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**Ask EMA - (ASK-38878) VERY URGENT: request of informations regarding the components of military vaccines**

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**Da :** AskEMA <askema-no\_reply@ema.europa.eu>

mar, 20 mar 2018, 15:24

**Oggetto :** Ask EMA - (ASK-38878) VERY URGENT: request of informations regarding the components of military vaccines

 1 allegato

**A :** catalano i <catalano\_i@camera.it>

**Rispondi a :** askema-no reply <askema-no\_reply@ema.europa.eu>

**Re: EMA request reference ASK-38878**

Dear Mr Catalano,

Thank you for your enquiry of 12 February 2018. Please find a detailed answer in the attached document.

We hope you will find this information useful.

Kind regards,

Inga Abed

**European Medicines Agency**

30 Churchill Place | Canary Wharf | London E14 5EU | United Kingdom

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*Original request: VERY URGENT: request of informations regarding the components of military vaccines*

*To whom it concerns: As Vicepresident of the latest Italian Parliamentary commission on military vaccines I studied the components of vaccines administrated to Italian soldiers to define if these components are under the limits imposed by the EU law for Marketing authorization. Since is very urgent for me to define if the components declared by the manufacturing holder of the vaccines are conform to the MA, I would like to ask you if could kindly give to me - the limit amount allowed in vaccines, - the safe amount for im injection allowed for humans and - the guidelines of reference for the following*

*compounds: ADIUVANTS Aluminium Aluminium hydroxide Amorphous Aluminium hydroxyphosphate aluminium hydrated hydroxide EXCIPIENTS 2-phenoxyethanol Amino acids for injection Calcium chloride dihydrate  $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$  Citric Acid Disodium phosphate dodecahydrate  $\text{Na}_2\text{HPO}_4 \cdot 12\text{H}_2\text{O}$  Ethanol Hydrolyzed Porcine Gelatin L-Arginine Lactose Magnesium chloride hexahydrate  $\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$  Magnesium sulfate heptahydrate  $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$  Mannitol Potassium dihydrogen phosphate  $\text{KH}_2\text{PO}_4$  Phenylalanine Polyethylene 400 (PEG 400) Polysorbate 20 Polysorbate 80 + Octoxynol 10 (Triton X-100) Potassium chloride KCl RRR-alpha-Tocopheryl hydrogen succinate Sodium borate Sodium Borate Decahydrate Sodium chloride NaCl Sodium citrate Sodium deoxycholate Sodium dihydrogen phosphate  $\text{NaH}_2\text{PO}_4$  Sodium dihydrogen phosphate dihydrate or Sodium phosphate monobasic dihydrate  $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$  Sodium phosphate dibasic dihydrate  $\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$  sorbitan trioleate Sorbitol Squalene Sucrose Urea L-Cysteine hydrochloride  $\cdot \text{H}_2\text{O}$  L-Arginine L-Glutamine L-Tyrosine Solution N°4 (Amino Acids) Solution N°6 (vitamins) Sodium hydrogen carbonate ( $\text{NaHCO}_3$ ) Sodium carbonate anhydrous D-Bactogalactose Saccharin Dextrose CONTAMINANTS Acetaldehyde Acetone Amberlite™ XAD4 Antibiotics Gentamicin sulfate Kanamycin acid sulphate Neomycin Neomycin sulphate Antifoaming agent Arsenic Bacterially-derived DNA Barium sulphate Bovine Serum Albumin (BSA)  $\text{CaCl}_2$  Caesium chloride ( $\text{CsCl}_2$ ) Cetyltrimethylammonium bromide (CTAB) Chloroform EDTA and phenylmethyl sulfonyl fluoride e PMSF Endotoxin Ethylene glycol Formaldehyde Free Fatty Acids (acidi grassi Haemagglutinin (HA) e Neuraminidase (NA) Heavy metals Heptaacyl MPL Human Serum Albumin (HSA) Hydrocortisone Isopropanol KDO 2-keto-3-deoxyoctonate (Sialic acid) L-cystine Methanol Monosodium L-Glutamate Ovalbumin PCB/Dioxin Phenol red Phospholipid Silicium (Silicon) Thiocyanate Thiomersal ( $\text{C}_9\text{H}_9\text{HgNaO}_2\text{S}$ ) Yeast DNA Yeast-derived polysaccharides Yeast-derived proteins (HBsAg etc..) B-propiolactone Phenol Medium 199 Adenine Thymidine Chicken eggs cells Chicken embryos cells Diploid human cells (MRC-5) Trometamol Chlortetracycline E172 E127 Hydroxypropyl methylcellulose phthalate (HP-MCP)-50 Dibutyl phthalate Diethyl phthalate Sodium hydroxide Hydrochloric acid Sulfate protamine Latex Polymyxin B Polygeline Octoxynol 9 Streptomycin Potassium L-glutamate Since this is a strigtly confidential work I ask you to keep highly reserved the communications between us King regards On. Ivan Catalano*

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This e-mail has been scanned for all known viruses by European Medicines Agency.

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