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Decision

Matter of: Bristol-Myers Squibb Company

File: B-294944.2

Date: January 18, 2005

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DIGEST

Agency's use of a price evaluation scheme in a pharmaceutical procurement that compares prices for two drugs on a per-tablet basis is unobjectionable where the record shows that the optimal dosing level for both drugs is a single pill taken once daily, and where the agency has no valid data for estimating other dosing levels of these drugs, and does not expect other dosing levels to be ordered in significant quantities.

DECISION

Bristol-Myers Squibb Company (BMS) protests the terms of request for proposals (RFP) No. RFP-797-NC-04-0016, issued by the Department of Veterans Affairs (VA) for Angiotensin II Receptor Antagonists, also known as Angiotensin II Receptor Blockers (or ARBs), for the treatment of patients with both hypertension and type 2 diabetes mellitus with nephropathy. The ARB selected in this procurement will be the only ARB designated on the VA's National Formulary[2] for treatment of the

[1] Merck & Co., Inc., the manufacturer of one of the drugs at issue in this procurement, intervened in this protest on a limited basis, pursuant to our discretionary authority at 4 C.F.R. § 21.3(j) (2004).

[2] 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

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condition described above. BMS argues that the RFP's price evaluation approach will not identify the proposal that will provide the actual lowest price to the government.

We deny the protest.

BACKGROUND

The RFP here was released on August 23, 2004, and anticipates award of a fixed-price, indefinite-quantity contract for a base period of 1 year, with up to four 1-year options. On its face, the RFP limited this competition to two ARBs--Irbesartan (manufactured by BMS and Sanofi, marketed as Avapro®) and Losartan (manufactured by Merck, marketed as Cozaar®). As indicated above, the RFP also advised that these drugs were being purchased for the treatment of hypertension and type 2 diabetes mellitus with nephropathy, and that the successful offeror's drug would be the only ARB listed on the formulary for treatment of this condition.[3]

Prior to the release of the RFP here, doctors from the VA's Pharmacy Benefits Management (PBM) Section, together with the VA's Medical Advisory Panel (MAP)--a panel of 13 physicians throughout the VA and the Department of Defense--prepared a Drug Class Review of all available ARBs. Agency Report (AR) at 2. This Drug Class Review was first completed in 2003, was revised in June 2004, and is appended to the RFP (as Attachment C). Id. Using the findings of the Drug Class Review, the VA's PBM and MAP doctors prepared a second document explaining the VA's purchasing approach for ARBs. This document--also appended to the RFP (as Attachment D)--is entitled, "Medical Determination of Minimum Needs for VA National Formulary Selection of an [ARB]," hereinafter the "Medical Needs Determination."

The VA's Medical Needs Determination reflects several decisions related to the dispute in this protest. Specifically, the document explains that ARBs are not the VA's preferred method of treating simple hypertension--i.e., hypertension not accompanied by complications such as heart failure or diabetic nephropathy. See Medical Needs Determination at 1, 3. In fact, the Determination advises that there are four different classes of antihypertensive medications, several of which should be tried prior to prescribing an ARB for simple hypertension. Id. at 3; see also AR,

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nationwide usage, increase the continuity of care, standardize the process for evaluating the safety and efficacy of drugs, and manage cost growth. Schering Corp., B-286329.3, B-286329.4, Feb. 2, 2001, 2001 CPD ¶ 19 at 2 n.2; VA Health Care: VA's Management of Drugs on its National Formulary, (GAO/HEHS-00-34, Dec. 14, 1999) at 4.

[3] For ease of reference, the remainder of this decision will refer to the medical condition of type 2 diabetes mellitus with nephropathy as "diabetic nephropathy."

Tab 4 (e-mail from PBM Section to the CO, and others, dated Sept. 16, 2004, explaining the hierarchy of treatment for simple hypertension).[4] As a result, while the VA concedes there may be some usage of ARBs to treat patients with simple hypertension, that is not the purpose of this procurement.

Instead, the VA has decided to purchase ARBs for two discrete conditions: (1) hypertension with diabetic nephropathy (the instant procurement), and (2) heart failure (which is being procured simultaneously via a different RFP). Medical Needs Determination at 1. The Determination advises that since these ARBs are being procured to treat other specific conditions (as opposed to simple hypertension), the "selection of an ARB does not require evaluation based on its use in patients with hypertension." Id. at 3. In further elaboration of this point with respect to the instant procurement, the Determination document explains that

> the most important factor in evaluating the benefits of an ARB in patients with hypertension and diabetic nephropathy are hard outcomes including a reduction in the composite endpoint of doubling baseline serum creatinine, end stage renal disease (ESRD), or all-cause mortality in patients with hypertension and type 2 diabetes mellitus (DM) and nephropathy.

Id. at 2. These benefits led to the decision to limit this procurement to Irbesartan and Losartan, rather than any of the other ARBs--all of which are considered effective in lowering blood pressure, and all of which are approved by the Food and Drug Administration for the treatment of hypertension. Id. at 3-4.

As initially issued, the RFP's pricing schedule identified three strengths of Irbesartan (75 mg., 150 mg., and 300 mg.) and three strengths of Losartan (25 mg., 50 mg., and 100 mg.). Next to each strength of each drug, the RFP also identified a percentage weighting factor. The schedule anticipated entry of a per-tablet price for each

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[4] This e-mail explains:

> As for uncomplicated hypertension, the Criteria for Use refers to the guidelines that state that diuretics and beta-blockers are the preferred agents. If there is a contraindication to these drugs then an ACE [angiotensin-converting enzyme inhibitors, often referred to as "ACE Inhibitors"] may be considered preferred therapy. After considering the use of the drugs in these three drug classes (diuretics, beta-blockers, and ACEs) the provider may choose to treat the patient with an ARB. The Criteria for Use does not recommend any one ARB over another for the treatment of uncomplicated HTN [hypertension]. Based on the treatment guidelines there should be little use of ARBs for the treatment of uncomplicated HTN.

strength, which was to be multiplied by its percentage weighting factor and totaled. RFP at 2, 31. Award was to be made to the responsible offeror with "the lowest overall total aggregate weighted price." Id. at 31.

As initially filed, BMS argued that the RFP's pricing schedule should also include a weighting for the average number of tablets to be taken per patient per day--an approach that the VA had used in past procurements. Without such a weighting, BMS argued, an offeror whose ARB is generally dosed once daily--as BMS's ARB is dosed--will be disadvantaged when forced to compete on a price-per-tablet basis with an offeror whose ARB is dosed more than once daily. Specifically, BMS pointed out that the VA could choose a medication that costs less per tablet, but pay more per day for treating VA patients.

During the course of this protest, the VA twice amended the pricing scheme initially identified in the RFP. In the second change to this scheme (the first change is no longer relevant), the VA adopted what it terms a "flat pricing approach." In essence, the VA removed any use of percentage weighting, required offerors to provide the same price per tablet regardless of tablet strength, and advised that award would be made to the offeror with the lowest tablet price. RFP amend. 5 at revised pages 2, 31.

DISCUSSION

The central issue in this protest--as initially filed, and as extended to the most recent revisions to the RFP--is that the solicitation's price evaluation scheme will not result in selection of the offeror that will have the lowest cost during performance. Underlying this challenge is an assumption that different patients will need different dosing levels so that the price of treatment will not be captured by a per-tablet price.

The Competition in Contracting Act requires that agencies consider the cost to the government in evaluating competitive proposals. 41 U.S.C. § 253a(b)(1)(A), (c)(1)(B) (2000); Health Servs. Int'l, Inc.; Apex Envtl., Inc., B-247433, B-247433.2, June 5, 1992, 92-1 CPD ¶ 493 at 3-4. While it is up to the agency to decide upon an appropriate and reasonable method for proposal evaluation, it may not use an evaluation method that produces a misleading result. Id. at 4. The method chosen must include some reasonable basis for evaluating or comparing the relative costs of proposals, so as to establish whether one offeror's proposal would be more or less costly than another's. SmithKline Beecham Corp., B-283939, Jan. 27, 2000, 2000 CPD ¶ 19 at 4-5.

Since a discussion of the relative cost of treating patients with these drugs requires a discussion of dosing levels, we note first that BMS and the VA agree that if the dosage of both drugs will always be the standard dosage recommended for the

treatment of diabetic nephropathy[5]--i.e., one 300 mg. tablet once daily for Irbesartan, and one 100 mg. tablet once daily for Losartan[6]--then the RFP's pricing methodology is sound. This is because the optimal dosing level for both drugs to treat this condition is contained in a single pill to be taken once daily. AR at 4 (citing prescription insert data included by BMS and Merck with their respective drugs); BMS Supp. Comments, Dec. 14, 2004, at 2.

In essence, the VA's decision not to include any form of weighting for the different doses of these drugs reflects its assumption that the most likely-used dosage--i.e., the standard dosage recommended for the treatment of diabetic nephropathy--can be compared on a one-pill to one-pill basis. In addition, the VA is asserting that this one-to-one comparison is preferable to weighting the different doses based on previous usage data, which it argues is not helpful here because it reflects the usage of ARBs prior to their inclusion on the VA's National Formulary, and prior to the formulary's limitation on the use of ARBs to the treatment of diabetic nephropathy.

BMS contends, however, that some subset of the VA's ARB usage will be at dosing levels different from those recommended for the treatment of diabetic nephropathy, and that the RFP's price evaluation scheme ignores this fact. Specifically, BMS argues that the VA's assumed one-to-one comparison overlooks the different dosages used when the VA's doctors prescribe an ARB for the treatment of simple hypertension, as well as in certain other situations. To remedy this situation, BMS contends that the VA should be required to include a tablet multiplication factor in the price evaluation scheme.

The record here supports the protester's premise that some portion of the VA's ARB use will be at dosing levels different from the standard recommended dose for treating diabetic nephropathy. That, in turn, supports the contention that the

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[5] The sentence above purposely shortens the compound phrase used by the VA to describe the purpose of this formulary procurement. Although this solicitation indicates on its face that it is to procure ARBs "for patients with hypertension and diabetic nephropathy," RFP at 1, the Chairperson of the VA's MAP explains that "[t]his procurement is for an ARB to prevent long-term complications in patients with type 2 diabetic nephropathy, not to treat hypertension in patients with diabetes." Declaration of the MAP Chairperson, Dec. 29, 2004, at 4. The Declaration is consistent with the medical literature appended to the RFP, which does not recommend the use of ARBs for the treatment of hypertension. Medical Needs Determination at 1, 3. In addition, this medical literature does not define the efficacy of these ARBs by their effect on hypertension--both are assumed to work well for that condition; instead, the efficacy of Irbesartan and Losartan was evaluated by measuring their impact on indicators of nephropathy. Id. at 2.

[6] VA Supp. Filing, Dec. 9, 2004, at 1.

possible use of different dosing levels could have an adverse effect on the pricing methodology's usefulness for predicting actual costs. Nonetheless, based on our understanding of the ways in which different dosing levels (and different tablet strengths) could be used, we have no reason to believe that this influence renders unreasonable the RFP's pricing approach. SmithKline Beecham, supra, at 5.

Our conclusion is premised on the following possible reasons for using the ARB selected with this procurement at dosages different from those recommended for the treatment of diabetic nephropathy: (1) the VA doctor is prescribing an ARB for the treatment of simple hypertension and is doing so either improperly (in disregard of the VA's guidance), or is doing so properly (after trying other classes of drugs for the treatment of simple hypertension and finding them ineffective or not well-tolerated); or (2) the VA doctor has just started prescribing an ARB regimen for the treatment of diabetic nephropathy and the patient is still "ramping up" to the recommended optimal dosing levels, or the patient is proving unable to achieve the target dosage recommended for the optimal treatment of diabetic nephropathy.[7]

With respect to the first possibility--the use of the formulary ARB for the treatment of simple hypertension--the VA's guidelines do not recommend the use of an ARB for simple hypertension. As mentioned earlier, the VA prefers diuretics and beta blockers, then ACE inhibitors, and then ARBs for treatment of this condition. AR, Tab 4 (e-mail from PBM Section to the CO, and others, Sept. 16, 2004). Based on these restrictions, we find reasonable the VA's conclusion that there will not be any significant use of the selected ARB to treat simple hypertension.[8]

With respect to the second possibility--the use of less than full dosages for new patients properly receiving an ARB who are ramping up to the target level, or the use of less than full dosages for patients who prove unable to achieve the target dosage levels--the VA explains that, as yet, it has no data on how many patients will fall in

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[7] The record here shows that when these drugs are being used for the treatment of diabetic nepropathy, dosing for new patients is started at a lower level and gradually increased to the appropriate long-term level for optimal treatment. AR at 4 (citing prescription insert data included by both BMS and Merck with these drugs); VA Supp. Filing, Dec. 9, 2004, at 1-2. The VA recognizes that some patients will not be able to achieve the target dose strengths for these drugs, but does not have complete data on how many patients will be unable to do so. VA Supp. Filing, Dec. 9, 2004, at 2.

[8] We also recognize the possibility that some VA doctors will ignore treatment guidelines and misuse the formulary by prescribing ARBs to treat simple hypertension in patients whose medical condition does not warrant the use of an ARB. We know of no requirement, however, that the RFP's pricing mechanism must anticipate improper use of the formulary.

this category. Without this data, we know of no reason that the VA should be required, at this juncture, to estimate what percentage of patients will not be able to achieve the target dose strengths of these drugs for treatment of diabetic nephropathy. Not only does the prior VA data not address this particular subset of patients being treated for diabetic nephropathy, but the data does not even indicate the specific condition for which patients received an ARB. VA Supp. Filing, Dec. 9, 2004, at 2.

To the extent that the pricing approach here reflects an estimate that, by far, the most likely dose of these ARBs is the dose the manufacturers themselves recommend for the treatment of diabetic nephropathy--which all parties agree permits a one-to-one price comparison of these drugs--and to the extent that the VA does not have adequate data to support a different approach, we see nothing unreasonable in the RFP's revised pricing methodology.[9] There is no requirement that estimates in a solicitation be absolutely correct; rather, they must be based on the best information available and present a reasonably accurate representation of the agency's anticipated needs. Bristol-Myers Squibb Co., B-275277, Feb. 5, 1997, 97-1 CPD ¶ 60 at 6; see also Lederle-Praxis Biologicals Div., Am. Cyanamid Corp., B-257104 et al., Aug. 22, 1994, 94-2 CPD ¶ 205 at 5.

In addition, we think some portion of the challenge here relates to judgments made by the VA not related to the pricing methodology in this RFP--i.e., the decision not to include an ARB on the formulary for the treatment of simple hypertension, and the decision not to identify ARBs as the first, second, or third line of defense for the treatment of simple hypertension. These are matters of medical judgment we will not second-guess in our bid protest forum. See GlaxoSmithKline, B-291822, Apr. 7, 2003, 2003 CPD ¶ 77 at 5.

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[9] For the record, we note that BMS does not mount any separate challenge to the solicitation's approach (first added by amendment 5 while the protest was pending), of requiring offerors to propose the same price for each of the three dosing levels identified for these drugs. By letter dated December 9, 2004, the VA advised BMS and our Office that it was removing any weights from the price evaluation methodology, and procuring these drugs on a "flat-pricing approach." BMS commented on the VA's proposed approach by letters dated December 14 and January 7. The VA issued amendment 5 on January 7. BMS filed its views on the amendment with our Office on January 13. BMS's views--consistently expressed in all three filings made after the VA's December 9 letter stating its intentions to adopt a flat-pricing approach--concern the lack of weights in the solicitation; BMS does not separately challenge the VA's decision to require offerors to provide the same price for all three dosing levels. As a result, our decision addresses the lack of weightings, it does not consider--nor have we received arguments that challenge--the agency's decision to require the same price for all dosing levels.

In conclusion, we note that the procurement here (together with its sister procurement for an ARB to treat heart failure) is the first listing by the VA of an ARB on its national formulary. To the extent that more useful dosing data is developed over the life of this contract, the VA may want to consider using that data in future procurements. In the meanwhile, BMS has not shown that the judgments underlying the agency's per-tablet pricing scheme are not reasonably accurate, or are inaccurate to such an extent that consideration of only the VA's past prescribing patterns would have yielded more accurate estimates of the agency's needs. See Bristol-Myers Squibb Co., supra.

The protest is denied.

Anthony H. Gamboa
General Counsel