without a corresponding biosimilar available
- Review Services Australia's processes and processing times for script approvals
- Prioritise development of efficient, electronic processes for authority medicines access.

Pending these changes being implemented, we have identified several recommendations to mitigate against the harmful consequences of delays:

For rheumatologists:

- When rebooking patients, consider the timing of the follow-up appointment to take into account adequate time for the processing of scripts where possible, noting follow-up prescriptions are for 24 weeks not six months
- Consider ticking the box on the prescription so it can be sent directly to the patient
- Ensure that clinic reception staff are aware of potential delays with scripts and the impacts on patients so that they can respond as needed to patients' reporting of delays.

For consumers:

- Ask for an appointment with your rheumatologist less than six months from your previous appointment to build in time for the processing of your script
- Do not wait until you have run out of medicine before following up – speak to your rheumatologist if you have not received the script within two weeks of running out of your medicine.