



Statement by Ontario Ombudsman André Marin on Avastin funding

Yesterday, I issued *A Vast Injustice*, a report on my investigation into the Ministry of Health and Long-Term Care's decision-making concerning the funding of Avastin for colorectal cancer patients. The basic premise of my report is that although the Ministry is entitled to consider cost in deciding whether to fund a cancer drug such as Avastin, any limit on the duration of funding should be supported by sound medical evidence.

My investigation determined that the Ministry's decision to cap funding of Avastin at 16 treatment cycles – regardless of whether or not patients continue to benefit from the drug – was dictated by cost concerns and was, in fact, contrary to the accepted standard of medical care in this province. I consequently made a number of recommendations, including that funding for Avastin be extended beyond 16 cycles where medically appropriate.

The Minister has recently been quoted in the media and the Legislative Assembly as having made a number of comments about the content of my report, which may cause some confusion regarding my findings.

I am issuing this statement to address some of the information that has appeared publicly in order to set the record straight.

1. It has been suggested that the Ministry's decision to place a hard cap on Avastin funding was based on the recommendation of the Committee to Evaluate Drugs, which includes representation by medical experts as well as other professionals and two patient members.

The Committee to Evaluate Drugs' involvement with the decision-making relating to Avastin's funding is detailed in paragraphs 41-45 of my report.

On December 12, 2005, Cancer Care Ontario's Gastrointestinal Disease Site Group, composed of approximately 30 oncologists with expertise in the clinical treatment of colorectal cancer, developed guidelines based on clinical evidence, which included the recommendation that Avastin be used together with other chemotherapy for the first-line treatment of patients with advanced colorectal cancer until progression of the disease. The guidelines do not suggest that a cap be placed on treatment.

On December 14, 2005, a subcommittee composed of Cancer Care Ontario officials and members of the Drug Quality and Therapeutics Committee (now known as the

Committee to Evaluate Drugs) recommended that the Ministry fund Avastin for first-line metastatic colorectal cancer patients until progression of the disease.

On January 11, 2006, the Drug Quality and Therapeutics Committee considered whether to recommend that Ontario fund Avastin. The committee did not consider that Avastin represented good value for money in comparison to other drugs and voted not to recommend that the Ministry fund it. The committee did not address the possibility of a funding cap. The Ministry accepted the committee's recommendation.

There is no record of the Ministry ever consulting the Committee again regarding funding of Avastin for colorectal cancer patients.

At paragraph 53 of my report, it is noted that Cancer Care Ontario officials made a presentation to the Ministry in April 2008 in which funding of Avastin was addressed. One of the recommendations was that the Ministry fund the drug. However, again there was no suggestion that the Ministry should limit funding to 16 treatment cycles.

Paragraphs 56-61 of my report document that it was the Ministry that specifically obtained information about the cost of funding Avastin to various points, and determined that 16 cycles of treatment would be sufficient to meet the needs of the majority of patients.

2. It has also been reported that the Ministry made its decision to limit funding of Avastin to 16 cycles based on the results of clinical studies.

At paragraph 81 of my report, it is noted that all of the clinical trials relating to Avastin involved treating patients until progression of the disease (i.e., until it fails to impede the growth of tumours). Patient responses to the drug vary. For instance, the median duration of treatment in one clinical study was 17 cycles, meaning that half of the patients in the trial needed less than 17 cycles and half needed more. There was no suggestion in the studies that treatment with Avastin should stop before 17 cycles; only that it be stopped at whatever point individual patients experience a progression of their disease.

Paragraphs 67-78 of my report detail the information we received concerning the justification for the 16-cycle treatment cap. Oncologists we interviewed indicated that they did not understand the reason for the cutoff. Even some Ministry officials acknowledged that there was no clinical support for the cap and confirmed that the decision to limit funding was purely financial. Cancer Care Ontario's Gastrointestinal Disease Site Group guidelines as well as other provincial and international guidelines continue to recommend Avastin be used until disease progression. This is also the recommendation of the drug's manufacturer.

The Ministry was given an opportunity to respond to my preliminary report, and its formal response is appended to my final report. The Ministry did not dispute the facts as they appear in the paragraphs I have referred to.

3. It has been reported that patients may apply through the compassionate review policy for consideration of extension of funding with Avastin.

The Ministry first made the suggestion that patients could use the compassionate review policy, while it worked on a new, specific policy for oncology products, in response to my preliminary report. The Ministry's response is appended to the report as well as discussed at paragraphs 123-137.

However, based on information provided by the Ministry concerning how its current policy would apply to patients seeking funding for Avastin, including a prominent oncologist with whom we consulted, I concluded that the compassionate review policy would still not provide any realistic relief for patients. To qualify for consideration of extension of funding, they would have to have tried other treatment alternatives that had failed or substantiate that no other funded regimen could be considered, for instance, for reasons of contraindication or intolerance. This is impractical for those receiving Avastin treatment, since it is a first-line treatment used before other alternatives.

4. It has been suggested that my report and recommendations in support of removing the 16-cycle hard cap on treatment were based on anecdotal and emotional evidence over clinical and medical evidence.

My report does document the stories of individual cancer patients and their struggles to continue to obtain funding for Avastin on the advice of their oncologists. However, my report clearly documents that my findings, conclusions and recommendations are based on information obtained from a variety of sources, including clinical studies, the evidence of medical specialists from Ontario and other jurisdictions, as well as documentary and oral evidence from Ministry officials.

– André Marin, Ombudsman of Ontario
October 1, 2009

The report *A Vast Injustice* and related materials may be viewed here:
<http://bit.ly/3dfQ8n>

The Ombudsman's press conference on the report is available at:
<http://www.youtube.com/user/OntarioOmbudsman>

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