

 **Health** that lasts a **lifetime!**
eubiologics 

**Vaccine for Infectious Diseases and Immuno-Oncology
Development & Manufacturing**

EuBiologics Co., Ltd.



www.eubiologics.com

I. Corporate Overview

Company Overview

Company Profile

Establishment	10 th March, 2010
Business Place	HQ: Seoul Facility - 2 Manufacturing sites in Chuncheon - R&D Center in Chuncheon
No. of Employee	Over 200
Revenue('20)	USD 23M
Market Capital	USD 700M Listed in KOSDAQ since Jan 2017
Business Area	- Vaccine Development, Manufacturing & Supply - CRMO(Contract R&D and Manufacturing Organization)

CEO Profile



Dr YEONGOK BAIK

- Bachelor, Master in Veterinary Medicine, Seoul National Univ.
- Ph.D. in Life Science, Korea Univ.
- CJ Corporation
- Director, Korea Institute of Industrial Technology

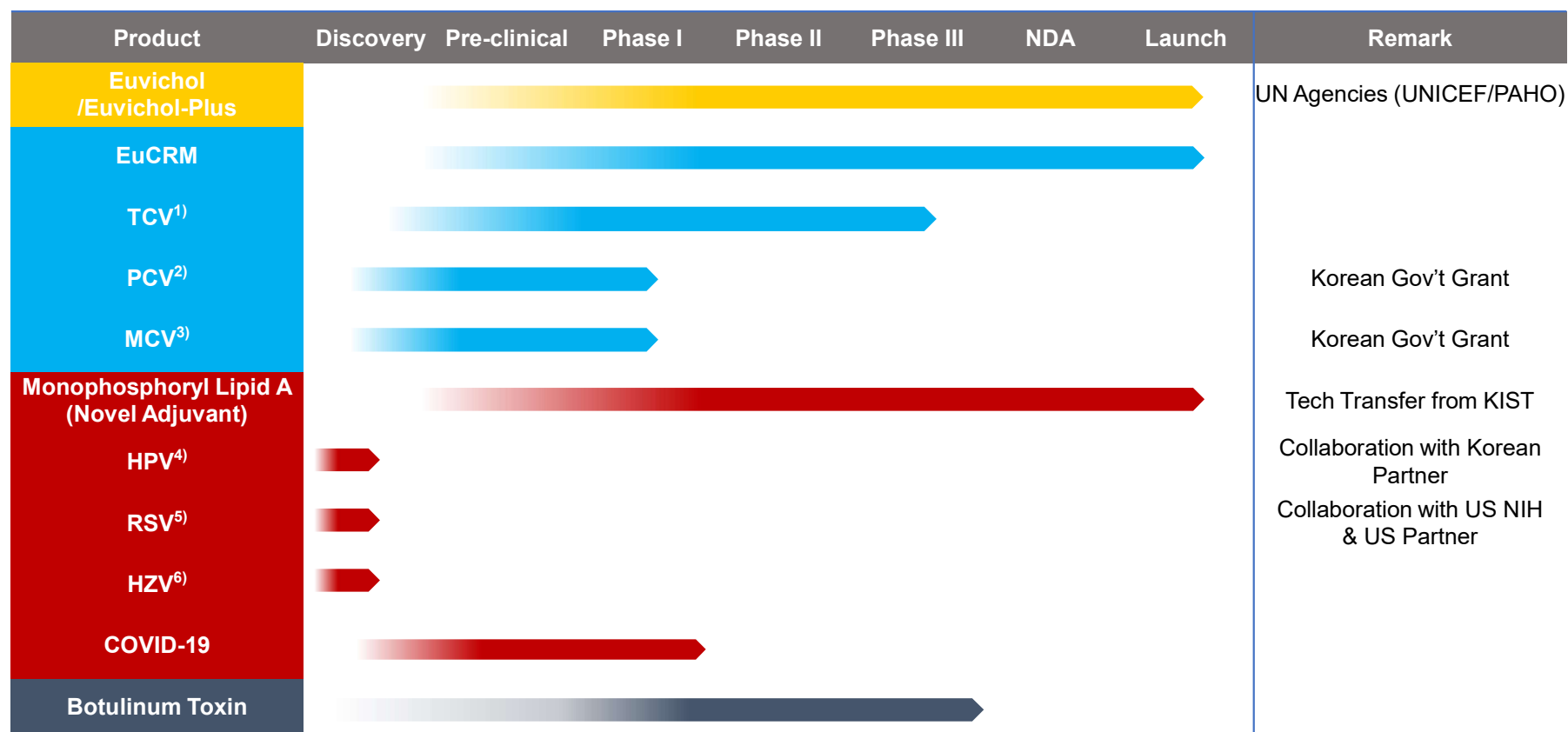
CEO Profile



SEUKKEUN CHOI

- Bachelor in Microbiology, Seoul National Univ.
- Green Cross Corporation
- CJ Corporation
- LG Life Sciences
- Plant head, Meditox

Pipeline



1) TCV: Typhoid Conjugate Vaccine 2) PCV: Pneumococcal Conjugate Vaccine 3) MCV: Meningococcal Conjugate Vaccine

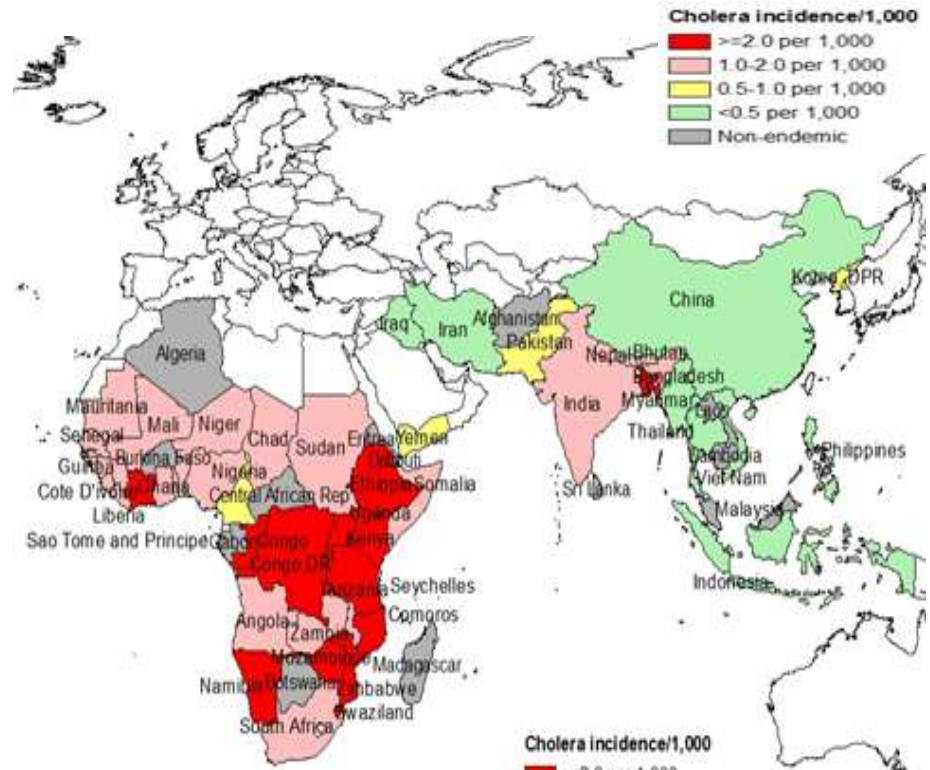
4) HPV: Human Papilloma Virus 5) RSV: Respiratory Syncytial Virus 6) HZV: Herpes Zoster Virus

II. OCV Development

Global Disease Burden of Cholera

Global Burden of Cholera: WHO reports;

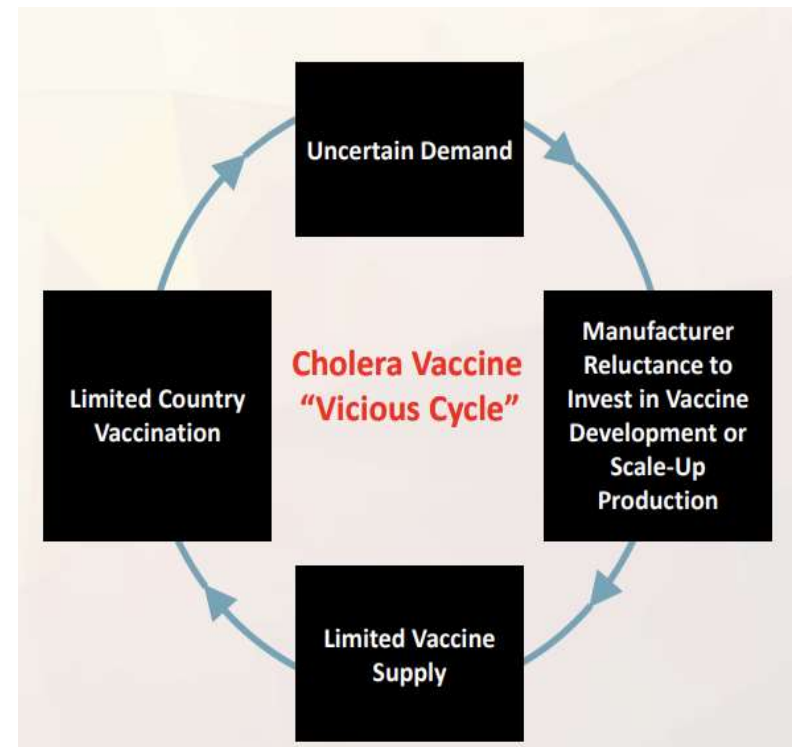
- **3 million cholera cases annually**
- Africa and Southeast Asian regions
- **Half of the cases in children less than 5 years**
- **About 100,000 deaths per year**
 - ✓ All deaths in Asia and Africa
 - ✓ About 97% of morbidity and mortality in endemic countries
 - ✓ About 92% in GAVI-eligible countries



The Global OCV Stockpile

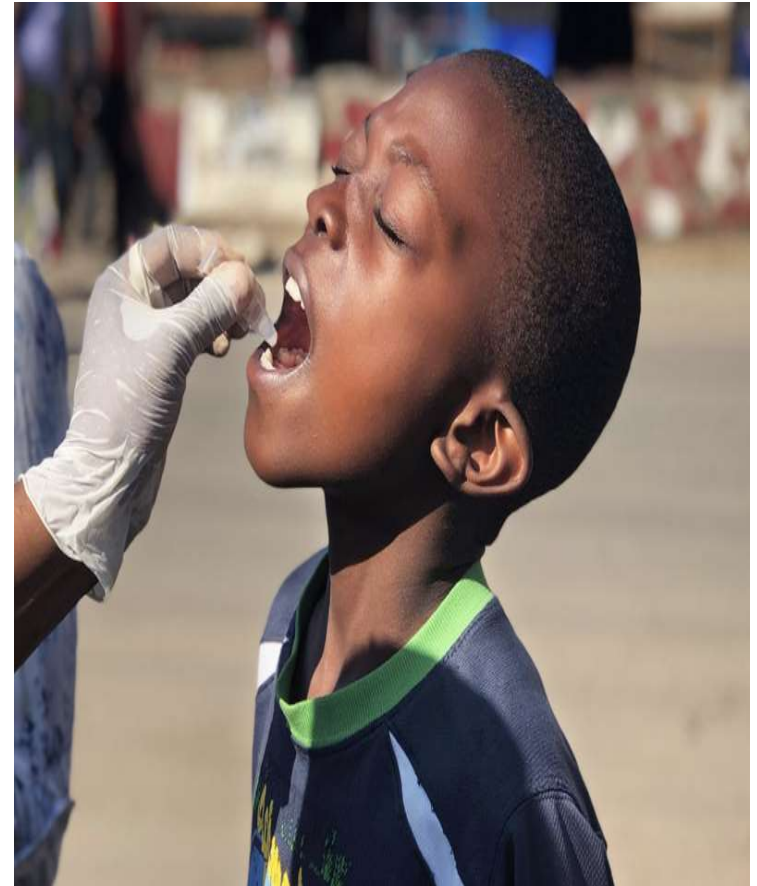
The global oral cholera vaccine (OCV) stockpile was founded in mid-2013 by five donors including BMGF.

- *Inexpensive and effective vaccines are under utilized because of the “vicious cycle” of uncertain demand and inadequate supply*
- *In order to convert the “vicious cycle” into a “virtuous cycle” of vaccine availability and country adoption, demand and/or supply stimuli are needed*
- *A cholera vaccine stockpile could break the “vicious cycle” and convert it into a “virtuous cycle”*



GAVI Support

- GAVI has supported the global OCV stockpile since 2014
- In 2013, the GAVI approved support for the stockpile as part of their Vaccine Investment Strategy (VIS). The contribution of over US\$ 110 million for the 2014-2018 period to increase access to OCV during emergencies and in countries that regularly experience cholera outbreak.
- In Nov 2018, GAVI decided to extend support for OCV to 2020 to include planned & preventive immunization
- OCV was included in GAVI 5.0 VIS (2021 to 2025)



eu**bi**ologics 

Euvichol® is the 2nd Oral Cholera Vaccine(OCV) developed by technology transfer from IVI, and equivalent to Shanchol™ (Shantha Biotechnics, India) in terms of quality, safety and effectiveness



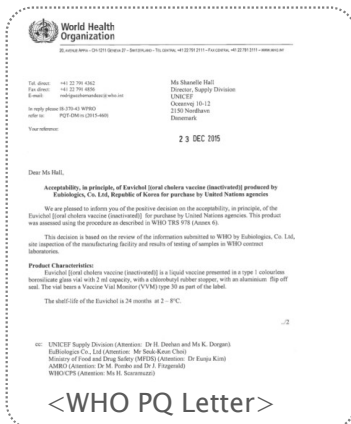
- Apr 2011 Non-clinical Trial for OCV in Korea
(<http://dx.doi.org/10.5487/TR.2012.28.4.225>)

- Oct 2012 Phase I Clinical Trial in Korea
(<http://synapse.koreamed.org/DOIx.php?id=10.3346/jkms.2014.29.4.494>)

- Aug 2014. Non-inferiority trial “A Randomized, Non-inferiority Trial Comparing Two Bivalent Killed, Whole Cell, Oral Cholera Vaccine (Euvichol vs Shanchol) in the Philippines ([http://linkinghub.elsevier.com/retrieve/pii/S0264-410X\(15\)01228-1](http://linkinghub.elsevier.com/retrieve/pii/S0264-410X(15)01228-1))

- Jan 2015 Approval of Marketing Authorization from MFDS

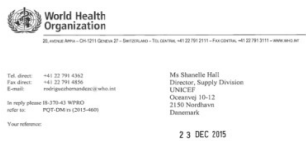
- Dec 2015 Euvichol Prequalification



Euvichol Milestone_Cont.



- May 2016 Executed a Long-Term Arrangement with UNICEF
- Sep 2016 PQ variation approval (600L without thimerosal) by WHO
- Mar 2017 Approval of plastic tube presentation by MFDS
- Aug 2017 PQ variation approval of plastic tube (Euvichol-Plus)



Dear Mr. Hall,

Acceptability, in principle, of Euvichol (oral cholera vaccine (inactivated)) produced by Eubiotics, Co. Ltd, Republic of Korea for purchase by United Nations agencies

We are pleased to inform you of the positive decision on the acceptability, in principle, of the Euvichol (oral cholera vaccine (inactivated)) for purchase by United Nations agencies. This product was assessed using the procedure as described in WHO TRS 578 (Annex B).

This decision is based on the review of the information submitted to WHO by Eubiotics, Co. Ltd, site inspection of the manufacturing facility and results of testing of samples in WHO contract laboratories.

Product Characteristics:
Euvichol (oral cholera vaccine (inactivated)) is a liquid vaccine presented in a type 1 colourless borosilicate glass vial with 2 ml capacity, with a chlorobutyl rubber stopper, with an aluminium flip-off seal. The vial bears a Vaccine Vial Monitor (VVM) type 30 as part of the label.

The shelf-life of the Euvichol is 24 months at 2 - 8°C.

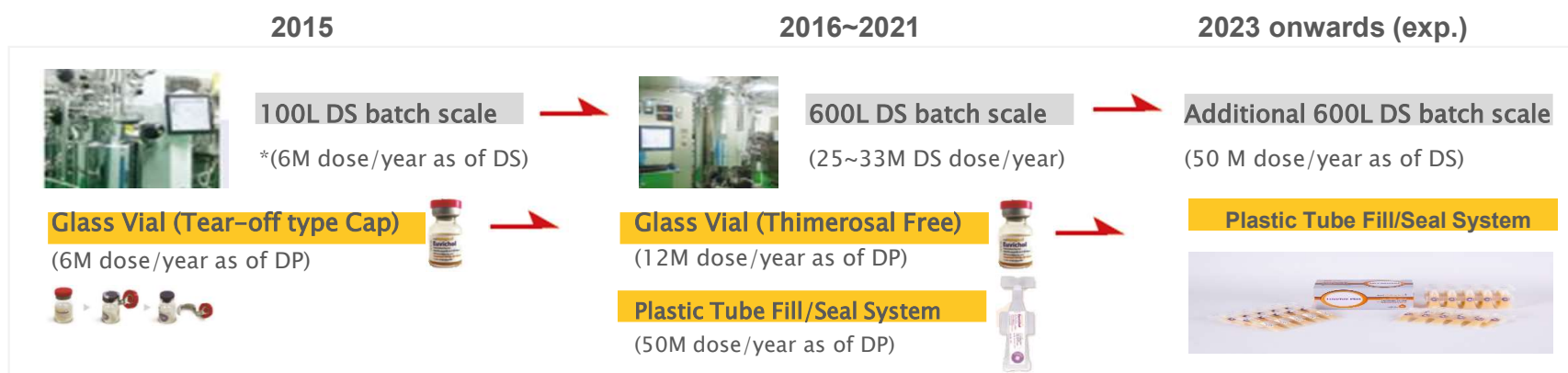
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WHO/2015/4000 (Attention: Dr H. Doherty and Mr K. Dargatzis)
Eubiotics Co. Ltd (Attention: Mr. Jeon-Kwon Choi)
Ministry of Food and Drug Safety (MFDS) (Attention: Dr Eunja Kim)
AMRO (Attention: Dr M. Pineda and Dr J. Flanagan)
WHO/CPI (Attention: Mr M. Sarmiento)



Scale-up and Development

EuBiologics has made continuous effort for capacity expansion and improvement of presentation. As of now, EuBiologics is able to produce up to 33M doses annually. With the support from BMGF, EuBiologics has been working on expansion of DS facility, which allows to produce up to 50M doses from 2023 onwards.



◆ Euvichol vs Euvichol-Plus

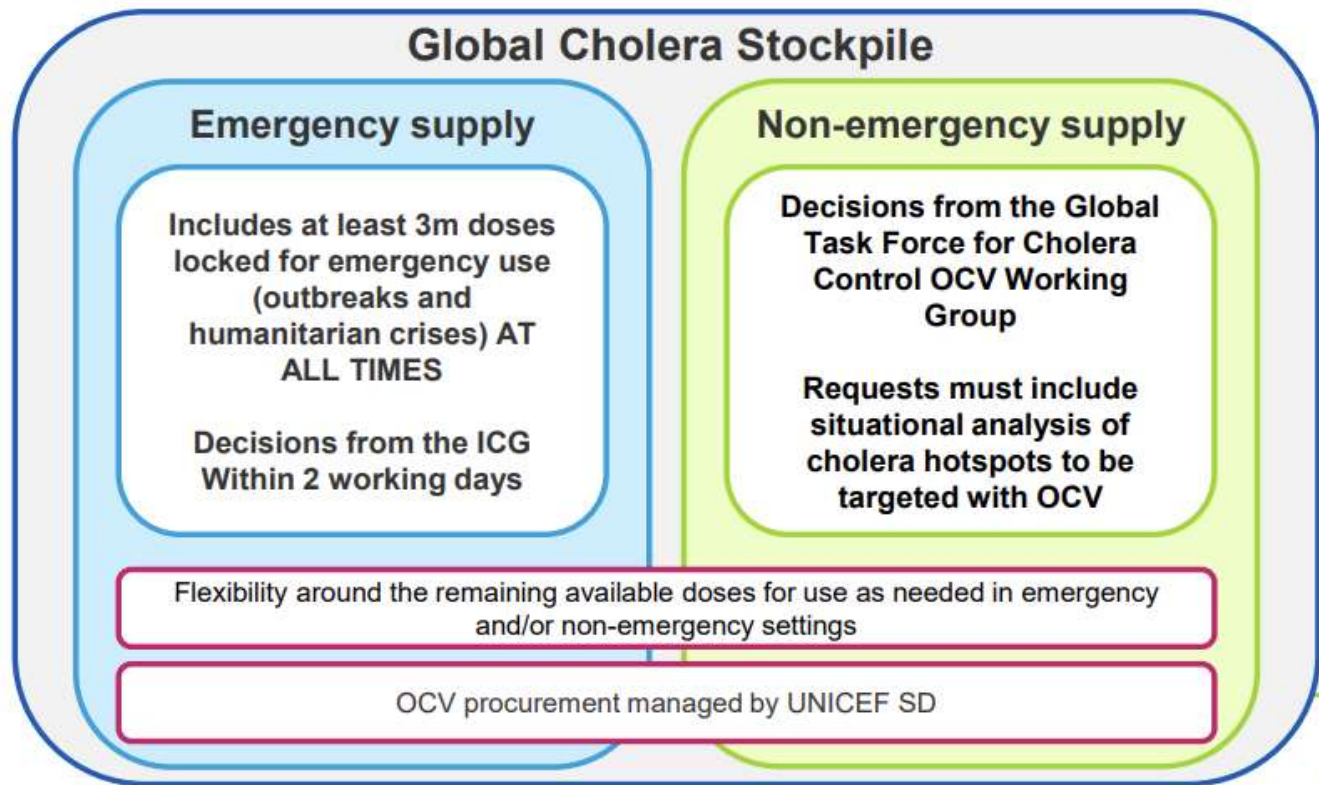
External Box for export	Width (mm)	Length (mm)	Height (mm)	Quantity	Volume /dose (cm ³)	Weight/dose (g)
Euvichol	570	530	425	2,400	53.5	14.6
Euvichol-Plus	700	700	505	6,400	38.7	6.7

👉 *Almost 30 % reduction in volume/More than 50% reduction in weight*

III. The Global OCV Stockpile

Decision-Making Mechanism

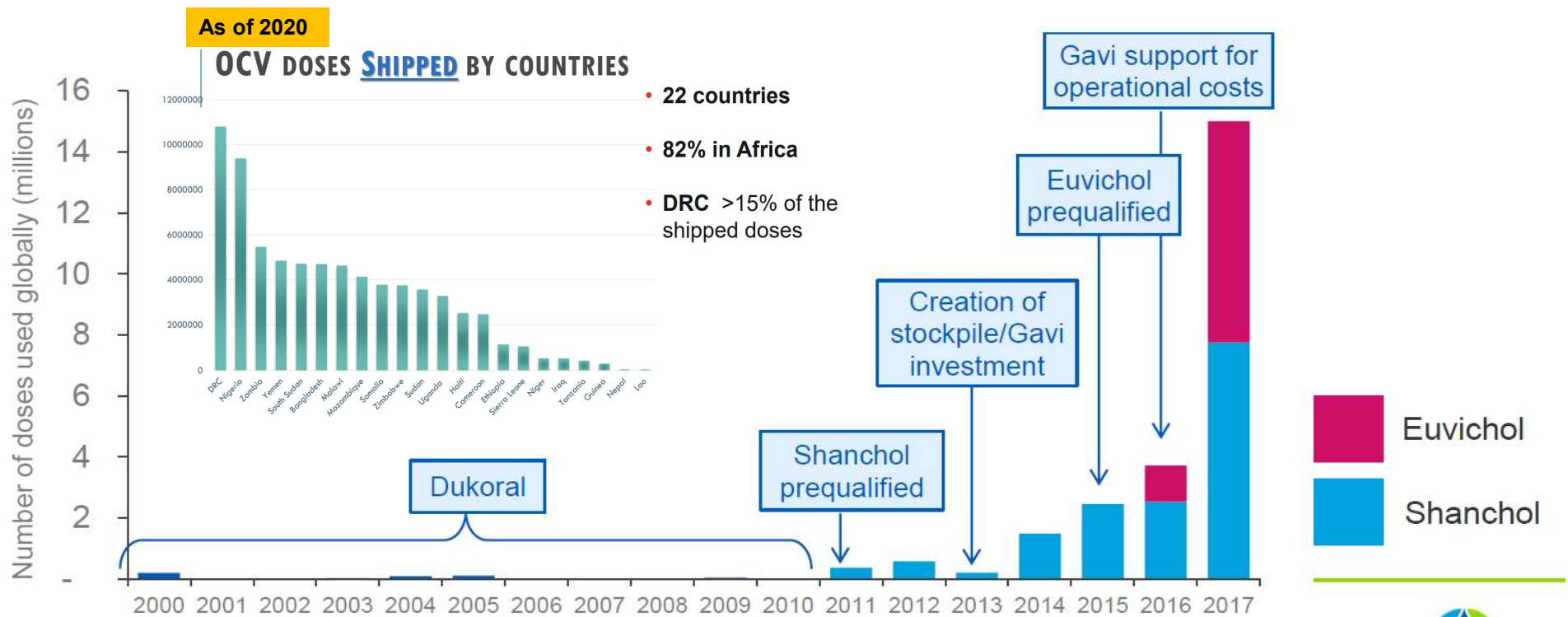
There are two mechanisms for deployment of global OCV stockpile, ICG for emergency and Global Task Force on Cholera Control for non-emergency supply (i.e. preventive campaigns)



Source: GAVI

Market Landscape

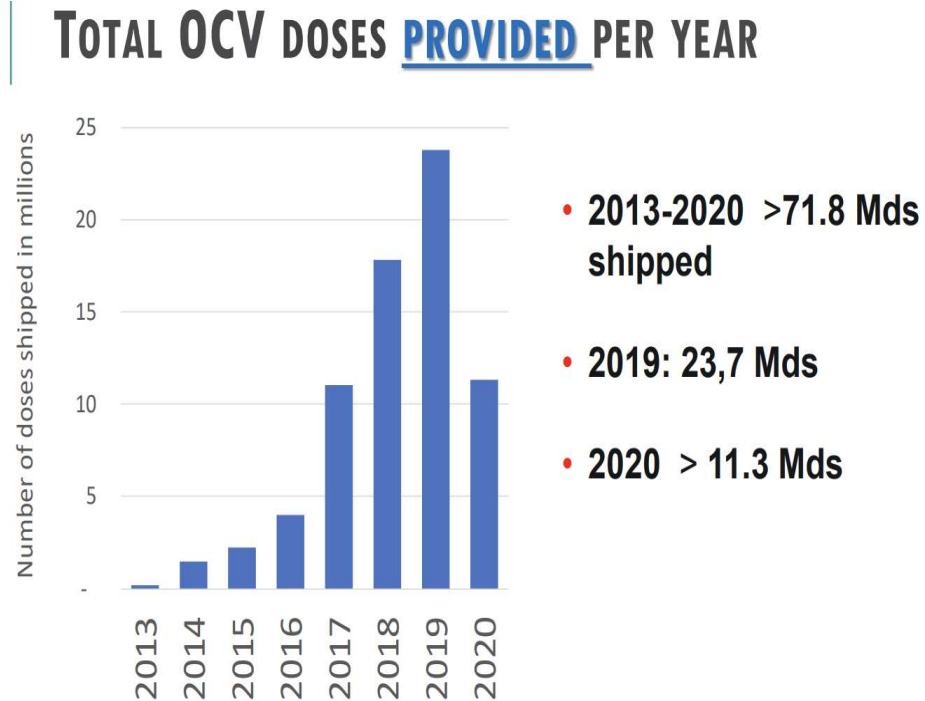
Due to the lack of supply prior to the prequalification of Euvichol, the OCV quantity procured by UNICEF was low. OCV is one of the successful cases of GAVI for market shaping.



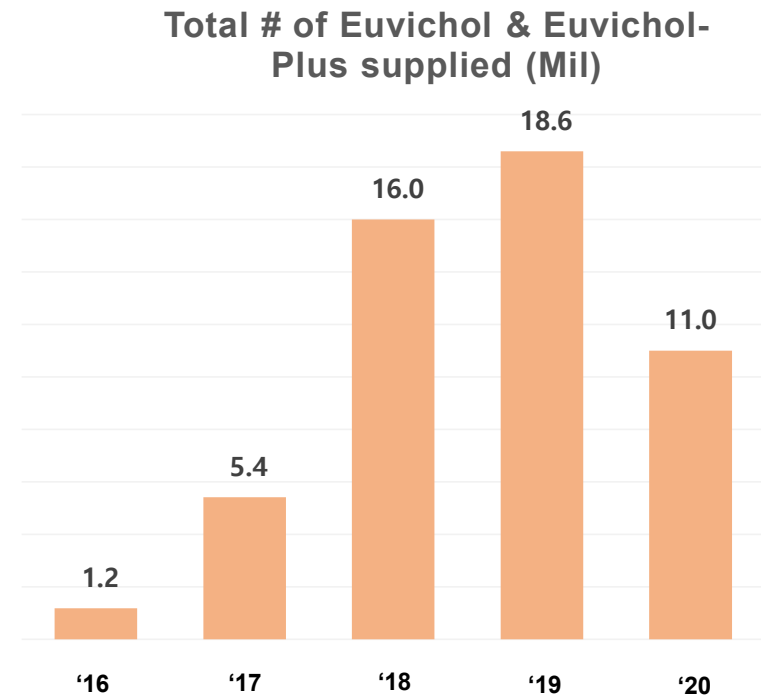
Source: GAVI

OCV Shipment

The total number of OCV doses procured by UNICEF has been significantly increased since 2016 and 71.8M doses have been supplied by 2020. EuBiologics has supplied about 55M doses of Euvichol and Euvichol-Plus to cholera endemic/outbreak countries through UNICEF since Oct 2016.



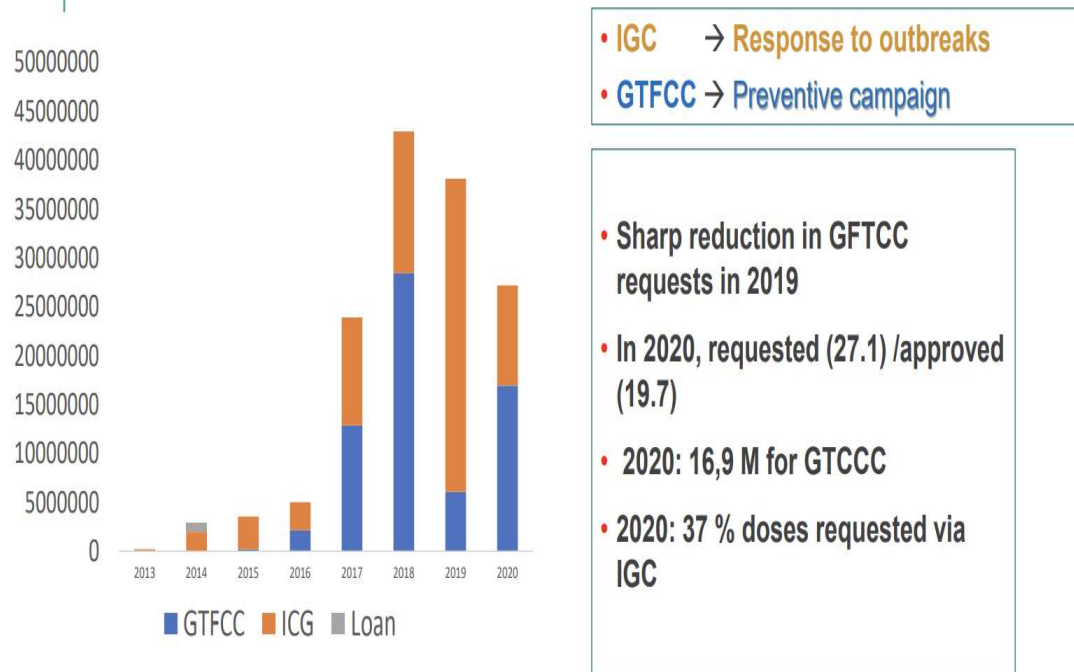
Source: Global Task Force on Cholera Control, WHO



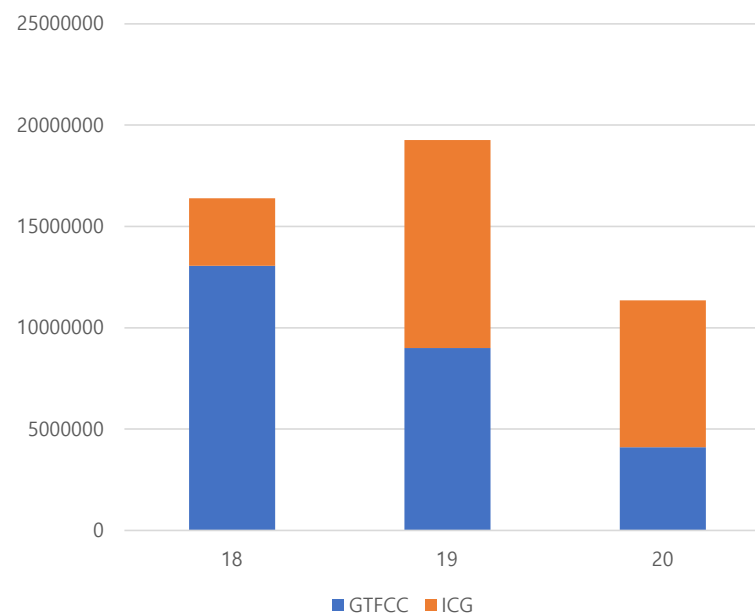
ICG vs GTFCC

ICG request represents a majority of OCV supply in 2019 and 37% in 2020.

OCV DOSES REQUESTED BY MECHANISM PER YEAR



Euvichol Supply ICG vs GTFCC



Source: Global Task Force on Cholera Control, WHO

IV. Stockpile Experiences

Contractual Agreement

The total emergency stockpile size for OCV is decided in ICG meeting every year and EuBiologics has been awarded accordingly.

Year	Total stockpile (Decision by ICG)	Stockpile Award of EuB
2017	2M doses	1.1M
2018	No decision made	-
2019	A revolving buffer of 8 million doses, of which 3 million available at all times	1.5M
2020	3M doses	1.5M
2021	N/A	-

Year 2017

The total quantity of the awarded doses will be allocated

- 1,100,000 vials of OCV-1 (1,100,000 doses) for the Emergency Stockpile
- 2,900,000 vials of OCV-1 (2,900,000 doses) for the Non-emergency Reserve,

Lead Time for Delivery (Emergency)

EuBiologics is required to be ready for shipment within 48 hours after receipt of PO. Finished product (after NRA release) shall be stored in cold storage as awarded, on a revolving stock basis.

**Order
Receipt**

Heads-up provided by UNICEF when the request submitted to ICG with quantity. Weekly OCV availability sheet sent to UNICEF

**Order
confirmation
in 24 hours**

9. ORDER CONFIRMATION

The Supplier shall acknowledge receipt of a Purchase Order by completing, signing and returning the Purchase Order acknowledgement:

- . within twenty four (24) hours of its receipt for outbreak response Purchase Orders
- . within five (5) working days of its receipt for preventive campaigns Purchase Orders

**Delivery lead-
time of
48 hours**

8.3 The delivery lead-time for quantities delivered from the Stockpile pursuant to Purchase Orders issued under this LTA-G is forty-eight (48) hours. The Supplier will use its best efforts to comply with the delivery lead time for the Goods required in the specifications and instructions set out in this LTA-G. "Delivery lead time" is the period from the date the Supplier receives a Purchase Order until the date the Goods are delivered in accordance with the applicable delivery term and instructions specified in this LTA-G and the relevant Purchase Order, and includes the period for packing the products and provision of all documentation

Lead Time for Delivery (Non-Emergency)

EuBiologics is required to be ready for shipment within 14 days after receipt of PO. No purchase orders given for non-emergency unless the stock level reaches at 1.5M

**Order
Receipt**

Heads-up provided by UNICEF when request submitted to GTFCC with quantity. Weekly OCV availability sheet sent to UNICEF

**Order
confirmation
in 5 working
days**

9. ORDER CONFIRMATION

The Supplier shall acknowledge receipt of a Purchase Order by completing, signing and returning the Purchase Order acknowledgement:

- . within twenty four (24) hours of its receipt for outbreak response Purchase Orders
- . within five (5) working days of its receipt for preventive campaigns Purchase Orders

**Delivery lead-
time of
14 days**


17.1.4 To ensure that the Freight Forwarder without undue delay can arrange dispatch of the consignment(s), the Supplier is required to complete and sign the Notification of Goods# Readiness form and send the form to the freight forwarder, to provide them with cargo particulars and Goods Readiness date as defined in the Standard Operating Procedures between the Supplier and the freight forwarder, normally 14 calendar days prior to the Purchase Order

Storage Requirement

- **Storage requirement of at least 1.5M doses at all times in 2020 and 2021**
 - *Non-priority orders (OCV needed for preventive campaigns or 2nd dose requirement) are postponed until the stock level reaches at 1.5M doses*
- **Stockpile is at a revolving stock basis, therefore, EuBiologics is required to continue production to receive orders**
 - *If not materialized, UNICEF rolled over the quantity to the next year*
- **However, production on hold if stockpile reaches at 8.5M due to the cold storage capacity**
 - *In 2020, 29M doses awarded but 11M doses supplied due to the COVID-19. The produced quantity remained at 15.5M*

Challenges

- **Challenges in production planning, workforce management, sales forecast**
 - Uncertainty over the production quantity due to the demand
- ✓ *Challenges to provide projection to DP CMO hired for glass vial*
 - Continuing production was not feasible due to storage capacity and shelf life
 - Managing the fixed cost and workforce (given OCV was the sole product for EuB)
- **Business sustainability at risk**
 - Financial losses incurred caused by lack of demand in '16 and '17
 - The pricing applied when proposal submitted to UNICEF in '15 (exp. quantity higher than the demand materialized) and no flexibility for pricing adjustment during the tender period till '18

- 
- **Appeal to the global stakeholders for demand materialization**
 - **Sustained with proceeds raised from IPO in 2017**
 - **Attract CRMO business to fill the gap**

Suggestions

- **Design the facility for multi-purposes to switch into other production/business**
 - Half-funded OCV expansion facility designed for multi-purposes to serve CMO
- **Close and timely communication to have up-to date information on upcoming orders**
 - Regular demand update from UNICEF and share the OCV weekly availability sheet
- **Risk sharing between manufacturers and UNICEF**
 - **Purchase orders given in advance**
 - ✓ For 2nd dose requirement of outbreak or planned preventive campaigns
 - ✓ Bulk in stock and produce in time for delivery (6 weeks from bulk to ready for shipment)
 - ✓ Bulk shelf life (48M) is longer than the finished product (24M)
 - **Innovative financing mechanism for stockpiled vaccines facing demand uncertainty**
 - ✓ Prepaid but stored at supplier's warehouse
 - ✓ Pricing ladder
 - ✓ Pricing proposal on a yearly basis (reflecting demand from the previous year)
 - ✓ Purchase commitment for a certain number of doses