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Comptroller General
of the United States

United States General Accounting Office
Washington, DC 20548

Decision

Matter of: GlaxoSmithKline

File: B-291822

Date: April 7, 2003

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DIGEST

Agency's decision to procure a drug for the treatment of migraine headaches from among four similar drugs solely on the basis of price is reasonable where after a detailed medical review the agency determined that any of these drugs would meet the agency's needs.

DECISION

GlaxoSmithKline protests the terms of request for proposals (RFP) No. 797-NC-03-0001, issued by the Department of Veterans Affairs (VA), for a triptan, a drug used in the treatment of migraine headaches. Glaxo objects to the RFP terms providing for the award of a contract for a single triptan to be designated on the VA's National Formulary.[1]

We deny the protest.

[1] A formulary is a list of prescription drugs, grouped by therapeutic class, which a health care organization prefers that its physicians prescribe. Drugs are chosen for a formulary on the basis of their medical value and price. The formulary system seeks to standardize drug use, ensure availability and consistency of the product for nationwide usage, increase the continuity of care, standardize the process for evaluating the safety and efficacy of drugs, and manage cost growth. See Agency Report at 1; Schering Corp., B-286329.3, B-286329.4, Feb. 2, 2001, 2001 CPD ¶ 19 at 2 n.2.

The RFP, issued October 23, 2002, sought to develop one source to be added to the VA's National Formulary for a single triptan for supply to the VA and the Department of Defense (DOD) under a fixed-price requirements contract for a 1-year base period with four 1-year options. The RFP listed four triptans that the agency determined met its minimum needs: almotriptan (trade name--Axert), rizatriptan (trade names--Maxalt and Maxalt MLT), sumatriptan (trade name--Imitrex), and zolmitriptan (trade names--Zomig and Zomig-ZMT). Award was to be made to "the lowest price, technically acceptable, responsible offeror whose offer conforms to the solicitation." RFP at 34. No technical proposals were requested from the offerors.

Prior to issuing the RFP, a VA Medical Advisory Panel (MAP) and Pharmacy Benefits Management (PBM) Healthcare Group conducted a drug class review of currently available oral dosage forms of triptans to determine their efficacy, safety, and administration in the management of migraine headaches.[2] The triptans examined were sumatriptan, rizatriptan, naratriptan, zolmitriptan, almotriptan, and frivotriptan. Agency Report, Tab 14, Drug Class Review, at 1. Among other things, the review examined the clinical efficacy, safety and adverse effects associated with each triptan as reported in various published clinical trials.[3] The review found that all triptan agents are generally well tolerated; that side effects are very similar; and that there is insufficient evidence available to conclude that the incidence of other adverse events differs significantly between the triptans. The review concluded, "All oral triptans are efficacious in comparison to placebo for the treatment of migraine headache," and recommended that only one oral triptan should be on the VA National Formulary to be chosen among sumatriptan, zolmitriptan, almotriptan, and rizatriptan. The review found that naratriptan and frivotriptan should not be considered front line agents because of less favorable pain-free results at 2 hours as compared to the other triptans. Id. at 7-8.

Following the drug class review, the VA's MAP, PBM, Veterans Integrated Service Network Formulary Leaders, and Neurology Advisory Group determined that the agency's minimum needs best would be met by "standardizing on one oral triptan that would best treat most patients while enhancing continuity of care throughout the VA system." Although the VA acknowledged that all six of the oral triptans examined in the drug class review were approved by the Food and Drug

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[2] The VA reports that the MAP is a group comprised of 13 physicians from throughout the VA, and DOD, all of whom are actively involved in direct patient care.

[3] The review centered on the examination of data associated with various "randomized, double blind, multicentered, placebo and/or comparative controlled clinical outcome studies." See RFP at 4; Agency Report, Tab 14, Drug Class Review, at 3-5. As part of this effort, the reviewers also looked at two recent meta-analyses that attempted to overcome the variability inherent in clinical studies by using a "number needed to treat" (NNT) analysis.

Administration, the VA decided that only those triptans with a proven safety record and that had the ability to produce a pain-free response within 2 hours in the highest percentage of patients would meet the agency's needs. Since the VA's study established that "almotriptan, rizatriptan, sumatriptan, and zolmitriptan demonstrate[d] similar outcomes, have similar side effects profiles, and sufficient safety data," the VA's medical groups determined that any one of these triptans could be considered for the National Formulary and that cost should be the determining factor in any competition. See Agency Report, Tab 13, Medical Determination of Minimum Needs at 1-4; RFP at 4.

Glaxo, which manufactures sumatriptan, contends that VA's decision to treat the triptans as essentially equal under the RFP lacks a reasonable basis because the underlying drug class review supporting this decision was based on inadequate and flawed data. Glaxo also asserts that the VA drug class review did not properly account for biases in the clinical studies, and that there were discrepancies in the meta-analyses (for example, they were allegedly inconsistent with a study that showed sumatriptan's superiority to one of the other approved triptans), such that the VA could not have reasonably relied upon the drug class review to conclude that all the listed triptans were equivalent. Glaxo further asserts that four recent studies, completed since the VA's December 2001 review, show a "material superiority" of sumatriptan over the other triptans. Glaxo argues that the VA should be required to consider this more recent data in establishing a single triptan on the formulary and directed to amend the RFP to solicit information from offerors regarding the ability of the triptans to give patients pain relief.

The determination of an agency's minimum needs and the best method of accommodating them are primarily within the agency's discretion. Pfizer, Inc., B-277733, Oct. 27, 1997, 97-2 CPD ¶ 119 at 2.

Here, as detailed above, the VA concluded that either almotriptan, rizatriptan, sumatriptan, or zolmitriptan could meet the agency's needs based on its drug review that concluded that the triptans demonstrated similar outcomes, side effects, and safety data in the treatment of migraine headaches. Although Glaxo questions the methodology and quality of the data used in the review, the VA explains that the purpose of the drug review was not to arrive at absolute answers by looking at a myriad of studies because studies, which often are funded by various pharmaceutical companies, depend on the questions asked, outcome sought and the interpretation of the data.[4] Instead, the VA's drug review generally only studied available medical literature, so the VA could decide which pharmaceuticals are the most appropriate for the VA's and DOD's patients. The VA maintains that the agency's drug review

[4] For example, the VA points out that the more recent abstract cited by the protester used a specific outcome involving the timing of medication administration, and was not designed to evaluate overall efficacy in terms of speed of relief.

considered variances in studies in the NNT analyses, and that the drug review supports the conclusion that the above listed triptans are interchangeable and equivalent for the majority of patients. Further, the VA reports that the more recent studies that the protester points to were considered after receiving Glaxo's agency-level protest of this RFP, but these studies did not change the VA's opinion that the drugs were therapeutically equivalent for its purposes.[5]

We find that the record establishes that the VA undertook a reasonable review of medical information prior to concluding that any one of the four triptans identified in the RFP is capable of meeting the agency's minimum needs. Notwithstanding Glaxo's detailed questions about what it maintains are "analytical and procedural flaws" in the study, it has not shown that the agency's reliance on the study results was unreasonable. For example, while Glaxo claims that the VA should have given more credence to the medical information that suggests that sumatriptan is superior, the VA has indicated that the purpose of its review was not necessarily to establish the superiority of any one triptan, but to decide from those that were available which would best meet the agency's needs. The VA medical professionals found that all of the four listed triptans were capable of meeting the agency's needs, notwithstanding the differences between them. Even accepting that sumatriptan could be considered superior, the agency's determination that the differences between the drugs were not material for its purposes has not been shown to be unreasonable.

Glaxo's objections to the process and the RFP's terms are predicated on its assertion that the VA should be required to consider additional information, conduct more comprehensive meta-analyses, and consider more recent abstract data, which it asserts supports the superiority of sumatriptan.[6] To this effect, Glaxo argues that the RFP should have requested that offerors provide information on the efficacy and safety of their triptan, and provided for a "best value" evaluation which would consider the percentage of patients who are pain free at 2 hours, as well as the safety of each triptan.

We disagree. Such an exercise would seem to be unnecessary and duplicative since the agency's medical advisors have already conducted an extensive review of the

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[5] The VA explains that it accorded less weight to these recent studies because the studies are in abstract form, which the agency views as less reliable, as opposed to randomized, controlled trials published in peer-reviewed journals, which was the standard that the drug review utilized to measure the efficacy and safety of these drugs.

[6] There is no merit to the protester's contention that the RFP was ambiguous for not specifying the information necessary from offerors to establish technical acceptability where, as here, the RFP clearly established price as the sole evaluation criterion and did not solicit technical proposals.

triptans, including Glaxo's additional data, and reasonably concluded that the four listed triptans were therapeutically equivalent for its purposes such that any of the four would satisfy its needs. The scope of the agency's review of triptans, including the methods for evaluating medical information; the significance given to the medical information; and the determination whether drugs are sufficiently therapeutically equivalent that only a single drug need be acquired for the National Formulary, all involve the agency's medical judgment and policies, which are inappropriate for review under our bid protest function. See Schering Corp., supra, at 5 n.11; Pfizer, Inc., B-277733, supra, at 2 n.2; Pfizer, Inc., B-276362, June 6, 1997, 97-1 CPD ¶ 205 at 6.[7] Also, the agency's discretion in determining its minimum needs extends to the evaluation criteria to be used in evaluating the proposals. See Pfizer, Inc., B-277733, supra, at 2-3. Since the VA has reasonably determined that the differences in the triptans were not material, there is no basis to question its determination to consider only price in determining which triptan to select for the National Formulary.

The protest is denied.

Anthony H. Gamboa
General Counsel

[7] To the extent that Glaxo questions the wisdom of the VA designating only one triptan for the National Formulary, the VA reports that there are procedures that permit treating a patient's particular clinical need with a non-formulary drug where the formulary drug is inappropriate. In any event, this also is a matter not subject to our review as involving the agency's medical policies and judgment. See Pfizer Inc., B-276362, supra, at 6.