



Survey on Hepatitis vaccine shortage among VHPB advisors

March 2018

Questions Survey

Hepatitis A vaccine

- Is there currently a hepatitis A vaccination shortage: Yes/No
- since:
- until:
- which type:
- Brand:
- Is there currently a Hepatitis A outbreak in which risk groups
- Are there prioritisation guidelines created
- Is there a need for prioritisation guidelines?

Hepatitis B

- Is there currently a hepatitis B vaccination shortage: Yes/No
- since:
- until:
- which type:
- Brand:
- Are there prioritisation guidelines created
- Is there a need for prioritisation guidelines?

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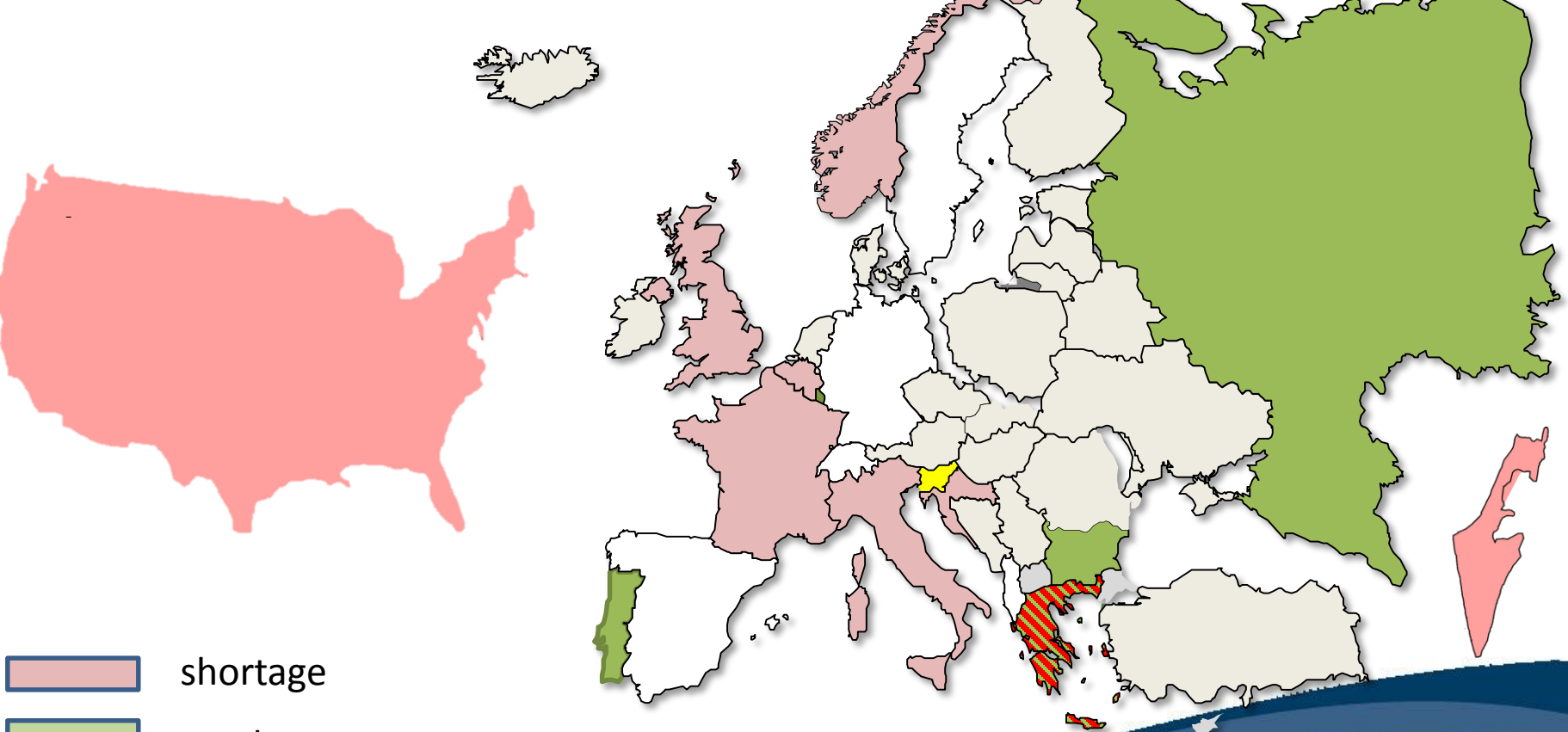
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Shortage Hepatitis A

13/17countries



shortage
 NO shortage
 No Reply



Hepatitis A vaccine

Country	since	Until	Type	Brand
Belgium	4/2017	15/07/2018	Havarix	GSK Not for Sanofi
Bulgaria				
Croatia	Last moths	?	Havarix	GSK
France	11/2016		Havrix1440 (adult)	GSK/ MSD
Greece	12/2017	05/2018	Pediatric (Vaqta) Ped/adult	MSD Not for GSK
Israel	12/2017	02/2018	Monovalent HAV	HAVrix GSK
Italy	02/2018 01/2018	05/2018	Avaxim Havrix	Sanofi GSK
Norway	Autum/2017		Adult dose	Havrix(GSK) Vaqta(Sanofi) Avax
Portugal				
Russia				
Slovenia	GSK replaced by Sanofi			
UK	Mid 2017	?	Hep monovalent	
USA	Summer '17	Spring '18	Merck production suspended	GSK unable to increase production

Hepatitis A vaccine

Country	since	Until	Type	Brand
Belgium	4/2017	15/01/2018	<p>Comment Belgium: - there is one more hep A vaccine from Merck: Vaxta and Vaxta Junior (25U) is no longer available since 10/7/2017 till 31/5/2018. the adult form of Vaxta is available. - pediatric form of Avaxim is not on the market in Belgium</p> <p>Greece: limited amount of GSK vaccines possible stock out in coming months</p>	
Bulgaria				
Croatia	Last months	?		
France	11/2016			
Greece	12/2017	05/2018		
Israel	12/2017	02/2018		
Italy	02/2018 01/2018	05/2018	Avaxim Havrix	Sanofi GSK
Norway	Autum/2017		Adult dose	Havrix(GSK) Vaxta(Sanofi) Avax
Portugal				
Russia			<p>Comment Slovenia: There is an increase in hepatitis A vaccination, mostly in MSM and, interestingly enough, in children (ie in January 2018 instead of usual 50 vaccines per month, there were 150 children vaccinated). No shortage of GSK combined HAV+HBV vaccine (Twinrix) was observed.</p>	
Slovenia	GSK replaced by Sanofi			
UK	Mid 2017			
USA	Summer '17	Spring '18	Merck production suspended	GSK unable to increase production

Hepatitis A vaccine

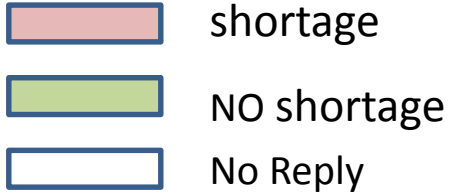
Country	outbreak	Guidelines	Need for guidelines
Belgium	No	No	Usefull
Bulgaria	No	No	Yes
Croatia			
France	No (sporadic cases)	Yes (since 03/17)	No
Greece	No (sporadic cases)	No	
Israel	No	Yes	Yes
Italy	No	No	Usefull
Norway	Small in MSM	Yes	Usefull on national level not EU
Portugal			
Russia	28 outbreaks of HAV registered		NO
Slovenia	No	No	NO
UK	Outbreak linked to food	yes	
USA	Substance users/ Homeless	Yes	YES

recommendations

- France: guidelines for Haut conseil de la santé publiqueA
- Israel: RECOMMENDED TO USE OF HAVRIX ONLY FOR SECOND DOSE, RECOMMENDED TWO SIMULTANEOUS DOSES OF HAVRIX JUNIOR UNTIL HAVRIX ADULT AVAILABLE (BOTH DOSE FORMS OF HAVRIX ARE CURRENTLY AVAILABLE, RETURNED TO STANDARD IMMUNIZATION PROCEDURES. WOULD BE WILLING TO CONSIDER UK GUIDELINES OF USING HAVRIX)
- Norway: MSM and close contacts to cases prioritised. Alternative for travel related vaccination published: 1. Use of Twinrix 2. Use of Havrix720 EU (child dose) at 0,1 and 6-12 months for adults (off-label)
- (Italy) During 2017 epidemics of hepatitis A, vaccination was primarily recommended to people at higher risk (MSM) and to close contacts with patient with hepatitis A)
- USA



Shortage Hepatitis B



Hepatitis B vaccine

Country	since	Until	Type	Brand
Belgium	06/2017 09/2017	03/2018 06/2018	Engerix 20µg HBVaxPro 10ug Twinrix	GSK MSD No shortage
Bulgaria				
Croatia	Since a year but replace product			
France				
Greece	06/2017	05/2018	MSD adult HBVaxPro 10mcg/1ml	MSD No shortage for GSK
Israel				
Italy	05/2017 02/2017 05/2017	02/2018 04/2018	Engerix 20µg HBVaxPro 10ug Twinrix	GSK MSD No shortage
Norway				
Portugal				
Russia				
Slovenia	GSK replaced by Sanofi			
UK	June 2017	Summer 2018	HBV monovalent	
USA	12/2017	Adult	one manufacturer - adult - through 2018; pediatric April 1, 2018	Merck

Hepatitis B vaccine

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Israel				
Italy	05/2017 02/2017 05/2017	02/2018 04/2018	Engerix 20µg HBVaxPro 10ug Twinrix	GSK MSD No shortage
Norway			<u>Slovenia:</u> The authorities would like to increase a supply for the year 2018 compared to the year 2017, however both GSK and Merck could provide only the amount mentioned in the previous year. To avoid possible future shortages, contracts have been already signed for the 2019 and 2020 supplies.	
Portugal				
Russia				
Slovenia	GSK replaced by Sanofi			
UK	June 2017	Summer 2018		
USA	12/2017	Adult	one manufacturer - adult - through 2018; pediatric April 1, 2018	Merck

Hepatitis B vaccine

Country	Guidelines	Need for Guidelines	Comments
Belgium	No	Usefull	FAGG, Belgian Regulatory Agency has all information on non-availability of drugs and vaccins on her website:
Bulgaria	No	Yes	
Croatia			
France	Yes, created in march 2017, have been removed since March 1st 2018	NO	
Greece	No		Limited amount-possible stock out in the following months
Israel	No		
Italy	No	Usefull	
Norway	No	No	
Portugal			
Russia	No	NO	The vaccine needs are covered mainly by two domestic manufacturers.
Slovenia	No	Not so	
UK	Yes		
USA	No - supply from other manufacturer adequate	Not at this time	Dialysis formulation not affected

Company information

(source: National Drug regulatory agencies and manufacturers)

Hepatitis A

MSD Sharp & Dohme GmbH	Hepatitis A vaccine (virus vaccine, inactivated)	Available again mid June'18
GSK	Havrix Adult	Restored capacity 2018
GSK	Havrix Junior	June'18

Hepatitis B

GSK	Engerix (paediatric/ Adult)	Resolved – return to historic volume during 2018 (due to increase demand shortage 17 constraints expected in 2018)
Merck	Hepatitis adult Paediatric	End 2018 April 2018

Conclusion end 2017 after first survey

- There are supply related constraints on securing access
 - Mentioned by companies and countries
 - Difficult to assess real consequences due to limited information
 - No supply issues in the WHO EURO Region in the recent years for HBV – new situation
 - Country specific HBV vaccine supply challenges (some countries yes, other no!)
- Need for recommendations specific for managing supply issues
 - (cfr. ECDC recommendations for pertussis Ag containing vaccine shortages)
 - Some NITAG made such product specific recommendations for HAV/HBV vaccines
 - Centralized emergency stock (at level of EU, WHO EURO, companies ...)
 - Have companies guaranteeing supply every 6 months, or switch tenders to competitor
 - Room for VHPB to draft guidelines to assist countries in making such recommendations