Availability of ^{99m}Tc-DMSA

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Imaging with ^{99m}Tc-dimercaptosuccinic acid (^{99m}Tc-DMSA) plays a very important role in initial diagnosis and follow-up of renal diseases in children. It is widely recognized that ^{99m}Tc-DMSA imaging is a highly sensitive technique to detect renal cortical damage. ^{99m}Tc-DMSA is the agent of choice for renal cortical imaging by planar scintigraphy (with pinhole magnification when needed) or by SPECT. This method can be of value in multiple pediatric clinical conditions at initial assessment and follow-up, including determination of split renal function, diagnosis of acute pyelonephritis and renal scarring (with or without vesicoureteral reflux), evaluation of the neonate with prenatal diagnosis of hydronephrosis and other congenital abnormalities, assessment of renal obstruction in young children and its effect on regional renal function, search for an ectopic kidney, diagnosis of a solitary kidney, diagnosis of renal infarction in renal vein thrombosis or renal transplants, assessment of regional renal function in renal duplication, cross-fused renal ectopia, polycystic renal disease, multicystic dysplastic kidneys, diagnosis of horseshoe kidney, and evaluation of hypertension of renal origin.

During the summer of 2014, DMSA (Kit for the Preparation of Technetium Tc99m Succimer Injection; GE Healthcare, Marlborough, MA) became commercially unavailable in the United States and was added to the U.S. Food and Drug Administration (FDA) Drug Shortages list on October 15, 2014. Initial indications suggested that the manufactured product would be available again in the following year, but delays from supplier changes and relocation of a manufacturing site resulted in a further anticipated delay (to August 2016). However, in July 2016 the manufacturer decided to delay production indefinitely.

Since then, DMSA was available only as an alternative formulation through licensed compounding pharmacies. Such products were made available in kit formulation but differed from the FDA's Reference Listed Drug (RLD) equivalent in compounding steps, shelf life, and/or shorter expiration times.

In August 2017, FDA's Drug Shortages list was updated to include the projected availability of the DMSA kit by September 1, 2017, declaring: "Due to the current critical shortage of DMSA Kit for the Preparation of Technetium Tc99m Succimer, Theragnostics, Inc. [Boston, MA] is coordinating with the U.S. FDA to increase the availability of the drug. Theragnostics has initiated temporary importation of DMSA Kit for the Preparation of Technetium Tc99m Succimer Injection into the U.S. market. This product is marketed in Germany and is manufactured in Dresden, Germany, by ROTOP Pharmaka GmbH for Theragnostics."

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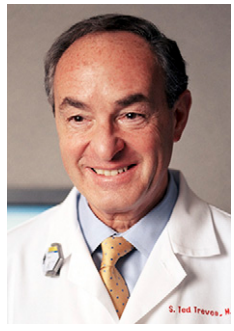

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Theragnostics also provided a "Dear Healthcare Professional Letter" on the FDA Drug Shortages page. This letter stated that "no other entity except ROTOP Pharmaka GmbH, Germany, through its distributor, Theragnostics, is authorized by the FDA to import or distribute the DMSA kit," and it further addressed prescribing information. Attachments were provided, showing a "Product Comparison Table" and "Labeling Comparison Table." These tables compared the Theragnostics DMSA product to the FDA's RLD.

Although the Theragnostics DMSA product is not an FDA-approved generic equivalent to the RLD, it is a proven manufactured diagnostic agent in Germany that is now available in the United States for medical use. The availability of ^{99m}Tc-DMSA for renal cortical imaging is welcome news for those clinicians dealing with children with suspected or diagnosed disorders of the genitourinary system.