Common Drug Review
Patient Group Input Submissions

tocilizumab (Actemra SC) for Rheumatoid Arthritis

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
Arthritis Consumer Experts — permission granted to post.
Canadian Arthritis Patient Alliance — permission granted to post.
The Arthritis Society — permission granted to post.

CADTH received patient group input for this review on or before September 24, 2014

CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter. This includes patient input received from individual patients and caregivers as part of that pilot project.

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

Arthritis Consumer Experts

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		tocilizumab (Actemra) for Rheumatoid Arthritis
Name of the patient group		Arthritis Consumer Experts (ACE Planning and Consulting, Inc.)
Name of the primary contact for this submission:		[redacted]
Position or title with patient group		[redacted]
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	Website	www.jointhealth.org
Permission is granted to post this submission		Yes

1.1 Submitting Organization

Arthritis Consumer Experts (ACE) is a national organization that provides science-based information, education and support programs in both official languages to people with arthritis. ACE serves consumers living with all forms of arthritis by helping them take control of their disease and improve their quality of life.

Arthritis Consumer Experts is committed to the following organizational objectives:

- To inform, educate and empower people with arthritis to help them take control of their disease and improve their quality of life;
- To provide evidence-based information in reader-friendly language to people with arthritis, the public, governments and media;
- To provide research decision-making training to people with arthritis to help them participate meaningfully in research organizations and in consultations with government.

ACE's membership and program subscribers include people with arthritis, their families, their caregivers, rheumatologists, and other health professionals.

1.2 Conflict of Interest Declarations

a) Regarding corporate members and joint working, sponsorship, or funding arrangements:

Arthritis Consumer Experts receives unrestricted grants-in-aid from the following private and public sector organizations: AbbVie Corporation, Amgen Canada, Arthritis Research Centre of Canada, BIOTECanada, Bristol-Myers Squibb Canada, the Canadian Rheumatology Research Consortium, Canadian Institutes of Health Research, Celgene Inc., GlaxoSmithKline, Hoffman-La Roche Canada Ltd., Janssen Inc., Pfizer Canada, Purdue Pharma L.P., Takeda Canada Inc., and the University of British Columbia. ACE also receives unsolicited donations from its community members (people with arthritis) across Canada.

In no way does the funding received by Hoffman-La Roche Canada Ltd. influence ACE's opinions or those expressed by the patients interviewed. There was no communication between ACE and Hoffman-La Roche Canada Ltd. in the preparation of this submission.

b) Regarding those playing a significant role in compiling this submission:
This is not applicable, as it was solely the staff and advisory board of Arthritis Consumer Experts that aided in the compilation of this information.

Section 2 — Condition and Current Therapy Information

2.1 Information gathering

The information was gathered through a request for patient input from JointHealth™ members and subscribers sent via email and posted on the JointHealth™ website. The response by the patients was given through telephone conversations and email correspondence.

2.2 Impact of Condition on Patients

a) What are the condition-related symptoms and problems that impact the patients' day-to-day life and quality of life?

The patients' day-to-day life is affected greatly by their RA. Patients have to consider what they can do for the day and how they will do it. The following are answers provided by the patients interviewed:

- **Interviewee A** indicates that she is always in pain, always tired and is no longer available to work. She thinks that the most important aspect of RA to control is to manage the pain.
- **Interviewee B** has been living with severe RA since 1992. She experiences pain throughout the entire body and also has fibromyalgia. She has severe stiffness in her whole body that does not get relief until 10 pm at night, which continues the vicious cycle of pain. At night, though not as stiff, she gets bad pain that affects her sleep throughout the night. Sometimes, it hurts to breathe as the pain is so severe that it affects the rib cage. In terms of day to day activities, she is unable to cook, clean, go up and down stairs with ease, walk for long distance (more than 100 feet) and run errands in town. She can drive. In terms of going on vacation, her vacation cannot be long. She manages pain during vacation by taking Prednisone. She has to pre-plan every single detail of the vacation. For example, finding accommodations and visiting places that do not have steps, arranging for breaks, limiting the duration of travel time from one point to another and being medically prepared.
- **Interviewee C** is a nurse and indicates that she has swollen painful joints as a result of her RA. She often feels tired and has a low haemoglobin count.
- **Interviewee D** is also a nurse and has been diagnosed with RA since April 30 of this year. She has been off work since then. She has trouble washing her hair and experiences stiffness and pain in her hand, wrist, elbows, knees, ankles, feet and shoulders. She cannot open bottles without using a vice grip, squeeze lemons, carry too much, do the laundry and has trouble opening doors. Her disease was classified as severe. After two months or so, she now experiences moderate disease activity. Her current HAQ score is 1.12 and DAS28 is 4.3, an improvement from the initial 7.3 when she was first diagnosed.
- **Interviewee E** has lived with RA for nearly twenty years. She thinks the most important thing to control is the pain. She has severe damage in some joints (mostly hands and feet) that affects her day-to-day activities. She had to change her wardrobe style, including wearing clothes with less button and zippers, and not wearing high top shoes as she cannot bend her ankles to get into them. She notes that with a little help and perseverance, she is able to do her own shopping, cooking, and cleaning. She continues to do reading and research in two main areas of interest and does the occasional fine needlework. She and her husband still do quite a bit of socializing and some

travelling in their motorhome. It is painful and difficult to tie shoelaces, vacuum and get things off a high shelf. It is also frustrating to deal with the fatigue and other people's perception of RA and its effects on a patient. Most people I have encountered think that RA is like osteoarthritis and tells me to just take a Tylenol and get on with it.

2.3 Patients' Experience with Current Therapy

b) How well are patients managing their condition with currently available treatments?

- **Interviewee A** currently receives 4 weekly infusions of tocilizumab (Actemra®). She is managing her RA and feels that her disease level is manageable. She feels 70% well. She has been on Enbrel®, Humira®, and Orencia® in the past, each used for a couple of years, but not together. Her reason for discontinuing the use of each of the medication was that over time, the medication lost its efficacy. There are no adverse effects that are more difficult to tolerate than others. She experiences difficulty in accessing current therapy because she has to travel to a doctor's clinic in order to get the infusion. Every time she goes to the office, she has to park and walk a long way and have to pay for parking. Her pain level is at 7 right now; she would like to be at a 2 or 3.
- **Interviewee B** has taken methotrexate, Enbrel®, Remicade®, cutramine, imunaran, sandimmune, Humira®, Orencia®, and Cimzia®. She has been going back and forth between some of these medications as some of them caused numbness to her body. She developed neuropathy in her fingers and toes as a result of using Enbrel® and developed a full body rash that lasted for a couple of months even with medications as a result of using Cimzia®. The only hardship she finds in accessing her current therapies is that her rheumatologist is very busy; therefore, is unable to be on top of the latest medication programs available in clinical or test trials.
- **Interviewee C** is currently taking Aleve to relieve her RA pain. She has been on anti-inflammatory medications, four different biologics, gold, and prednisone. The medications didn't help her relief any of her pain or swelling and she was constantly feeling fatigue. She experienced stomach bleed on the anti-inflammatory.
- **Interviewee D** was taking methotrexate (25 mg subcutaneously) and Plaquenil® (discontinued in June as she experienced ringing in her ears). She also takes leflunomide (20mg, three times a week), but had to discontinue because she lost more than ten percent of her body weight, felt bloated and experienced abdominal pain. She is currently taking 5mg folic acid for six times a week.
- **Interviewee E** had success with methotrexate but had to discontinue due to some side effects she was experiencing. Then she was on Orencia® but after six years, had to discontinue because the medication has lost its efficacy. According to her, an ideal drug would make life relatively pain free, stop inflammation, and stop joint deterioration, preferably in one pill or via self-injection.

To summarize, all of the patients interviewed believe that the more options there are, the better. Having more options could mean better access to medication, having a backup plan in case the current therapy treatment stops working, and having an economically sound solution in case the current therapy treatment is no longer covered under an insurance plan. All the patients interviewed agree that the best treatment is one that has fewer adverse effects, eliminates pain, easy to self-administer and non-invasive.

In support of research, ACE recently conducted a survey with people living with arthritis. Patients ranked "being able to function and live a normal life" and "having affordable and accessible treatment options" as the top two priorities for them. ACE believes additional therapies will provide each patient with more options for their unique circumstances, when considering which medication to take for their disease.

2.4 Impact on Caregivers

What challenges do caregivers face in caring for patients with this condition? How do treatments impact on the caregivers' daily routine or lifestyle? Are there challenges in dealing with adverse effects related to the current therapy?

- **Interviewee A**'s husband has to do all the housework, such as cleaning, grocery shopping, and doing the laundry. Her husband has to make sure he's doing what he needs to do and whatever she needs him to help with.
- **Interviewee B**'s husband has to do everything in the house while she does the paperwork. Her husband cooks, cleans, and does the grocery shopping. It is very stressful and time-consuming for him and she feels very bad for putting him in that position.
- **Interviewee D**, because of her recent diagnosis, was initially very angry that she could not do everything she was doing before her RA, such as gardening, golfing, playing with the grandkids, and knitting. Her family had to help her manage her initial shock and fear of the unknown. She was constantly busy researching about RA and had less time to spend with her family. Her family did not understand and did not want to hear all the bad stuff regarding RA.

The patients interviewed expressed concerns of adverse effects over a prolonged period. Even though their medication(s) is successful in treating their RA, a risk of developing other medical conditions is a strong possibility. All the patients agree that they will take the medication that is most effective in treating their RA and that poses the least chance of adverse effects.

Section 3 — Related Information about the Drug Being Reviewed

3.1 Information Gathering

The information was gathered through a request for patient input from JointHealth™ members and subscribers sent by email and posted on the JointHealth™ website. The responses from the patients were given through telephone conversations and email correspondence.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had To Date with the New Drug?

a) Based on no experience using the drug:

- **Interviewee A** expects the subcutaneous form of tocilizumab to improve her life and lessen or eliminate her pain. She indicated that she much prefers having subcutaneous than an infusion because she can self-administer it. She hopes that the medication will reduce her visits to her rheumatologist. She is willing to experience adverse effects as long as it's nothing life threatening.
- **Interviewee B** is concerned about starting subcutaneous tocilizumab as the BC Health Care system currently only covers the infusion form of tocilizumab. She does not think it is cost effective for the healthcare system and questions why the healthcare system should pay for infusions done at a hospital when patients can self-inject at home. Her main challenge of accessing current treatment is that she has to travel 45 minutes to the next town to receive an infusion at a hospital. She is willing to experience adverse effects as long as it's nothing life threatening or long-lasting. She hopes the medication will improve her inflammation by 20 or 40%.
- **Interviewee C** hopes that the subcutaneous tocilizumab will work better than the IV tocilizumab. As she is a nurse, she also feels comfortable about self-injecting with the subcutaneous tocilizumab.
- **Interviewee E** indicates that an ideal drug would make life relatively pain free, stop inflammation, and stop joint deterioration, preferably in one pill or via self-injection.

According to all of the patients, it is difficult to determine with certainty that patients' lives will be improved by subcutaneous tocilizumab, but they are all willing to try subcutaneous tocilizumab because of the ease of administration. The patients expect any success story to parallel the results from the data and studies of previous treatment methods for other similar medication.

Each person living with arthritis responds differently to each medication, and no single biologic therapy is effective in everyone with a particular condition. In the patients' opinion, access to subcutaneous tocilizumab means a new chance for them to have a treatment that will be more effective in managing their disease if another biologic(s) used before it, fails. Allowing access to the medication can also give professionals the tools to help their patients achieve remission.

ACE recommends a well-rounded treatment plan for RA that includes medication, education, physiotherapy and occupational therapy, and a healthy diet. Initiation of the right medication in autoimmune arthritis is vital for helping someone gain back and maintain joint health. A patient's support network can help the patient achieve an optimal response to therapy.

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

Only **interviewee D** has had experience with subcutaneous tocilizumab. She has been receiving subcutaneous tocilizumab through the Alberta Blue Cross since August 8, 2014. Since starting the medication, she has had several colds, experiences coughing up of mucus, and had an infection in her eyes that was managed by antibiotics. She is uncertain whether the cold is from her medication or being around her grandkids. Occasionally, she gets a sore throat. As she has been on the medication for less than a month (just two doses), she cannot evaluate the effectiveness of the medication but hopes she will learn more in twelve weeks' time. She likes the subcutaneous tocilizumab better than the IV version, as there are fewer side effects. As a nurse, she is also aware that the shelf life of subcutaneous tocilizumab is longer.

ACE, like other arthritis organizations in Canada, believes clinical trials are extremely important to advancing research into new and effective treatments. As well, patients across the country who are refractory to current therapies rely on the emerging treatments being tested in clinical trials.

How is the new drug expected to change a patient's long-term health and well-being?

All the interviewees said they hoped that tofacitinib will lessen their RA pain so that they can manage to do day-to-day activities. The ease of administration will mean that they can devote more time to doing modified housework and help around their household. They can also avoid the strenuous and long travel to and from their rheumatologist's office.

Arthritis Consumer Experts (ACE) is focused on connecting with, and helping, people who live with rheumatoid arthritis, among other forms of arthritis. It is on their behalf that ACE advocates for positive reimbursement recommendations. Doing so appropriately offers more medication options and creates and environment for the physician and patient to practice "personalized medicine" and possibly achieve disease remission. Focusing on remission as the treatment target delivers the best chance of a person with arthritis to gain back some semblance of a normal life and maximize their full potential as human beings.

The patients concluded with a plea to the healthcare system to find medications that help people with RA achieve remission. When a patient achieves remission, they are able to live a normal life free from adverse effects and maximize their full potential as human beings.

Section 4 — Additional Information

Throughout the CADTH Patient Input Template, the term “condition” is used. Since CADTH reviews products that are largely for people living with diseases, and that are being developed to treat debilitating, possibly life ending diseases such as rheumatoid arthritis, which is a serious incurable autoimmune form of arthritis.

Using the word “condition” is not medically accurate, nor is it respectful of patients living with serious chronic diseases. Please see www.rheumatology.org/Practice/Clinical/Diseases_And_Conditions/Rheumatoid_Arthritis/

ACE requests that the term “condition” be replaced with “disease”—or at least “disease and/or condition”— consistently throughout the document.

Canadian Arthritis Patient Alliance

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		Actemra/tocilizumab
Name of the patient group		Canadian Arthritis Patient Alliance
Name of the primary contact for this submission:		[redacted]
Position or title with patient group		[redacted]
Email		[redacted]
Telephone number(s)		[redacted]
Name of author (if different)		
Patient group's contact information:	Email	[redacted]
	Telephone	514-805-5105
	Address	204 Gerrard Street East, Unit 3, Toronto, Ontario, M5A 2E6
	Website	www.arthritispatient.ca
Permission is granted to post this submission		Yes

1.1 Submitting Organization

CAPA is a grass-roots, patient-driven, independent, national education and advocacy organization with members and supporters across Canada. CAPA creates links between Canadians with arthritis, assists them to become more effective advocates and seeks to improve the quality of life of all people living with the disease. CAPA believes the first expert on arthritis is the individual who has the disease, as theirs is a unique perspective. We assist members to become advocates not only for themselves but all people with arthritis. CAPA welcomes all Canadians with arthritis and those who support CAPA's goals to become members.

1.2 Conflict of Interest Declarations

a) We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:

In the past year, CAPA has received both restricted and unrestricted funding and in-kind support from: Abbvie, Amgen, Janssen, Novartis, Pfizer, UCB Pharma, The Ontario Rheumatology Association, The Canadian Rheumatology Association, and The Arthritis Society.

b) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

None to declare.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

We had one-on-one conversations with two people living with RA who are currently on Actemra IV. Another member is also using Actemra IV, but for Juvenile Idiopathic Arthritis (JIA). More information was obtained through personal experiences of the Board of the Canadian Arthritis Patient Alliance in living with inflammatory arthritis and using IV drugs versus subcutaneous drugs.
We also consulted websites such as www.arthritis.ca to collect information about RA.

2.2 Impact of Condition on Patients

Rheumatoid Arthritis (RA) is the most common form of inflammatory arthritis. It affects approximately 300 000 Canadians. More women have RA and it is most often diagnosed between the ages of 25 and 50. It is the leading cause of disability in Canada. In RA, the body's immune system attacks the joint lining and sometimes other internal organs. Swelling in the joint causes pain and destruction. It is now common knowledge that newly diagnosed patients should be treated early in the disease to avoid irreversible joint damage, control pain and improve overall quality of life for the patient.

When RA is not controlled, patients experience significant pain and joint stiffness. They feel tired and can lack concentration. Consequently, this affects their ability to go on with their normal activities, such as work, school, family life, etc. Ultimately, if no medication can stop RA progression, it can lead to major joint surgeries such has joint replacements or joint fusions. Because of the extensive damage to their joints, some patients who do not respond to the available treatments might also have to use technical or mobility aids such has bath lifts, canes or wheelchairs, have their house/car adapted and rely paratransit to do daily activities.

2.3 Patients' Experiences With Current Therapy

RA is treated with several types of medication, used alone or in combinations. Non-steroidal anti-inflammatory drugs (NSAIDS) and corticosteroids are used to control overall joint inflammation. They provide the patient some relief, but other types of medication are necessary to decrease and prevent disease progression. One of those types is disease-modifying anti-rheumatic drugs (DMARD) with drugs such as methotrexate, plaquenil, etc. DMARDs are associated with some important health risks, so physicians and patients must balance these risks with the potential benefits of taking the drug when choosing the best course of treatment. In the last two decades, a new type of medication was developed: biologics. These medications, including the drug reviewed here, have proven to be very effective in slowing disease progress and preventing disability. Two CAPA members contacted specifically mentioned that Actemra was the most successful of the biologics they had used so far. Unfortunately, biologics in general have their downsides: they suppress the immune system, making patients at high risk of infection. Biologics also take some time to become effective and some patients do not respond to them and need to try a number of them before finding one that works. Their effectiveness decreases over time forcing patients to change their medication from time to time. They are also very expensive.

Biologics are administered either subcutaneously or intravenously (IV). Actemra is currently only reimbursed in its IV form which causes some burden on the patients. For example, the three people reached by CAPA reported that they had to travel to a clinic to receive their drug – as opposed to some IV biologics that can be administered at home. The time involved in receiving the medication (approx. 1.5 hours plus travel time) was a great hassle to everyone we spoke with. One member, a 39 year old woman with moderate to severe arthritis, shared that it takes her "*a total of 2.5 hours of time away from work*" every month. Another woman with RA mentioned that she did not like to receive Actemra at the clinic because on top of having to travel, the clinic made her feel "*like we are cattle, squashed in a clinic with uncomfortable chairs, with people who do not speak to each other, not even the nurses*". She added that having to come to a clinic every 4 weeks will prevent her from travelling for longer periods of time when her husband retires. Furthermore, she shared that IV is painful, especially when the nurses "*blows your vein, and you are left with massive bruises".* A very common issue raised by CAPA Board members is that many have a great deal of vein scarring making it extremely difficult for nurses to insert the IV needle. One member reported that at each infusion of Actemra, she had to endure approximately 8 IV needle attempts before the nurse can find a vein that works. The consensus was that everyone would prefer to receive this medication subcutaneously either with an auto-injector or a pre-filled syringe.

2.4 Impact on Caregivers

In the cases where the patient is severely disabled, provincial governments will provide some services to people with RA. Because RA develops earlier in life, some patients will not be able to access these services because they do not fit the reimbursement profile in which services are monopolized by the elderly. They will then have to rely on their significant others or their families for support. In some situations, people with RA will need to rely on caregivers for assistance like getting dressed or cooking during a flare or after a surgery. One young adult with severe juvenile rheumatoid arthritis shared that she had to rely on her mother a lot even when she lived on her own. This caused a lot of tension and prevented them from having a regular adult mother-daughter relationship. Specific to IV Actemra, one patient mentioned that she often saw spouses in the waiting room because they had to drive the patient to the clinic.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

We had one-on-one conversations with two people living with RA who are currently on Actemra IV. Another member is also using Actemra IV, but for Juvenile Rheumatoid Arthritis (JRA). More information was obtained through personal experiences of the Board of the Canadian Arthritis Patient Alliance in living with inflammatory arthritis and using IV drugs versus subcutaneous drugs.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) Based on no experience using the drug:

From a patient perspective, the drug reviewed will greatly improve the lives of patients with RA because a subcutaneous drug would give them more freedom and control over its administration. They would not have to take time off work or arrange their schedules and travel arrangements to visit the clinic monthly. They would be able to inject in the comfort of their home. Patients with difficult veins would not have to endure having many needles stuck in their arms every 4 weeks. Overall, patients would be able to take the same efficient drug but it would be administered in a more pleasant way. Patients would benefit from the positive effects of Actemra in controlling RA and ultimately be less at risk of becoming disabled and a burden to the public health system and their caregivers.

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

Nothing in addition to what has already been mentioned in the submission.

Section 4 — Additional Information

The Canadian Arthritis Patient Alliance finds it unconscionable that CADTH would put out a call for patient input for a drug that is currently in a queue with no set time frame for when this drug will be made available to patients who are currently waiting for access to it. As mentioned in this submission patients endure a degree of hardship with the IV form of Actemra and will find the self-injectable indication much easier to use but because of CADTH's queue they have no idea when the new form will be accessible to them.

The Arthritis Society

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		Actemra, Rheumatoid Arthritis
Name of the patient group		The Arthritis Society
Name of the primary contact for this submission:		[redacted]
Position or title with patient group		[redacted]
Email		[redacted]
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	Website	www.arthritis.ca
Permission is granted to post this submission		Yes

1.1 Submitting Organization

The Arthritis Society has been setting lives in motion for over 65 years. Dedicated to a vision of living well while creating a future without arthritis, The Society is Canada's principal health charity providing education, programs and support to the over 4.6 million Canadians living with arthritis. Since its founding in 1948, The Society has been the largest non-government funder of arthritis research in Canada, investing more than $185 million in projects that have led to breakthroughs in the diagnosis, treatment and care of people with arthritis. The Arthritis Society is accredited under Imagine Canada's Standards Program. The website www.arthritis.ca provides more detailed information.

1.2 Conflict of Interest Declarations

The Arthritis Society does not believe that it or those individuals playing a significant role in compiling this submission have a conflict of interest that influences the information provided in this patient group submission.

The Arthritis Society accepts funding from many pharmaceutical companies in order to work towards fulfilling its mission of enabling Canadians with arthritis to live well and be effective self managers; to lead and support research and care; and to achieve its public policy priorities. In order to be fully transparent and meet the request to disclose pharmaceutical manufacturers who have provided support to the organization please be aware that over the past 12 months The Arthritis Society has accepted funding from the following members of the pharmaceutical industry: Abbvie, Amgen, Bayer, Bristol Myers Squibb, Celgene, Eli Lilly, GlasxoSmithKline, Janssen, Novartis, Pfizer, Roche, UCB. The vast majority of The Arthritis Society's funding comes from individual donors as personal charitable giving. The Society abides by all Canada Revenue Agency and Imagine Canada requirements, and has specific guidelines on advocacy relating to pharmaceuticals that are available upon request.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

Information was obtained from the following sources:

- The primary information source to complete Section 2 is The Arthritis Society's July 2014 Patient Empowerment Survey (PES). In July 2014, using an independent market survey firm, the Society polled 1,500 Canadians living with arthritis to better understand their needs. The 15-minute online survey specifically asked about their experience with arthritis and issues relating to treatment. Quotas were set for some of the less prevalent forms of arthritis, such as lupus, psoriatic arthritis and ankylosing spondylitis. The results are being analyzed by an established arthritis research group.
- One-on-one e-conversations with patients and caregivers through The Arthritis Society's engagement on social media and the website - pain.ca.
- A literature review to better understand patients' and caregivers' experiences in living with arthritis and the need for better treatments.

2.2 Impact of Condition on Patients

Rheumatoid arthritis (RA) is a type of inflammatory arthritis and an autoimmune disease. An autoimmune disease is one where the body's immune system becomes confused and begins to "attack" the body.

In RA, the target of the immune attack is tissue in the lining of the joints and, sometimes, in other internal organs (such as the eyes, lungs or heart). This causes swelling, pain, inflammation and joint destruction.

RA usually begins slowly, starting in a few joints and then spreading to other joints over a few weeks to a few months. As time goes on, RA involves more and more joints on both sides of the body often in a "symmetrical" pattern. This means if joints in your right hand are swollen, then joints in your left hand will probably be swollen.

The symptoms of RA vary from person to person. Some people have only a few joints involved or mild inflammation, whereas others have many joints involved or severe inflammation. The symptoms of RA also vary from times when the joints feel good to other times (often for no reason at all) when the joints become more stiff, sore and swollen.

What aspects of this condition are more important to control than others?

- Pain. The PES told us that pain prevents individuals with RA from participating in normal activities at the following levels: 15% reported that pain hindered their normal activities on a daily basis, 19% a few times a week, 15% about once a week, and 31% once or twice in the past month.

2.3 Patients' Experiences With Current Therapy

We believe it is essential to have access to a range of Disease Modifying Anti-Rheumatic Drugs (DMARDS), including biologics and Methotrexate, so that there are options to allow for individualized approaches to disease management.

Existing therapies also include Celebrex, Tramacet, and pharmaceutical opioids for acute pain. Where they work, current treatments are extremely effective. For others, current treatments are not at all effective, or not effective enough. Through research for this submission we have learned:

- Many patients are not managing their condition as well as they and their physician know is possible.
- Some have had to leave the workforce and others are finding it difficult to self-manage their disease and their overall health using prescribed therapies such as strengthening and cardiovascular exercises and experience muscle weakening thus unstable joints.
- A patient told us "Current treatment is effective, to a point. I will never be able to run across the street or live in a house with stairs, and I'm not yet 40."
- Flares remain unpredictable.
- We heard "My treatment is very effective, for now. I'm scared it will fail me eventually and I will never be able to find another that works."
- A patient told us "I can feel my (biologic) working immediately during the infusion. It has made a huge difference for me."
- Others feel their current therapy is not doing enough and that they are not able to walk for more than about a minute at a time, and "Without my current treatment regimen, I feel sure I would not be able to work."

The PES also gave us insight into the hardships faced by individuals living with RA. We asked individuals living with RA on a scale from 1-5 to rate how much their RA symptoms limited their day-today activities and impacted their quality of life. 46% reported their ability to work was extremely or somewhat limited because of their RA, 44% reported their ability to socialize with family and friends was extremely or somewhat limited, 58% reported their ability to exercise and be physically active was extremely or somewhat limited, 43% reported their ability to have an intimate relationship with partner, spouse or significant other was extremely or somewhat limited, and 48% reported their overall quality of life in the past year was extremely or somewhat limited.

Unfortunately, there are many adverse effects that can be present with the pharmaceutical treatment of RA. They include: fever, night sweats, weight loss, tiredness, feeling full after eating only a small amount; stomach pain, easy bruising or bleeding, pale skin, feeling light-headed or short of breath, rapid heart rate, nausea, itching, loss of appetite, dark urine, clay-colored stools, and jaundice.

Patients have told us:
- "If I try to take a higher dose I have stomach problems."
- "I suffer from nausea and I'm not able to do anything on the day I take methotrexate, so I lose a whole day every week to vomiting."
- "I get huge site reactions from injections."

There are major access issues. The cost of medications requires private insurance for coverage, or some patients and their family members who do not have insurance take on additional work to pay for the pharmaceuticals. The requirements to be approved for medications are onerous on the patient. Many provincial drug plans also require significant paperwork and constant checking in to see of the patient requires the medication.
- Patients have told us: "Medication is very expensive."
- Patients have also reported challenges in finding general practitioners to manage their disease, and that there are lengthy waiting lists to see a rheumatologist in some areas of the country.

For people diagnosed with RA in their 20s and 30s, treatment will be needed over the entire remainder of their lifespan, which could be 50 years or more. As the body may develop a resistance to a medication after several years, it is important that biologics with a variety of targets be made available to people

with RA so that their doctors can continue to treat them with the full arsenal of medications available to them.

Patients often need to use a variety of drugs to control their arthritis, some in combinations NSAIDS, DMARDS, biologics, corticosteroids, and natural health products.

- A patient told us: "Daily/weekly needles are really difficult if you need to travel for work or for pleasure. They need to be kept chilled and it can be really difficult to take them on airplanes (through security). Getting approval from PharmaCare for enough supply to go on an extended trip is almost impossible."

2.4 Impact on Caregivers

What challenges do caregivers face in caring for patients with this condition? What impact do treatments have on the caregivers' daily routine or lifestyle? Are there challenges in dealing with adverse effects related to the current therapy?

- Families, friends, and all caregivers of individuals living with rheumatoid arthritis are hit hard with the demands of caregiving.
- Patients have told us: "It's hard on your caregiver when you are vomiting for an entire day because of a medication. They have to plan their life around losing a day (every week) to look after you, or at the very least not be able t count on you to help with family responsibilities."; "Caregivers may have to help with needles, which can be tricky and often scary; especially when a needle causes pain to the person you are giving it to. It is awful to hurt the person you are trying to help."
- Caregivers also suffer emotionally when they see the patient suffer knowing that there is little they can do about it because the current treatment regime is not providing the outcomes hoped for.
- We also learned that proper dose, frequency, and ease of application are concerns for health care providers working within a busy practice, and for caregivers who often have little training or expertise.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

Information was obtained from the following sources:

- One-on-one e-conversations with patients and caregivers through The Arthritis Society's engagement on social media and the website - pain.ca.
- A literature review to better understand patients' and caregivers' experiences in living with arthritis and the need for better treatments.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

RA is a lifelong condition and often requires complex management, including a regime of powerful drugs that can have multiple affects and interactions. Too many Canadians live with the fear that a drug which has been effective in managing their symptoms can suddenly stop working, requiring a substantial increase in dosage or a change to a new medication. Every day The Arthritis Society sees the difference made by availability of effective medications on Rheumatoid Arthritis. People with Rheumatoid Arthritis who developed the disease before the availability of many of the newer Disease-Modifying Anti-Rheumatic Drugs (DMARDs) or who have not found a drug or drug combination that works for them have severe and disabling joint damage and can experience episodes of incapacity due to the consequences of their disease. Regularly, we hear these people, who are mostly women as RA is far more prevalent in women, tell their stories of how they have lost their jobs and struggle to fulfill their

family roles or engage in social activities. The Society benefits from their commitment to helping others through volunteering. However, we always have to have a backup plan, as frequently their disease prevents these volunteers from honouring their commitments, or their joint damage does not allow them to complete simple tasks like posting a flip chart page on a wall. A new treatment option can make a profound difference in the lives of these people.
Canadians and their physicians must be able to select the approved therapy that is best for the management of arthritis. If a drug is approved by Health Canada to be marketed in Canada ability to pay must not be a barrier to access.

Specifically dealing with Actemra the research tells us that Actemra is an effective treatment option for RA. Patients have told us the drug slows down the progression of their disease and can improve their physical function.