USP to cut back on salt in drug names

Prop quiz: What does the United States Pharmacopeial Convention (USP) call capsules containing both amlodipine besylate and benazepril hydrochloride?

Answer: Amlodipine and benazepril hydrochloride capsules.

What does USP call tablets containing only amlodipine besylate?

Answer: Amlodipine besylate tablets.

Yet, the strength of the calcium-channel blocker in both products is expressed in milligrams of amlodipine, not its besylate salt. And the strength of the constituent angiotensin-converting enzyme inhibitor, benazepril, is expressed in milligrams of its hydrochloride salt.

That inconsistency is an example of what USP wants to avoid in the future through its new drug naming policy, which becomes official on May 1.

The policy, which is not retroactive, states in part: “The titles of USP monographs for drug products and compounded preparations formulated with a salt of an acid or base use the name of the active moiety. . . . The strength of the product or preparation also is expressed in terms of the active moiety.”

Exceptions, the policy later states, may be considered for the rare cases in which the specific salt form of the active moiety provides vital information from a clinical perspective.

The titles of USP monographs, by law, are the official nonproprietary names of drugs in the United States. When a USP monograph does not exist, the law allows FDA to assign a name to the drug. But the FDA-assigned name, according to USP, is an “interim” name.

USP this past May estimated the number of FDA-approved drug products without USP monographs at roughly 300. About 200 of the drug products have a salt in their name and the strength is expressed in terms of the salt, and the rest of the products have a salt in their name but the strength is expressed in terms of the active moiety.

The titles of monographs for this latter, smaller group, USP said, will be determined on a case-by-case basis.

A goal of the new policy is to have concise, consistent names for drug products, said Roger L. Williams, chief executive officer of USP and a former deputy director for pharmaceutical science at FDA, in announcing the policy.

Marjorie Shaw Phillips, ASHP’s representative to the group advising USP on how to communicate the new policy, said the lack of consistency has been known for a while.

“After years and years of a lot of examples of confusion and safety issues, I think it’s positive that we’re going to have a consistent naming process going forward,” she said.

Oftentimes, Phillips said, USP assigns the name for a monograph years after FDA has approved a nonproprietary name for the company’s new drug. But the monograph’s title may turn out not to be the same as the FDA-approved nonproprietary name. She said USP’s policy, which FDA is bearing in mind, will prevent companies from having to alter the name of a drug after getting it on the market.

“Clinical practitioners don’t think about this very often unless the salt is important, and most of the time it isn’t,” Phillips, pharmacy coordinator at Georgia Health Sciences Medical Center in Augusta, said.

One eventual effect that clinical practitioners may appreciate, she said, is shorter drug names in computerized prescriber-order-entry systems and on prescription container labels.

Another eventual effect is easier recognition of a salt’s importance to clinical therapy. “For new drugs,” Phillips said, “if there is a salt as part of the name, that should be a really red flag to you that there is something significant about the salt that you need to consider either in the route of administration or dosing or in patient selection.”

The pharmaceutical industry has known about the upcoming policy since at least 2007. USP said it posted the policy, termed a revision to the United States Pharmacopeia chapter on nomenclature, online that year. ASHP commented on the proposed policy in 2006.

Actually, ASHP objected to the proposed policy.

The Society warned about confusion and the potential for errors by practitioners.

Removal of the name of the salt from the title of monographs for drug products, ASHP posited, “could result in decreased understanding of important distinctions concerning biopharmaceutics, stability, compatibility, and solubility for some drugs.” Also, practitioners may inappropriately substitute a drug salt that is not therapeutically equivalent to the drug salt that had been prescribed or ordered. For patients whose intake of a specific salt must be controlled or monitored, the name of the salt in a drug product is important for practitioners to know.

Those were just three of ASHP’s reasons for objecting to the proposed policy.

More recently, ASHP offered a positive comment about the policy: a new drug product’s strength and dosing instructions will be expressed in the same way.

Specifically, ASHP said, there should not be another situation as with fosphenytoin, wherein the title of the monograph is fosphenytoin sodium, the product’s strength is expressed in phenytoin sodium equivalents and milligrams of fosphenytoin sodium, and the dose is expressed in phenytoin sodium equivalents.

—Cheryl A. Thompson

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