Inaccessibility to Quinidine Therapy Is About to Get Worse

The problem of inaccessibility to quinidine, as bad as it is (1), is likely to get worse in the near future. The problem started when AstraZeneca discontinued its production in 2006 (2,3). Now, a subcontractor of Sanofi-Aventis, the sole producer of hydroquinidine, discontinued production of this valuable medication. Available supplies of hydroquinidine will reach their expiration date by the end of this year or 2014. We are aware of a continuous effort by Sanofi-Aventis to renew the production of hydroquinidine. However, serious shortages are likely to occur in the near future.

Inaccessibility to alternative quinidine products is due to limited product distribution more than limited production. The limited number of patients in need and the low price of the drug create a negative incentive to increase the number of countries where quinidine is sold. Absence of established product distribution results in requirements for special regulatory processes in order to get quinidine supplies on an "ad-hoc" basis for patients in need. It is ironic that special permits are required to prescribe quinidine in 10% of all countries (1) even though quinidine was the most commonly prescribed antiarrhythmic medication in these very same countries only 2 decades ago. Obtaining these special permits results in delays of days to weeks between prescription of quinidine and actual supply (1). Given the life-threatening and urgent nature of the indication for the drug (arrhythmic storm with recurrent ventricular fibrillation), these waits are unacceptable. We therefore call again on the professional medical societies to work closely with national health care authorities to ensure expedited access to quinidine (3,4). Specifically, this process should consider attenuating the costs to the manufacturer to "list" the drug with the national health regulator to ensure that quinidine is readily and legally available in all countries, coupled to a commitment by the manufacturer to persist with ensuring availability and distribution of the drug.

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Reply

Sanofi currently holds marketing authorizations for hydroquinidine hydrochloride prolonged-release capsules in France since 1980 (Serecor 300 mg) and in Spain since 1973 (Lentoquine 250 mg).

In Israel, hydroquinidine is not registered but is supplied by Sanofi via a special institutional procedure authorizing the use of Serecor, upon request by Israeli medical institutions.

Hydroquinidine is an antiarrhythmic class IA medicine indicated for the prophylaxis and treatment of supraventricular arrhythmias or ventricular arrhythmias and the prevention of cardiac electric shock in some patients carrying implantable defibrillators. This product is particularly used for preventing life-threatening ventricular arrhythmias due to Brugada syndrome and idiopathic ventricular fibrillation.

Following the cessation of the activities of the third-party subcontractor responsible for manufacturing the hydroquinidine micro-granules used in Serecor prolonged release capsules, Sanofi has transferred the manufacturing process to 2 other third-party subcontractors.

Sanofi is continuously working in close cooperation with the French Health Authorities to comply with all regulatory requirements, to minimize the impact of these issues on supply to market and to maintain the availability of hydroquinidine.

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Reply

*There is no disease so **rare** that it does not deserve attention.*

The French Brugada Association (Association du Syndrome de Brugada) (1) was created in 2005 with the following goals: 1) to provide up-to-date information to patients with Brugada syndrome and their relatives; 2) to serve as a referral mechanism of patients to specialized medical centers; and 3) to serve as an educational authority for topics such as the risk of specific potentially harmful medications (2). The Association also promotes improving access to insurance for genetic carriers.

Last March we incidentally found out from a pharmacist that it will soon be difficult to find quinidine in France. We

contacted Sanofi headquarters and were informed that a third party had discontinued the production of the active ingredient of Sérécor (hydroquinidine). At the present time, the situation in France is very concerning because the inventory of Sérécor will reach its expiration date soon. Moreover, hospitals and pharmacies are rationing supplies. As a result, patients who experienced arrhythmic storms in the past and are presently stable on quinidine therapy have repeatedly contacted our Association for help.

Negotiations are in process between our Association, the French Health Authorities, and the Sanofi group. Sanofi seems cooperative but admits the problem is serious. The option of juridical action to ensure supplies of a medication for which there is no appropriate therapeutic alternative does exist in France. Therefore, we call upon authors and clinicians to provide us with appropriate information about the beneficial effects of quinidine in their patients with Brugada syndrome.

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