Mephyton® (phytonadione) – First-time generic

- On May 15, 2018, Amneal launched an AB-rated generic version of Valeant's Mephyton (phytonadione) 5 mg tablets.

- Mephyton is approved in the following coagulation disorders which are due to faulty formation of factors II, VII, IX and X when caused by vitamin K deficiency or interference with vitamin K activity:

    — Anticoagulant-induced prothrombin deficiency caused by coumarin or indanedione derivatives
    — Hypoprothrombinemia secondary to antibacterial therapy
    — Hypoprothrombinemia secondary to administration of salicylates
    — Hypoprothrombinemia secondary to obstructive jaundice or biliary fistulas but only if bile salts are administered concurrently, since otherwise the oral vitamin K will not be absorbed.

- Phytonadione is also available generically as an intravenous emulsion.

    — Intravenous phytonadione carries the same indications as Mephyton and is also approved for prophylaxis and therapy of hemorrhagic disease of the newborn and hypoprothrombinemia secondary to factors limiting absorption or synthesis of vitamin K (eg, obstructive jaundice, biliary fistula, sprue, ulcerative colitis, celiac disease, intestinal resection, cystic fibrosis of the pancreas, and regional enteritis).

- Annual U.S. sales of Mephyton were $106 million, according to March 2018 IQVIA™ data.