EDITORIAL

Manoj K. Singh
Founding Partner

The regulatory body of any country should be the strongest body as it is responsible in taking all necessary action in its jurisdiction to maintaining the quality of the drug during its research, manufacturing and distribution. It plays an important role in running the health care system of the country. Any amendments made in acts and regulatory guidelines should be placed on the public domain to make an easy access of such amendments and guidelines to public and various stakeholders dealing with drug manufacturing.

We are pleased to present this Vol. III Issue X of S&A – Pharma Newsletter. Through this newsletter, we aim to share recent information allied to regulatory reforms and updates from pharmaceutical sector in India as well as from foreign jurisdictions, based on information collated through research and appraisal of applicable statutory provisions.

In the present issue, we start with an article on government's proposal to form new drug recall system to curb substandard drugs in the Indian market, followed by a discussion on the Health Ministry's proposal to amend Medical Device Rule, 2017, to regulate all medical devices under DCGI. The issue then throws some light on the partnership between EVI and Hilleman Laboratories to advance a safe, efficacious and affordable Shigella vaccine developed by Hillman. Further on, the issue writes upon the *'Malaria Elimination Research Alliance (MERA)'* initiated by ICMR to bring the stakeholders together in the process to fasten the elimination of the disease. The issue goes on to give the readers details on the guidance issued by Health Ministry for the evaluation of in-Vitro Diagnostic medical devices. Further, the issue discusses the launch of two diagnostic kits developed together by ICMR-IVRI under 'Make in India' initiative.

The volume also discusses o recent Healthcare updates from India presented as a separate section under '*India HealthCare Highlights October 2019'*.

From the international arena, a separate section discusses recent regulatory updates from US FDA and WHO under the headings '*US FDA Pharma Updates October 2019'* and '*WHO Updates October 2019'* respectively.

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Trust you enjoy reading this issue as well. Please feel free to send your valuable inputs / comments at newsletter@singhassociates.in

Thank you.

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Government launches two diagnostic kits developed under 'Make in India' initiative

On October 15, 2019, the government released two diagnostic kits developed together by Indian Council of Agricultural Research (ICAR) & Indian Veterinary Research Institute (IVRI) under the '*Make in India'* initiative. These two diagnostic kits named the *Bluetongue sandwich ELISA (sELISA)* and *Japanese Encephalitis (JE) IgM ELISA kit* are for the detection of Antigen and control of JE in Swine respectively. These new, indigenously developed technologies are ten times cheaper than the imported kits and also have the potential to earn foreign exchange.

The *Japanese Encephalitis (JE) IgM ELISA kit* detects the active infection of JE virus in the swine population which causes the outbreak of JE in humans. As compared to the price of available commercial kit in the market, the indigenous kit will be 10 times cheaper in cost and each kit is meant for testing around 45 samples.

The *Bluetongue sandwich ELISA (sELISA) kit* detects Bluetongue Virus as antigen and helps in preventing the spread of BT virus through vector management and quarantine.

About JE

Japanese encephalitis (JE) is a viral disease that infects animals and humans, caused by a flavi virus that affects the membranes around the brain. It is transmitted by mosquitoes in humans causing inflammation of the membranes around the brain. Japanese encephalitis is a leading cause of viral encephalitis in Asia generally spread from western pacific region in east to Pakistan in west and from Korea in north to Papua New Guinea in south[1].

About BT

Bluetongue (BT) virus is an insect-transmitted viral disease of domestic and wild ruminants that includes the camelid species. The disease is widespread among sheep, goats, cattle, buffaloes and camels in the country. The BT virus can be controlled via vaccination of susceptible animals, vector control and quarantine of infected animals with the good management practices[2].

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1 https://www.nhp.gov.in/disease/neurological/japanese-encephalitis

2 https://pib.gov.in/PressReleseDetail.aspx?PRID=1588210

Health Ministry to regulate all medical devices under DCGI

On October 18, 2019, the Health Ministry proposed a draft amendment in Medical Device Rule 2017 (MDR) under Drugs and Cosmetic Act, 1940 (Act) to regulate all medical device notified under clause (b) of section 3 of the Act except the medical devices and devices specified in the Annexure of Eighth Schedule of MDR. The proposal says that all the devices shall be registered with the Central Licensing Authority (CLA) using SUGAM portal established by the Central Drugs Standard Control Organization (CDSCO) on voluntary basis for a period of eighteen months from the commencement of this Rule, and thereafter, it shall be mandatory. In order to register their medical devices, one should upload relevant information using Online System for Medical Devices:

- The manufacturer is required to upload the company details, manufacturing site details, certificate of compliance with respect to ISO 13485, standard accredited by National Accreditation Board or International Accreditation Forum in respect of such medical device, applicant details etc. Once the registration process is completed, a registration number will be generated. The manufacturer shall mention this registration number on the label of the medical device.
- The importer of medical device under Rule 19A of MDR is required to upload the details of company or firm or any other entity importing the medical device including specifications and standards of that medical device, details of medical devices, certificate of compliance with respect to ISO 13485, standard accredited by National Accreditation Board or International Accreditation Forum, Free sale certificate from country of origin etc. Once the registration process is completed, a registration number will be generated. The importer shall mention the registration number on the label of the medical device.

However, the CLA may verify the uploaded documents at any point of time or in order to investigate quality/ safety related failure/ complaints. Subsequently, if found to be non-compliant to the Rule, it may cancel the registration number for the said medical device/s or suspend it for a period as CLA thinks fit. The CLA may offer the registrant an opportunity to show cause as to why such an order should not be passed[1].

The draft amendment is resulted after the recommendation of *2nd Drug Technical Advisory Board (DTAB) which says that all medical devices should be regulated in Drugs and Cosmetics Act, 1940, in a phased manner as following:

Phase I: All manufacturers and importers of all non-regulated medical devices should register the details of the devices manufactured/imported by them in SUGAM portal established by CDSCO, further -

- The said registration should be voluntary up to 18 months from the date of notification and thereafter, it shall become mandatory for all importers and manufacturers in the country.
- During this phase, all manufacturers and importers should report the Serious Adverse Events (SAEs) to CDSCO as well as Materiovigilance Programe of India (MvPI) for safety and performance evaluation of the devices and take appropriate regulatory interventions for patients' safety.
- Similarly the complaints regarding failure in Quality Management System, design, product quality etc., should be reported to CDSCO for appropriate investigation and regulatory actions.

Phase II: Once the 18 months registration period of phase I is over, the registration of Class A & B devices (low risk devices) shall be followed by mandatory licensing within 12 months. After the 12 months period, no person, company, organization should be allowed to manufacture, import, sell or distribute Class A & Class B Medical Devices without prior license under the Medical Devices Rules, 2017.

1 http://www.egazette.nic.in/WriteReadData/2019/213308.pdf

Phase III: Registration of Class C & D (High risk devices) devices shall be followed by mandatory licensing within 24 months after 18 months of registration period is over. After the 24 months period, no person, company, organization should be allowed to manufacture, import, sale or distribute Class C & Class D Medical Devices without prior license under the Medical Devices Rules, 2017.[2]

Note – The government has sought comments from all stakeholders and persons affected by this within 30 days of the date of draft notification.

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2 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=ODc5

Partnership between Hilleman and European Vaccine Initiative to develop new Shigella vaccine

On October 07, 2019, the European Vaccine Initiative (EVI) announced a grant of €8.6 million funding to Hilleman Laboratories, India, for developing new Shigella vaccine. The partnership between EVI and Hilleman Laboratories announced that a multidisciplinary, international consortium coordinated by EVI, has now received support from the European and Developing Countries Clinical Trials Partnership (EDCTP) to advance a safe, efficacious and affordable Shigella vaccine being developed by Hilleman Laboratories.

Other partners in the project are Leiden University Medical Center, the Netherlands, the Groupe de Recherche Action en Santé, Burkina Faso, the Centre for Infectious Disease Research, Zambia, and the University of Gothenburg, Sweden.

Through this partnership, the Hillman Laboratories is expected to receive funding support from EDCTP and technical support from the consortium members. The partnership aims to develop the new Shigella vaccine candidate up to mid-clinical stage, specifically to the preparation and conducting Phase Ia/Ib clinical trial in European and African adults, followed by an age de-escalating Phase II trial in Burkina Faso, and a multi-centre phase IIb clinical trial in Burkina Faso and Zambia. Moreover, specific epidemiologic data will be generated on the incidence of Shigella disease in the two African countries among children under five. The partnership is a landmark announcement as there is still no vaccine available for use against Shigella[1].

About Shigellosis

Shigellosis is an acute enteric infection further causing diarrhea. Shigellosis is mostly caused by consumption of food and water contaminated with Shigella bacteria. The disease affects almost 165 million people every year, and more than 212,000 deaths in all age groups. It is reported as that after rotavirus, it is the second most common cause of diarrhoeal deaths in children under five years of age. More than 50% of the Shigella burden lies in Africa.

About ShigOraVax vaccine

Vaccination has proven to be a key effective measure for preventing morbidity and mortality from childhood diarrhoeal diseases. There is proven efficacy of anti-diarrhea vaccines even against the rotavirus, the most common cause of acute gastroenteritis in children.

Hilleman Labs has developed a low-cost, easy-to-administer Shigella vaccine in collaboration with National Institute of Cholera and Enteric Disease (NICED) Kolkata and Indian Council of Medical Research (ICMR) Institute, New Delhi, India. ShigOraVax will be the first-ever Indian vaccine developed to benefit people living in low and middle income settings. The vaccine is under clinical phase testing safety and immunogenicity to establish clinical proof-of-concept in endemic setting.

Note – This partnership is a landmark development in the area of vaccine development against diarrhea, as there is no vaccine available against diarrhea caused by bacteria of genus Shigella.

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1 https://www.hillemanlabs.org//uploads/news/1570437384_news_ShigOraVax_news%20release-EVI_final_191004%20-%2007-Oct%202019.pdf

ICMR launched Malaria Elimination Research Alliance to improve malaria elimination

The Indian Council of Medical Research has recently launched the programme '*Malaria Elimination Research Alliance (MERA)*' to fasten the elimination of the disease. The overall goal of the programme is to bring together all the stakeholders working on malaria including researchers, health-care professionals, government and non-government organizations, public health representatives, and policy makers under one roof.[1]

Background

Malaria, a serious disease caused by parasites, could become epidemic if not controlled properly; hence the government is eagerly working to come up with certain programmes in order to fight the disease and increase the elimination of the disease. In this view the government launched MERA with following key objectives:

- to prioritize research to address gaps and challenges,
- to orchestrate research with stakeholder engagement,
- to promote and facilitate planning and conduct of prioritized research, and
- to translate and disseminate research into impact.

However, the programme also observes certain challenges based upon the epidemiological data and upon the knowledge of vector biology; the two important challenges of MERA are:

1. Epidemiology and Parasite Biology admits challenge

- Dynamics of P. vivax - clinical biology, epidemiology and transmission.
- P. vivax relapse - pathobiology, diagnosis and anti-relapse therapy with special reference to implementing G6PD testing before therapy and compliance to anti-relapse therapy.
- Severe malaria - Clinical picture, pathogenesis
- Role of low-density plasmodium infections in malaria transmission
- Monitoring antimalarial drug resistance with special reference to artemisinin resistance.
- Novel methods of surveillance and models of malaria elimination with special reference to strategies for surveillance in private sector.
- Best practices for malaria control including vector management.

2. Vector Biology and Control

- Studies on the changing behaviour of mosquito vectors such as feeding and resting behaviour, and population dynamics in persistent transmission areas under different phases (categories) of malaria elimination.
- Assessment and quantification of outdoor/residual transmission by vectors that feed outdoors or biting early in the evening or are resistant to insecticides.
- Socio-cultural behavior of the human population residing permanently or temporarily in forest ecosystem in relation to malaria transmission and vector control interventions.
- Pattern of human population movement in vulnerable areas and association with vector population dynamics in relation to space and time (receptivity) for assessment of transmission risk.
- Studies on community behavior, accessibility and utilization of current vector control operations

1 https://icmr.nic.in/sites/default/files/whats_new/Call_MERA.pdf

under the national programme, including study of logistics supply chain.

- Frequency and level of vector resistance to the insecticides that are in use for malaria vector control in high risk and residual transmission areas.

The programme is open for all the individuals holding permanent positions in medical colleges/ universities, educational and research institutes, NGOs, industries.

Conclusion

Malaria is a serious and widespread disease requiring urgent government interventions to speed-up the malaria control and elimination programme. The MERA is one such programme bringing all concerned stakeholders at same level to synergize the elimination objective.

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Health Ministry issues list of Medical device Testing Laboratories for performance evaluation of invitro devices for grant of manufacturing license

On October 4, 2019, the Ministry of Health and Family welfare issued a guidance for the evaluation for in-Vitro Diagnostic medical device along with the reference list of the laboratories considered for conducting the performance evaluation of the in-vitro diagnostic tool.[1]

Background

The Health Ministry had earlier issued a new Medical Devices Rules (MDR) 2017, under Drug and Cosmetic Act effective from January 01, 2018. The MDR aimed to regulate manufacture, sale and distribution of the medical devices in the country. However, the ministry has recently issued a guidance on the performance and evaluation of the in-vitro diagnostic tool and reference list of laboratories considered for conducting '*Performance Evaluation of In vitro diagnostics'*. The ministry periodically publishes this guidance to announce the updated list of laboratories. As per this new guidance four (4) laboratories have been included for testing/evaluation of the particular in-vitro diagnostic medical device as described below:

Sr. No	Name and address of the Medical device Testing Laboratory	Scope of testing
1	Ms Sipra labs limited	Copper -T Tubal Rings Hypodermic Syringes Blood Bags
2	M/s Star Imaging & Path Lab Pvt. Ltd.	Bilirubin (Total and Direct) Test Reagents I Kits Creatinine test reagent I kit Aspartate Amino Transferase (AST I SGOT) test
3	M/s Alcatec Research Laboratories India Pvt. Ltd.	Sterilized Surgical Ligatures Sterilized Disposable Device Sterilized Surgical Sutures
4	M/s Sree Chitra Tirunal Institute For Medical Sciences & Technology, Thiruvananthapuram	CardioVascular Devices (Biological Evaluation as per ISO 10993) Neuroprosthesis (Biological Evaluation as per ISO 1 0993) Orthopedic Implants (Biological Evaluation as per ISO 1 0993) All medical devices and Materials (Biological Evaluation as per ISO 1 0993) Dental Implants (Biological Evaluation as per ISO 1 0993)

On October 4, 2019 recent amendment in the Medical Device Rule was made under which the following clause is included in the fourth schedule in part 11 of paragraph (ii):

1 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTEwMg==

- In case of in vitro diagnostic medical devices performance evaluation report shall be submitted by the manufacturers. [2]
- The recent amendment in the rule is known as the Medical Device (amendment) Rules, 2018. The rale shall come into force on the date of their publication in official gazette/.

Note - The above laboratories shall be designated to evaluate the in vitro diagnostic medical devices from all manufacturers and generate the performance evaluation report for the purpose of the grant of the manufacturing license.

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2 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTEwMg==

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1 https://www.nhp.gov.in/disease/neurological/japanese-encephalitis

2 https://pib.gov.in/PressReleseDetail.aspx?PRID=1588210

India Healthcare Highlights October 2019

This segment of the newsletter shares recent information related to regulatory reforms from Healthcare and Pharmaceutical sectors in India. This segment collates information on monthly basis via conducting research and appraisal of applicable statutory provisions. Below are the highlights for September 2019.

1. Health Ministry urges states to increase healthcare spending[1]

On October 10, 2019, the Health Ministry during 13th Conference of the Central Council of Health and Family Welfare (CCHFW) has advised the participating Health Ministers from States/UTs to increase their healthcare spending to a minimum 8% of state budget so as to meet the goals of National Health Policy 2017 which envisages healthcare spending as t 2.5% of GDP by 2025. The Council of Health and Family Welfare is an apex advisory body to consider and recommends broad lines of policy in regard to matters concerning Health and Family Welfare, in all its aspects. The Union Minister for Health & Family Welfare is its Chairperson, while the State for Health & Family Welfare is the Vice-Chairperson. Member, NITI Aayog, ministers in charge of the Ministries of Health & Family Welfare, Medical Education and Public Health in the States/Union Territories with Legislatures, representatives of UTs, Members of Parliament (4), Non-Officials (6), and eminent individuals (11) are Members of the Council. The first meeting of the CCHFW was held in 1988.

2. TB Alliance, Mylan to commercialize pretomanid to treat TB in India[2]

Non-profit drug developer, TB Alliance, and Mylan have announced a global collaboration to make the experimental drug pretomanid accessible for use to treat pulmonary tuberculosis (TB). Pretomanid is a new chemical entity and member of nitroimidazooxazines class of compounds. The first preclinical development of pretomanid was reported in year 2002 by TB Alliance, therefore 20 clinical trials alone or in combination with other anti-TB drugs involving 1,200 people in 14 countries have been reported. The two pretomanid-based regimens under development include: (i) Bedaquiline, Pretomanid and Linezolid (BPaL 6-9 month regimen) indicated for XDR-TB and MDR-TB that is treatment-intolerant or non-responsive (ii) Bedaquiline, Pretomanid, Moxifloxacin and Pyrazinamide (BPaMZ six month regimen) indicated for DS-TB and MDR-TB. India has the world's highest share (27 per cent) of all TB cases and accounted for nearly a quarter of TB related mortality in 2017 which makes this country on priority list of who requires these regimens on urgent basis.

3. Fifth Amendment of MDR 2019 exempt the state and central laboratory for two years from NABL accreditation[3]

On October 16, 2019, the Health Ministry via a gazette notification announced that the testing laboratories of State Governments and Central Government shall be exempted from the requirement of the accreditation by the National Accreditation Board for Testing and Calibration Laboratories for a period of two years from the date of coming into force of the Medical Devices (Fifth Amendment) Rules, 2019. This notification in furtherance of amendment to the Medical Device Rules, 2017, was published as required by sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940.

1 https://www.biospectrumindia.com/news/22/14880/health-ministry-urges-states-to-increase-healthcare-spending.html

2 https://www.biospectrumindia.com/news/73/13429/tb-alliance-mylan-to-commercialize-pretomanid-to-treat-tb.html

3 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTE3NQ==

4. Cipla acquisitions of novel anti-infective from Venus Remedies Limited will boost Indian critical care system[4]

Indian pharmaceutical company, Cipla Limited announces the acquisition of a novel and patented anti-infective product, *Elores*, from Venus Remedies Limited. The acquisition will boost Indian market by strengthening its presence in the branded Indian critical care space and also to the fight against Anti-Microbial Resistance (AMR). Elores is a novel combination of Ceftriaxone (a third generation beta-lactam cephalosporin), Sulbactam (a beta-lactamase inhibitor) and Disodium EDTA (an Antibiotic Resistance Breaker) indicated for the treatment of life threatening infections caused by gram-negative bacteria. It preserves the efficacy of the antibiotic using appropriate Antibiotic Resistance Breakers (ARBs). The product was launched in India in 2013 across select tertiary care hospitals in the country after approval from the Drug Controller General of India. Cipla introduced the extremely effective antibiotic Colistin in India, and has a large portfolio of oral and injectable anti-microbial brands. Today, the company is a leader in the anti-infective segment in country.

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4 https://www.cipla.com/press-releases-statements/cipla-acquires-novel-anti-infective-elores-further-anti-microbial

USFDA Pharma Updates October 2019

This segment discusses the recent drug approvals from the United State Food and Drug Administration (USFDA) for various severe diseases. The write-ups describe the role of a new drug in the treatment of serious conditions such as Ebola virus and rare skin condition - erythropoietic protoporphyria. The US FDA is the one of the strongest regulatory body globally which takes care of health of the public by assuring the safety and effectiveness of human drugs, medical devices and other products used and approved in United States.

1. FDA allowed the marketing of "first rapid diagnostic test for detecting Ebola virus antigens"

On October 10, 2019, the USFDA allowed the marketing of the rapid diagnostic test (RDT) used to detect the Ebola virus antigens (proteins) in human blood from certain living individuals and samples from certain recently deceased individuals suspected to have died from Ebola. The OraQuick Ebola Rapid Antigen Test is the first kind of its type approved by FDA to be marketed in the U.S. for the Ebola Virus Disease (EVD). EVD caused by the Ebola virus, is a severe, often fatal disease in humans that can spread through direct contact with blood or body fluids or objects contaminated with body fluids, as well as from the bodies of those who have died from the virus. The approval is followed by the multiple clinical studies of blood samples and cadaveric oral fluid from the 2014 West African outbreak and from a variety of analytical studies. The FDA has granted the marketing authorization of the OraQuick Ebola Test to OraSure Technologies, Inc.[1]

2. FDA approved the first treatment of pain-free light exposure for patients with rare disease disorder

On October 08, 2019, the USFDA approved Scenesse (afamelanotide) to increase pain-free light exposure in adult patients with a history of phototoxic reactions (damage to skin) from erythropoietic protoporphyria. Scenesse is the synthetic peptide used to prevent skin damage from the sun in people with erythropoietic protoporphyria. The approval follows two parallel group clinical trials with patients with erythropoietic protoporphyria who received either Scenesse or placebo form of the implant subcutaneously every two months. The median total number of hours spent in direct sunlight with no pain was improved for patients receiving Scenesse compared to the patients taking placebo. The approval of Scenesse was granted to Clinuvel.[2]

3. FDA awards two grants for natural history studies in rare diseases

On October 8, 2019, the USFDA announced two research grants to natural history studies in rare diseases. Natural history studies observe the progress of specific diseases over time ranging from the onset to pre-symptomatic to clinical stages to a final outcome in the absence of treatment. The FDA received 31 grant applications that were reviewed and evaluated for scientific and technical merit by more than 45 rare disease, natural history, regulatory and statistical experts that included representatives from academia, patient groups, the National Institutes of Health and the FDA. The grants were awarded to:

1. University of Texas MD Anderson Cancer Center (Houston, Texas), Elizabeth Grubbs, prospective
2. study in medullary thyroid carcinoma - approximately $1.7 million over four years
3. Vanderbilt University Medical Center (Nashville, Tennessee), Jonathan Soslow, prospective study in cardiac disease in Duchenne muscular dystrophy - approximately $2.4 million over four years.

The FDA uses these funds for the Orphan Products Grants Program to support these natural history studies as well as clinical trials for rare diseases. [3]

1 https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-rapid-diagnostic-test-detecting-ebola-virus-antigens

2 https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-increase-pain-free-light-exposure-patients-rare-disorder

3 https://www.fda.gov/news-events/press-announcements/fda-awards-two-grants-natural-history-studies-rare-diseases

WHO Updates October 2019

This segment of the newsletter is focused to share the recent regulatory reforms and updates on Healthcare and Pharmaceutical domain from World Health Organization (WHO). This segment collates information periodically via conducting research and review of pharmaceutical updates from the WHO. Below are the highlights for the month of October 2019:

1. WHO Launches first World Report on Vision

On October 08, 2019, the WHO launched the first "world report on vision" stating that more than 1 billion people worldwide are living with vision impairment because they do not get the care they need for conditions like short and far sightedness, glaucoma and cataract. The burden of eye conditions and vision impairment is high in people living in rural areas, those with low incomes, women, older people, and people with disabilities, ethnic minorities and indigenous populations. Low- and middle-income regions of western and eastern sub-Saharan Africa and South Asia have rates of blindness that are eight times higher than in all high-income countries.[1]

2. WHO launched digital app to improve health conditions in older people

WHO has launched a digital app on the social media in order to improve the health conditions in older people. The tool will increase the training of health and social workers to better address the diverse needs of older people. The tool is the result of two years of extensive consultations with leading experts and stake-holders including civil society representatives. The world's population is ageing at a fast pace. By 2050, one in five people will be over 60. The number of aged over 80 is projected to triple from 143 million in 2019 to 426 million in 2050. While every older person is different, physical and mental capacities tend to decline with increasing age.[2]

3. WHO accepts the US declaration on Universal Health Coverage

World Health Organization (WHO) has accepted the US declaration on Universal Health Coverage (UHC). The landmark declaration was announced after the WHO and partners declared the need to double health coverage between now and 2030 or leave up to 5 billion people unable to access health care. In adopting the declaration, U.N. Member States have committed to advance towards UHC by investing in four major areas around primary health care. These include mechanisms to ensure no one suffers financial hardship because they need to pay for healthcare out of their own pockets, implementing high-impact health interventions to combat diseases and protect women's and children's health. In addition, countries must strengthen health workforce and infrastructure and reinforce governance capacity. They will report back on their progress to the U.N. General Assembly in 2023.[3]

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1 https://www.who.int/news-room/detail/08-10-2019-who-launches-first-world-report-on-vision

2 https://www.who.int/news-room/detail/30-09-2019-who-launches-digital-app-to-improve-care-for-older-people

3 https://www.who.int/news-room/detail/23-09-2019-who-welcomes-landmark-un-declaration-on-universal-health-coverage

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