

An Advocacy Success Story

By Rosie Scuccimarri, MD, FRCPC; and Carter Thorne, MD, FRCPC

Naproxen (Naprosyn®) is the preferred non-steroidal anti-inflammatory drug (NSAID) for treating juvenile idiopathic arthritis (JIA) and is widely used in pediatric rheumatology. In November 2013, pharmacists received a memo notifying them that Roche Canada was discontinuing production of naproxen suspension. Unfortunately, Roche did not notify the prescribers. It is only as stock disappeared, and when patients could no longer renew their prescriptions, that this was brought to the attention of the pediatric rheumatology community. This was of concern given that there is no generic for naproxen suspension, it is difficult to compound, and incurs an additional expense to the consumer.

Given this information, the CRA established an ad hoc committee and requested the aid of Mr. Denis Morrice from the Ontario Rheumatology Association (ORA), to deal with the implications of Roche's decision. The CRA committee quickly established communication with executives of Roche to see if this decision could be reversed. They learned that since 1997, Roche had been outsourcing production of naproxen suspension to a third-party supplier and that this company had stopped production of all oral suspension products.

In February 2014, as a result of the pressure from the CRA, Roche reached out to the pediatric rheumatology community to inform them that they were looking for a solution. It is at this point that Roche executives established weekly teleconferences with the CRA *ad hoc* committee. Roche began investigating a number of potential alternate companies that could produce a generic oral suspension formulation; they also began looking for alternate supply for interim use. By the end of February, Roche had tracked down a large supply of naproxen suspension from a Finnish manufacturer; the issue now was importation of the product.

In parallel, the CRA committee began communicating with Health Canada, initially through a face-to-face meeting in Ottawa, then through teleconferences. Various alternatives to facilitate importation of the Finnish product were discussed, including a Phase 4 study; this option was deemed too demanding, both on

the part of Health Canada and the prescribers. Finally, availability through the Special Access Program (SAP) of Health Canada was considered and contact was made with the appropriate Health Canada administrators. After a number of teleconferences with Health Canada, and satisfying regulatory compliance with the pharmaceutical companies involved, special access to the Finnish naproxen suspension was granted. In a further display of responsibility, Roche accepted the recommendation of the CRA representatives that patients and families would not bear the financial burden associated with this process, and thus the product was to be provided at no cost to the patient during the time of the SAP.

On July 2nd, 2014, after months of discussion, Roche announced that they had sold the Canadian rights to naproxen suspension to Pediapharm of Montreal. Pediapharm took over responsibility for the importation and distribution of the imported product for the SAP, while establishing local, Canadian manufacturing capacity. By mid-July, Pediapharm received the first shipment of the Finnish product in Canada, and on July 22nd, the Health Canada SAP for naproxen suspension was opened.

The CRA committee continues to have regular teleconferences with Pediapharm to ensure that patients are acquiring naproxen suspension via the SAP. Pediapharm is currently working on getting naproxen suspension back on the Canadian market. They believe that this could be possible by March 2015, which is incredible given that at the beginning of this venture, the CRA committee had been informed that it could take from two to five years! Pediapharm is also reviewing the situation with provincial payers since, in some jurisdictions, naproxen suspension has been taken off the provincial formularies.

The *ad hoc* committee's quick action and commitment to getting naproxen suspension back on the market is truly an advocacy success story. The *ad hoc* committee was able to identify key stakeholders including Roche Canada and Health Canada, and establish a collaborative relationship based on a shared vision of "best outcomes for patients".

The CRA committee could not have done this without the tireless input and dedication of Mr. Morrice, and the

involvement of the Association des médecins rhumatologues du Québec (AMRQ), The Arthritis Society (TAS), Best Medicines Coalition (BMC), and the Canadian Arthritis Patient Alliance (CAPA). For more information on how to access naproxen suspension for your patients, go to: www.rheum.ca/en/the_cra/drug_updates.

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News from the Scientific Committee

By Evelyn Sutton, MD, FRCPC

Quebec City was so much fun last time, members told us we had to go there again! Pack your bags, review your French language tapes, and join us from February 4-7, 2015 for state-of-the-art lectures, workshops, and interactive sessions. Translation is the theme in its broadest sense—knowledge translation in research, adult and pediatric clinical care, education, and policy development to name but a few. World-class experts will share their knowledge during the State of the Art address and the Dunlop-Dotteridge lecture, as well as various workshops. This year, we have facilitated a special “Meet the Experts” bazaar where you can discuss clinical questions with these experts.

The format this year will remain similar to past years with a generous mid-day break to allow you to explore beautiful Quebec City; skiers are perfectly located to head to the hills. We will review your evaluations—if participants prefer more content during the day, we will adjust future meetings accordingly. We will of course have the ever-popular Great Debate (“Be it resolved that pre-arthritis is real and must be treated”), workshops, as well as abstract and poster sessions. New this year is Clinical Pearls and Challenging Cases; see your email inbox for an invitation to submit your clinical pearl or instructive case and have a chance to win an allegedly fabulous prize!

I look forward to seeing you all in beautiful Quebec City!

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ANNUAL GENERAL MEETING

The next Annual General Meeting of the CRA will take place Friday, February 6th at the Fairmont Chateau Frontenac Hotel.

The meeting is open to CRA members in good standing only.

Please visit www.rheum.ca for meeting registration information.