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S&A PHARMA NEWSLETTER

EDITORIAL

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Founding Partner

The Health and Pharma regulatory sector are very crucial not only because of its faster growth and evaluation of practice standards globally, but also due to its rising commitment towards quality drugs approval, production, marketing and distribution globally. In India the drug approvals, production, marketing and distribution is regulated by Central Drug Standard Control Organization (CDSCO), whereas the essential drugs pricing and availability is ensured by National Pharmaceutical Pricing Authority (NPPA).

S&A is happy to bring out its first Pharma newsletter publication this month. We have covered many interesting articles highlighting regulatory policies and Pharma updates globally related to regulation and development health policies of quality standards of drugs for ensuring safety and efficacy. Hope you enjoy reading this one!

To begin with, we discuss and summarize the CDSCO's approval of briveracetam as adjuvant therapy for the treatment of partial onset seizure. Then a survey report from the most recent staff retention survey released by European medicines agency (EMA) aimed to study the impact of relocation of EMA's headquarters from London to another alternative site post BREXIT.

Then we have covered highlights from European Society of Cardiology (ESC) Congress 2017, and Highlights from the European Society for Medical Oncology (ESMO, 2017). Some major and landmark practice changing clinical trials were presented and discussed at these conferences.

Next is a NPPA's recommendation on filing of forms though Integrated Pharmaceutical Database Management System (IPDMS), where Pharmaceutical companies are legally bound to report information through IPDMS, and Non-submission of mandatory information is therefore tantamount to harming public interest.

Next is a report from World Health Organization (WHO) on Antibiotics availability worldwide. This report shows a serious paucity of new antibiotics under development to combat the growing threat of antimicrobial resistance.

Then there is a report on a new pricing agreement which is aimed to launch new high quality anti retroviral therapy in low and middle income countries, the agreement aims to make innovative therapy accessible to patients.

We wrap up this issue of newsletter with news of US FDA approval of the first continuous glucose monitoring system which does not requires calibration using a blood sample from the fingertip (often referred to as a "fingerstick").

We sincerely hope that you find the articles of this newsletter interesting & enriching.

Please feel free to send your valuable inputs / comments at newsletter@singhassociates.in

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Thank you.

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Contents

1. CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO) APPROVES BRIVERACETAM INDICATED AS ADJUVANT THERAPY FOR THE TREATMENT OF PARTIAL ONSET SEIZURES 04

2. BREXIT: EUROPEAN MEDICINES AGENCY (EMA) WARNS OF 'PERMANENT DAMAGE' 06

3. HIGHLIGHTS OF EUROPEAN SOCIETY OF CARDIOLOGY (ESC) CONGRESS 2017 09

4. EUROPEAN MEDICINE AGENCY RECOMMENDS MODIFIED-RELEASE PARACETAMOL TO BE REMOVED FROM THE MARKET 12

5. FILING OF FORMS THOUGH INTEGRATED PHARMACEUTICAL DATABASE MANAGEMENT SYSTEM (IPDMS) IS NOT OPTIONAL, IT IS MANDATORY 14

6. FDA CONDUCTS MAJOR GLOBAL OPERATION TO PROTECT CONSUMERS FROM POTENTIALLY DANGEROUS PRESCRIPTION DRUGS SOLD ONLINE 17

7. THE WORLD IS RUNNING OUT OF ANTIBIOTICS: WHO REPORT CONFIRMS 19

8. EUROPEAN MEDICINES AGENCY - MEETING HIGHLIGHTS FROM THE COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP) SEPTEMBER 11-14, 2017 21

9. CDSCO APPROVES PRIVATE DRUG TESTING LABORATORIES UNDER THE DRUGS AND COSMETIC ACT, 1940 23

10. HEALTH MINISTRY OF INDIA LAUNCHES TWO NEW CONTRACEPTIVES 24

11. WORLD HEALTH ORGANIZATION (WHO) LAUNCHES NEW NON-COMMUNICABLE DISEASES (NCDS) PROGRESS MONITOR 2017 25

12. HIGHLIGHTS FROM THE EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY (ESMO) 2017 CONGRESS 28

13. USFDA HEMATOLOGY/ONCOLOGY (CANCER) APPROVALS & SAFETY NOTIFICATIONS: JANUARY TO SEPTEMBER 2017 33

14. NEW PRICING AGREEMENT TO LAUNCH NEW HIGH-QUALITY ANTIRETROVIRAL THERAPY IN LOW- AND MIDDLE-INCOME COUNTRIES AT SIGNIFICANTLY REDUCED PRICE 41

15. CDSCO NOTICE REGARDING STRICT REGULATORY CONTROL OVER MANUFACTURE, SALE AND DISTRIBUTION OF OXYTOCIN AND TO CURB ITS MISUSE 43

16. US FDA APPROVES FIRST CONTINUOUS GLUCOSE MONITORING SYSTEM FOR ADULTS NOT REQUIRING BLOOD SAMPLE CALIBRATION 46

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO) APPROVES BRIVERACETAM INDICATED AS ADJUVANT THERAPY FOR THE TREATMENT OF PARTIAL ONSET SEIZURES

On September 07, 2017, the Central Drugs Standard Control Organization (CDSCO) India has approved Briveracetam film coated tablets, in strengths of 50 mg, 75 mg and 100 mg, indicated as an adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in patients with epilepsy, aged 16 years and older.[1]

The import and marketing approval for Brivaracetam 50mg, 75 mg &100mg film-coated tablets has been granted to UCB India Pvt. Ltd. based on the global clinical study report including data generated from various clinical studies conducted on 256 Indian patients on tablet formulations. The Subject Expert Committee (ESC) of CDSCO observed that the data from the Indian subset analysis is in line with the global data.

However, the UCB India Pvt. Ltd. also submitted an application for the grant of permission for importing and marketing of Brivaracetam 10 mg/ml oral solution and Brivaracetam 10 mg/ml solution for injection formulations for Indian patients. The committee observed that the firm has no data either on oral solution or solution for injection formulation tested on Indian patients. The committee also observed that the drug is indicated for patients above 16 years of age for which the recommended dose is 50 mg or above and the relevance of lower doses such as 10 mg and 25 mg have not been justified by the firm[2].

ABOUT BRIVERACETAM

Briveracetam is a chemical analog of levetiracetam, an anticonvulsant drug which acts by binding to the ubiquitous synaptic vesicle glycoprotein. Briveracetam is used in combination with other medicines to treat partial-onset seizures with or without secondary generalization, in patients with epilepsy, from 16 years of age and older.

The most common side effects of Briveracetam observed in clinical trials are: sleepiness, dizziness, tiredness, nausea and vomiting. Most of these side effects were reported to be mild to moderate.

ABOUT PARTIAL-ONSET SEIZURES

Seizure episodes are a result of excessive electrical discharges in a group of brain cells. Different parts of the brain can be sites of such discharges. Seizures can vary in frequency and can also vary from the briefest lapses of attention or muscle jerks to severe and prolonged convulsions.
Partial onset seizure as defined by the Epilepsy foundation that the term focal is used instead of partial to be more accurate when talking about where seizures begin. Focal seizures can start in one area or group of cells in one side of the brain. Partial seizure is categorized into two types -

- Focal Onset Aware Seizures (Simple partial seizure): When a person is awake and aware during a seizure, it's called a focal aware seizure. This used to be called a simple partial seizure.

1 http://www.cdsco.nic.in/forms/list.aspx?lid=2034&ld=11

2 http://www.cdsco.nic.in/writereaddata/Recommendation17_3_2017.pdf

- Focal Onset Impaired Awareness (Complex partial seizure): When a person is confused or their awareness is affected in some way during a focal seizure, it's called a focal impaired awareness seizure. This used to be called a complex partial seizure[3].

One seizure does not signify epilepsy (up to 10% of people worldwide have one seizure during their lifetime). Epilepsy is a chronic disorder of the brain that affects people worldwide. It is characterized by recurrent seizures.

3 http://www.epilepsy.com/learn/types-seizures?gclid=EAIaIQobChMIlJam_KOV1gIVkRePCh1xygmXEAAYASAAEgLGQPD_BwE

BREXIT: EUROPEAN MEDICINES AGENCY (EMA) WARNS OF 'PERMANENT DAMAGE'

On September 26, 2017, the European Medicines Agency (EMA), released the results of its most recent staff retetion survey which was undertaken to study the impact of relocation of EMA's headquarters from London to another alternative site, post BREXIT[4].

The survey was launched on September 4, 2017 in the context of EMA's business continuity planning, after all candidate host cities were known and EMA staff had the opportunity to study in detail the 19 Member States' bids. The results of the survey have raised some serious concerns as the results reveal that for certain locations staff retention rates could be significantly less than 30%. This would mean that the Agency would no longer be able to continue its functions status quo; and in absence of any back-up it would have important consequences for public health in the EU. In a best-case scenario, EMA could keep up to 81% of its workforce.

EMA has developed a dedicated business continuity plan (BCP) prioritizing the Agency's activities in order to be prepared to cope with potential significant staff loss due to its relocation. The plan has three priority levels for EMA's activities according to their impact on public health and the ability of the Agency to function properly. In case of a business continuity situation the Agency will first decrease the activities and therefore the Full Time Equivalents FTEs spent on category 3 (lowest priority), followed by category 2 (medium priority) and lastly by category 1 (highest priority)[5].

The number of (FTEs) needed for the three categories are based on time recording of staff (temporary agents, contract agents and national experts) in 2016.

Priority level	Activities	Full Time Equivalents (FTEs) required
Category 1	**The highest prioritized activities are Category 1** activities which are either directly related to the assessment and safety monitoring of medicines or vital for maintaining the infrastructure of the European medicines regulatory network. These activities include for example co-ordination of actions to protect the safety of patients in all EU Member States.	462 FTEs
Category 2	**Medium priority, Category 2** activities are public health and strategic activities such as the contributions to fight against antimicrobial resistance, collaboration with health technology assessment bodies and initiatives for availability of medicines.	140 FTEs
Category 3	**Category 3 activities are the lowest priority** and cover governance and support activities such as corporate governance, audits, participation in and organisation of meetings and conferences.	110 FTEs

To prepare for a business continuity situation with potential significant loss of staff, the Agency performed in early September a staff survey using EU Survey, the European Commission's official survey management tool. Staff were asked to indicate whether they were very likely, likely, unlikely or very unlikely to move with the Agency to each of the 19 candidate host cities, based on the official Member State offers and the extent to which they fulfil their (and their family's) needs and expectations to settle in a new location.

4 http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/09/news_detail_002814.jsp&mid=WC0b01ac058004d5c1

5 http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/09/WC500235516.pdf

In accordance with the current business continuity planning, four clusters of candidate cities have emerged. The first cluster includes those cities where 65% or more of EMA staff indicated that they are likely to move. In the second cluster are cities where staff retention would range between 50 and 64%. The third cluster includes those cities to which between 30 and 49% of staff are likely to relocate. In the last cluster are those cities where less than 30% of EMA staff said they would follow.

The results showing staff retention and possible impact on working of EMA along with likelihood of success of compensatory measures with time needed to full recovery are tabulated below:

Business Continuity category	Survey Results	Impact	Likelihood of success of compensatory measures	Time needed to full recovery
Group 1 Over 65% staff retention: meets EMA requirements and ensures that EMA is operational on time.	5 candidate cities: • average of 73% • range between 65% and 81%	Depending on the extent of specific staff loss: • Approval of new medicines and safety monitoring are largely maintained, but with possibility of delays • Progress on a number of public health initiatives (e.g. support to initiatives on antimicrobial resistance and for the elderly, cooperation with health technology assessment bodies) will move at a slower pace	High	2-3 years
Group 2 50% to 64% staff retention: meets EMA requirements but raises concerns that EMA is operational on time.	5 candidate cities: • average of 54% • range between 51% and 60%	• Patients wait longer for new medicines • Safety monitoring has to be ring-fenced by rerouting resources and de-prioritizing other tasks • Public trust in the system starts to erode • Europe risks losing its appeal/ cutting edge in scientific research • Implementation of new legislation will be significantly delayed (e.g. veterinary medicines, clinical trials, and medical devices)	Medium	3-5 years

Business Continuity category	Survey Results	Impact	Likelihood of success of compensatory measures	Time needed to full recovery
Group 3 30% to 49% staff retention: only partially meets EMA requirements and, therefore, raises major concerns with regards to EMA business continuity.	1 candidate city: • average of 48%	• Patients are at serious risk because of delays in access to medicines and poor safety monitoring • Some life-saving medicines may not be available to patients in some countries • Loss of innovation • Uncoordinated temporary solutions taken in Member States lead to inequalities between EU citizens	Low	5-10 years
Group 4 Below 30% staff retention: does not meet EMA requirements and, therefore, does not ensure EMA business continuity.	8 candidate cities: • average of 18% • range between 6% and 28%	EMA is unable to operate - public health crisis • Unravelling of the EU single market for medicines – no centralized authorizations - medicines become unavailable - need to import from third party countries • Need to rely on third party countries for approval and importation (e.g. USA, Japan) • Patients exposed to side effects – deaths – litigation	Need for emergency legislative measures at EU level. Need for emergency legislative measures at national level.	Permanent damage to the system

CONCLUSION

The results of the survey emphasize the importance of the upcoming decision on the EMA's future seat as the retention of skilled and experienced staff is crucial for the Agency's continuity of operations. EMA said that some staff losses can be absorbed with EMA's business continuity plan, but beyond a critical threshold the Agency will no longer be able to fulfil its mandate to protect the health of European citizens. European Medicines Agency has warned of 'permanent damage' from this relocation. The European Commission is due to publish its own assessment of all the bids later this month, with national governments making a final decision in November.

HIGHLIGHTS OF EUROPEAN SOCIETY OF CARDIOLOGY (ESC) CONGRESS 2017

The European Society of Cardiology (ESC), a nonprofit knowledge-based professional organization which is dedicated towards improvement and harmonization of standards of diagnosis and treatment of cardiovascular diseases.The ESC also creates, organizes and supports many scientific and academic activities and products for the purpose of knowledge and skill developments of cardiology professionals. The ESC currently comprises of 56 National Cardiac Societies, 6 Associations, 15 Working Groups and 5 Councils, covering different sub-specialties of cardiology from various parts of Europe. Moreover, the ESC also organizes several cardiology congresses every year, and the ESC Congress has become one of the largest medical congresses of cardiology in Europe.

ESC Congress 2017 was held in Barcelona, Spain from 26 - 30 August 2017 with 32,700 attendees and 500 speaker sessions. The highlights of ESC Congress 2017 were mostly from the late breaking clinical trials such as- CANTOS Trial, RACE 3, CASTEL- AF, REHEARSE- AF etc.

CANTOS TRIAL:

The Canakinumab Anti-inflammatory Thrombosis Study (CANTOS)[6] is a randomized controlled trial and has been carried out in more than 10,000 high-risk patients who had a prior Myocardial infarction (MI) and persistently elevated high-sensitivity C-reactive protein (hs-CRP) levels. The result suggested that the Canakinumab, an anti-inflammatory drug from Novartis significantly decreased the risk of recurrent major Cardio vascular (CV) events without effecting cholesterol, and also dramatically cuts rates of new lung cancer and lung-cancer mortality.

Moreover, the result showed that patients who received subcutaneous Canakinumab 150 mg every 3 months had a 15% risk reduction of nonfatal MI, nonfatal stroke, and CV death compared with those who received placebo (*P*=0.02075). Canakinumab also reduced the 17% risk of unstable-angina hospitalization observed as secondary outcomes. This is the breakthrough as without lowering cholesterol but by lowering inflammation we have risk reductions of nonfatal MI, nonfatal stroke, and CV death[7].

The next breakthrough trials during ESC Congress 2017 were presented for heart disease like Atrial Fibrillations (AF), which continues to burden patients and healthcare systems worldwide.

THE RACE 3 STUDY

(Routine vs. Aggressive upstream rhythm control for prevention of Early Atrial Fibrillation in Heart Failure) was presented by Professor IC Van Gelder, University Medical Center Groningen. The RACE 3 was a randomized controlled trial (RCT) with 250 participants, where patients with persistent AF and mild heart failure received aggressive therapy (aldosterone antagonists, statins, dietary restrictions, counseling, and cardiac rehabilitation) vs. conventional rhythm-control therapy. The result suggested that the aggressive therapy delivered Sinus rhythm to almost 75% of patients compared to 63% patients of conventional rhythm-control therapy (*P*=0.021) for 1 year. However, the success of RACE 3 would accelerate the move to treat risk factors and cardiac rhythm in patients with persistent AF and mild heart failure[8].

6 https://clinicaltrials.gov/ct2/show/NCT01327846?term=Cantos&draw=1&rank=1

7 http://www.medscape.com/viewarticle/884745

8 https://clinicaltrials.gov/ct2/show/study/NCT00877643?term=RACE+3&cond=Atrial+Fibrillation&rank=1&view=record

The multicenter Phase IV **CASTLE-AF** (Catheter Ablation vs. Standard Conventional Treatment in Patients with LV Dysfunction and AF)[9] trial from Dr Nassir Marrouche, University of Utah has enrolled about 420 patients with systolic heart failure and an ICD and AF. The results of this study suggested that, the combined mortality and worsening heart failure admissions rates were lower with ablation (28.5% versus 44.6% for controls, HR 0.62, 95% CI 0.43-0.87, P=0.007) during a median follow-up of 37.8 months. According to the Co-investigator of the study, Mr. Johannes Brachmann "*Until now we had no evidence that ablation, arrhythmia medications, or any other treatment was superior to another in saving lives and reducing hospitalization. This study has the potential to change the way physicians manage many patients suffering from heart failure and atrial fibrillation*". [10]

The **RE-DUAL PCI** (Randomized Evaluation of Dual Antithrombotic Therapy with Dabigatran vs. Triple Therapy with Warfarin in Patients with Nonvalvular Atrial Fibrillation Undergoing Percutaneous Coronary Intervention) trial showed significantly lower rates of major or clinically relevant non-major bleeding events for dual therapy with Pradaxa® (Dabigatran) when compared to triple therapy with Warfarin. The available combination of potent antithrombotic therapies with triple therapy is associated with high rates of major bleeding in these patients. RE-DUAL PCI™ tested an alternative treatment strategy of dual therapy with Pradaxa® which lowers the risk of primary safety end point 48% with Pradaxa® 110 mg dual therapy and 28% with Pradaxa® 150 mg dual therapy.[11] However these two regimens could be used as alternative in future for patient›s risk of bleeding and thromboembolic events.

Further ESC congress also provided updates from:

- The prevention trial REHEARSE-AF (REmote HEArt Rhythm Sampling using the AliveCor heart monitor to scrEen for Atrial Fibrillation)[12], where UK researchers assessed the utility of the AliveCor smartphone device for AF screening. In this study, the twice-weekly screening with the AliveCor Kardia device picked up 3.9-fold more AF than found in routine care (19 vs. five cases out of the evenly divided 1,001 participants). While the trial was underpowered for hard clinical outcomes, the number of strokes and transient ischemic attacks or systemic embolic events was nominally lower with the intervention (six versus 10, HR 0.61, 95% CI 0.22–1.69).
- The Danish VIborg VAscular (VIVA) screening trial[13], VIVA is an RCT designed to evaluate the benefits of screening (for peripheral artery disease, abdominal aortic aneurysm, and hypertension) and modern vascular prophylaxis in a population of 50156 men aged 65 to 74 years. The results suggested that more than 20% of those attending screening had positive test results: 3% had an abdominal aortic aneurysm, 11% had peripheral artery disease, and 11% had suspected hypertension that was untreated.
- "A result of this magnitude has never been seen before in general population screening programmes," said Prof Lindholt. "We believe that it is primarily explained by the 2.5 times higher incidence of elective aneurysm repairs and the doubled initiation rates of antithrombotic and lipid-lowering therapy in the group invited to screening."[14]

9 https://clinicaltrials.gov/ct2/show/NCT00643188

10 https://www.medpagetoday.com/cardiology/arrhythmias/67574

11 https://www.boehringer-ingelheim.com/RE-DUAL-PCI-ESC-2017

12 http://www.isrctn.com/ISRCTN10709813?q=%22REmote%20HEArt%20Rhythm%20Sampling%20using%20the%2Alive Cor%20heart%20monitor%20to%20scrEen%20for%20Atrial%20Fibrillation%20%22&filters=&sort=&offset=1&totalResults =1&page=1&pageSize=10&searchType=basic-search

13 https://clinicaltrials.gov/ct2/show/NCT00662480?term=Viborg+Screening+Trial&rank=1

14 https://www.escardio.org/The-ESC/Press-Office/Press-releases/screening-for-vascular-disease-saves-one-life-for-every169-patients-assessed

- The Bayer/Janssen-sponsored COMPASS trial[15], a RCT enrolled 27,402 participants aimed to use Rivaroxaban for secondary prevention of major adverse cardiac events in patients with known atherosclerosis. The Phase III trial COMPASS trial was halted more than a year ahead of its planned March 2018 completion because, in an interim analysis, the primary end point of MI, stroke, or cardiovascular death has reached its pre-specified criteria for superiority[16]. However, as per data presented at ESC Congress 2017 the Rivaroxaban (Xarelto) 2.5 mg twice daily, plus aspirin 100 mg once daily showed 24% risk reduction of stroke, cardiovascular (CV) death and heart attack in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD) when compared to aspirin 100 mg once daily alone.

CONCLUSION:

The aforementioned studies and their results, which are indented for the treatment, prevention, screening and management of cardiovascular events and risks have potential to change the present treatment approach used by the physicians, and also provide new concepts of alternative therapy areas to be further explored by the scientific communities.

15 https://clinicaltrials.gov/ct2/show/NCT01776424

16 http://www.medscape.com/viewarticle/875572

EUROPEAN MEDICINE AGENCY RECOMMENDS MODIFIED-RELEASE PARACETAMOL TO BE REMOVED FROM THE MARKET

On September 1, 2017, The European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has recommended that modified or prolonged-release paracetamol products that are designed to release paracetamol slowly over a longer period should be removed from the market. The decision was taken in view of the difficulties in managing overdose in patients, due to the complex way these medicines release paracetamol into the body[17].

The Committee, after evaluating published studies and consulting experts, confirmed that when used in the approved way, modified-release paracetamol tablets have acceptable benefits and risks. However, experience has shown that in event of overdose, because of the way paracetamol in modified-release products is released in the body, the usual treatment procedures developed for immediate-release products are not appropriate. The PRAC therefore recommended the suspension of the marketing authorizations of these medicines.

The review of modified-release paracetamol was initiated on June 30, 2016, following a request from the Swedish Medicines Authority, the Medical Products Agency under Article 31 of Directive 2001/83/EC. The Swedish Medicines Authority had noted problems in managing overdose with such a product since marketing approval. The PRAC evaluated published studies and reports of overdose with these medicines, consulted experts in the management of poisoning and assessed how overdose with paracetamol is managed in the EU and other parts of the world.

Experience has shown that in overdose (particularly at high doses), because of the way the paracetamol in modified-release products is released in the body, the usual treatment procedures developed for immediate-release products are not appropriate and effective. If doctors are not aware that modified-release paracetamol has been taken, it affects decisions regarding the dosage, timing and duration of the antidote; overdose may result in severe liver damage or death. In modified-release products which also contain the painkiller tramadol, case may be further complicated because of the additional effects of overdose with tramadol.

In many cases, it may not be known whether an overdose of paracetamol involves immediate-release or modified-release products, making it difficult to decide what type of management is needed. The Committee could not identify means to minimize the risk to patients, or a feasible and standardized way to adapt the management of paracetamol overdose across the EU to allow for treatment of cases that involve modified-release preparations. It concluded on balance that the risk following overdose with these medicines outweighs the advantage of having a longer-acting preparation. The Committee, therefore, recommended that marketing of modified-release paracetamol medicines should be suspended. Immediate-release paracetamol products, which are not affected by this review, will continue to be available as before.

The agency also said that it remains important that patients seek medical advice quickly if they have taken, or think they may have taken, more than the recommended amount of any paracetamol-containing product. Patients should also consult a healthcare professional if they have any other concerns about their medication.
Paracetamol is a medicine that has been widely used for many years to relieve pain and fever in adults and children.

17 http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/09/news_detail_002806.jsp&mid=WC0b01ac058004d5c1

ABOUT PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE (PRAC)[18]

The Pharmacovigilance Risk Assessment Committee (PRAC) is the European Medicines Agency's (EMA) committee responsible for assessing and monitoring the safety of human medicines. The PRAC was formally established in line with the pharmacovigilance legislation which came into effect in 2012 to help strengthen the safety monitoring of medicines across Europe.

18 http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000537.jsp&mid=WC0b01ac058058cb18

FILING OF FORMS THOUGH INTEGRATED PHARMACEUTICAL DATABASE MANAGEMENT SYSTEM (IPDMS) IS NOT OPTIONAL, IT IS MANDATORY

The National Pharmaceutical Pricing Authority (NPPA) is an executive regulatory body under the Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers, Government of India. The NPPA is engaged in efficient implementation of the Drug Price Control Order (DPCO) conferred by Section 3 of the Essential Commodities Act, 1955 (10 of 1955). Thereby, the NPPA is authorized to carry out price fixation & revision of scheduled drugs, monitor the availability of scheduled formulations and active pharmaceutical ingredients used therein, and monitoring the prices of non-scheduled formulations as conferred in DPCO, 2013.

Earlier, DPCO 1995 were effectively implemented by NPPA which followed cost-based mechanism for price fixation. With the transition from DPCO 1995 to the DPCO 2013, the market-based mechanism for price fixation was implemented; therefore, the use of reference data and source of market based data has assumed critical importance. Due to the absence of a robust in-house database in this regard, the DPCO 2013 has permitted that initially the required market based data may be sourced from IMS Health subject to necessary validation exercise by the NPPA wherever considered necessary. Moreover, it has also been decided that whenever the data of IMS Health is not available or found to be inadequate, it would be supplemented by Pharma Trac, which is another specialized pharmaceutical market-based data source like IMS Health.

Meanwhile, the NPPA, to carry out aforementioned functions efficiently, desired a reliable database and by exercise of power contained in paragraph 9(2) of the DPCO, 2013 has developed the Integrated Pharmaceutical Database Management System (IPDMS) in collaboration with the National Informatics Centre. The IPDMS aims at facilitating on-line submission of mandatory returns/ reports under the DPCO, 2013 by manufacturers as defined under DPCO, 2013, wherein manufacturers for the purpose of this Order means "any person who manufactures, imports and markets drugs for distribution or sale"[19].

The IPDMS was launched on the NPPA website on September 18, 2014 with immediate effect for the purpose of registration, for which a self-contained guide was also uploaded on the web site. Further, on June 25, 2015 the Hon'ble Union Minister of Chemicals and Fertilizers formally launched "Pharmaceutical Price Data Bank" which was later renamed to "Pharma Data Bank", a digital platform under IPDMS. Thereafter, all manufacturers were requested to register themselves and complete all registration formalities, which included keying-in of company details, details of production/ procurement sources and product list. Few points of registration and filing explained under IPDMS help Guideline -

- The IPDMS was initially designed to capture form II, III and IV, but later NPPA included capturing of Form I - V of DPCO, 2013 online from all the Pharmaceutical Manufacturer/ Marketing/ Importer/ Distributor Companies.
- The DPCO 2013 prescribes various forms in Schedule II to the Order, which are required to be complied with by all drug manufacturers:

Form	Description
Form - I	Proforma for application for price fixation/revision of a new drug formulation related to National List of Essential Medicine (NLEM) formulation

19 http://dpco2013.com/files/data/ipdms/64821472538556.pdf

Form – II	Proforma for submission of revised-prices for Scheduled formulations
Form – III	Proforma for quarterly return in respect of Production/Import and Sale of NLEM Drugs.
Form - IV	Proforma for submission of the details in respect of discontinuation of the production and/or import of Scheduled formulation
Form - V	Proforma for price list

- The IPDMS system can only be accessed by authorized users. Each company shall be provided a login id and password on the basis of registration information. User shall furnish Company Details, Head office/ corporate office address, Contact Person Details, Product Source details and Product details in the Online Registration Form and can get the Company registered[20].

Later, the DoP and the NPPA had taken initiative to make online submission of data mandatory for all the Pharmaceutical Manufacturer/ Marketing/ Importer/ Distributor Companies. Therefore, the software of IPDMS was designed, developed and fine-tuned after detailed and extensive consultation with the industry. Moreover, the problems of industry (regarding IPDMS registration and data uploading) were again addressed in various meetings with industry representatives. Further, the outcome of meetings emphasized that "The online information regarding price, production, import and sales of scheduled formulations provides consumers with information on different price-points facilitating informed decision making for efficacious and cost-effective treatments. Non-submission of mandatory information therefore tantamounts to harming public interest and to violation of the provisions of DPCO, 2013 read with the Essential Commodities Act, 1955"[21].

Thereafter, the NPPA issued various instructions repetitively regarding registration of all pharmaceutical companies in IPDMS, and also for filing all mandatory forms as provided in Drug Price Control Order (DPCO), 2013. However, despite all efforts by NPPA the response of companies is not very encouraging.

In this regard, on September 5, 2017 all the companies, whether registered or unregistered, , which have not filed all mandatory forms for all their products (Including Form V for coronary Stents) covered under DPCO, 2013 were once again requested to take note of previous instructions and ensure their compliances therein. The request has been raised based on the following observations:

- It has been observed that some of the companies continue to submit the requisite forms in physical mode only, even though it was intimated that forms submitted through physical mode will not be taken into consideration after 01-09-2016[22].
- Despite several instructions, it is observed that the Form II as per Wholesale Price Index reduction effective from 01-04-2016 and Form III and IV have not been filed by many companies through IPDMS.
- It is also observed that in many cases, only the marketing company is filling the requisite form, whereas the form is to be filed by manufacturers too as defined in Para 2(n) of DPCO, 2013, which includes manufacturing companies as well. Such IPDMS filing will be considered incomplete in the context of office memorandum (O.M.) dated 01-02-2017[23].
- An indicative list of 634 companies was identified by comparing the companies reported in market based database, referred to by this office, who have not registered in IPDMS. These companies were directed to

20 http://nppaindia.nic.in/nppareg/help.pdf
21 http://dpco2013.com/files/data/ipdms/42941472538124.pdf
22 http://dpco2013.com/files/data/ipdms/76831472537668.pdf
23 http://www.nppaindia.nic.in/order/NoticeDated01022017.pdf

register themselves on IPDMS and file all mandatory forms as required under DPCO, 2013 vide O.M. dated 01-05-2017[24].

Companies are also advised to not submit forms in physical format unless specifically asked by NPPA office related to any specific case.

CONCLUSION:

"Pharma Data Bank", a digital platform under IPDMS when fully operationalized, will be a useful tool for collection of data/information and also for monitoring and analysis of data for the industry.

Pharmaceutical companies are legally bound to report information through IPDMS, and non-submission of mandatory information therefore, tantamounts to harming public interest, and to violation of the provisions of DPCO, 2013 read with the Essential Commodities Act, 1955.

24 http://www.nppaindia.nic.in/order/notice01052017.pdf

FDA CONDUCTS MAJOR GLOBAL OPERATION TO PROTECT CONSUMERS FROM POTENTIALLY DANGEROUS PRESCRIPTION DRUGS SOLD ONLINE

Illegally marketed opioids are among the products targeted, along with the websites that sell them, during international Operation Pangea X

On September 25, 2017, the United States Food and Drug Administration (US-FDA), announced that in partnership with international regulatory and law enforcement agencies, it recently took action against more than 500 websites that illegally sell potentially dangerous, unapproved versions of prescription medicines, including opioids, antibiotics and injectable epinephrine products to American consumers[25].

These actions were part of a major global operation that the FDA participated in, to target illegal drugs being marketed online; shipped and distributed through the postal system, directly to American consumers. Among other actions, the FDA also issued warning letters to the operators of a majority of the illegal websites that were targeted in the operation. FDA worked with internet registrars to confiscate certain websites. Patients who buy prescription medicines from illegal online pharmacies may be putting their health at risk because the products, while being passed off as authentic, may be counterfeit, contaminated, expired or otherwise unsafe.

The FDA Commissioner Scott Gottlieb said "These rogue online pharmacies are often run by sophisticated criminal networks that knowingly and unlawfully distribute illicit drugs, including counterfeit medicines and controlled substances. Consumers go to these websites believing that they are buying safe and effective medications, but they are being deceived and put to risk by individuals who put financial gains above patient safety".

FDA defines Rogue Pharmacies as online pharmacies that offer potentially dangerous prescription drugs to U.S. consumers; they are also engaged in illegal activities in violation of the U.S. Federal Food, Drug, and Cosmetic Act, including:

- offering for sale unapproved prescription drugs of unknown origin, safety, and effectiveness;
- offering prescription drugs without a prescription;
- offering prescription drugs without adequate directions for safe use; and
- offering prescription drugs without FDA-required warnings to consumers about the serious health risks associated with the prescription drug.

The US FDA is concerned about the ease with which consumers can purchase opioid products online, given the immense public health crisis of addiction being faced by the United States. Some of the websites sold unapproved versions of multiple prescription opioids directly to U.S. consumers. Easy and illegal availability of these controlled substances fuels the misuse and abuse of opioids.

This effort was part of Operation Pangea X, as part of the 10th Annual International Internet Week of Action (IIWA), a global cooperative effort led by Interpol, to combat the unlawful sale and distribution of illegal and potentially counterfeit or substandard medical products on the internet. The IIWA ran from September 12 -19,

25 https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577178.htm

2017. The goal of Operation Pangea X was to identify the makers and distributors of illegal prescription drug products and to remove these products from the supply chain.

During Operation Pangea X, the FDA sent 13 warning letters to the operators of 401 websites[26]. The FDA also seized nearly 100 website domain names, such as buyhydrocodoneonline.com, canadian-pharmacy24x7.com and buyklonopin.com. FDA inspectors, in collaboration with other Federal Agencies, screened packages suspected of containing illegal drug products at IMFs in Chicago, Miami and New York during the IIWA. These screenings resulted in nearly 500 parcels being detained for appropriate FDA compliance follow up. Parcels found in violation of the Federal Food, Drug, and Cosmetic Act will be refused entry into the country.

The FDA also said that in addition to health risks, illegal online pharmacies can pose other risks to consumers, including credit card fraud, identity theft and computer viruses.

ABOUT OPERATION PANEGA

Operation Pangea[27] is an international week of action tackling the online sale of counterfeit and illicit medicines and highlighting the dangers of buying medicines online. Coordinated by INTERPOL, the annual operation brings together custom authorities, health regulators, national police and the private sector from countries around the world.

Activities target the three principal components used by illegal websites to conduct their trade – the Internet Service Provider (ISP), payment systems and the delivery service.

The operation has gained significant momentum since its launch in 2008. The first phase of the operation brought together 10 countries; a number which has now risen to more than 100.

26 https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm348680.htm

27 https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea

THE WORLD IS RUNNING OUT OF ANTIBIOTICS: WHO REPORT CONFIRMS

On September 20, 2017, The World Health Organization (WHO) launched a report on "*Antibacterial agents in clinical development – an analysis of the antibacterial clinical development pipeline, including tuberculosis (TB)*". The report shows a serious lack of new antibiotics under development, to combat the growing threat of antimicrobial resistance.

The report observed very few potential treatment options have been identified so far, for those antibiotic-resistant infections, which pose greatest threats to health, including drug-resistant TB which kills around 250 000 people each year. Most of the drugs at present in the clinical pipeline are modifications of existing classes of antibiotics and are only short-term solutions.In addition to multidrug-resistant TB, WHO has also identified 12 classes of priority pathogens, where some of them causing common infections such as pneumonia or urinary tract infections are increasingly becoming resistant to existing antibiotics and are urgently in need of new treatments.

The WHO report also identifies 51 new antibiotics and biologicals in clinical development to treat priority antibiotic-resistant pathogens, as well as tuberculosis and the sometimes-deadly diarrheal infection *Clostridium difficile*. However, only 8 among all these antibiotics are classed by WHO as innovative treatments that will add value to the current antibiotic treatment arsenal.

Innovativeness of eight antibiotics belongs to five distinct new antibiotic classes, and they fulfill at least one of the four criteria that were used to assess the extent to which agents in the pipeline can be classified as innovative:

- Absence of cross-resistance to existing antibiotics (NCR)
- New chemical class (C)
- New target (T) or
- New mechanism of action (MoA)

Table 1. Antibiotics and combinations containing new chemical entities that are developed for priority pathogens list with Innovativeness[28]

Sr. No.	Name (synonym)	Phase	Antibiotic class	Route of Administration (Developer)	*Innovativeness assessment			
					C	T	MoA	NCR
1	Vaborbactam + meropenem (Carbavance)	New drug application filed	Boronate BLI + carbapenem	Intravenous (The Medicines Co.)	Yes	No	No	Inconclusive
2	Lefamulin	3	Pleuromutilin	Intravenous & oral (Nabriva)	Yes	No	Yes	Inconclusive

28 http://apps.who.int/iris/bitstream/10665/258965/1/WHO-EMP-IAU-2017.11-eng.pdf

Sr. No.	Name (synonym)	Phase	Antibiotic class	Route of Administration (Developer)	*Innovativeness assessment			
					C	T	MoA	NCR
3	Gepotidacin	2	NBTI (Triazaace-naphthylene) I	Intravenous & oral	Yes	No	Yes	Yes
4	Zoliflodacin	2	NBTI (Spiropy-rimidenetrione)	Oral (Entasis)	Yes	No	Yes	Yes
5	Murepavidin (POL-7080)	2	Novel mem-brane targeting AB	Intravenous (Polyphor)	Yes	Yes	Yes	Yes
6	Brilacidin	2	Novel mem-brane targeting antibiotic	Intravenous (Innovation Pharmaceuti-cals)	Yes	Yes	Inconclu-sive	Inconclusive
7	Afabicin (Debio-1450)	2	FabI inhibitor	Intravenous & oral (Debio-pharm)	Yes	Yes	Yes	Yes
8	VNRX-5133 + un-known antibiotic	1	Boronate-BLI + unknown class	IIntravenous (VenatoRX)	Yes	Yes	Inconclu-sive	No

Innovativeness assessment:* ***Yes**-Criterion fulfilled;* ***Inconclusive****-Inconclusive data or no agreement by the advisory group;* ***No****-Criterion not fulfilled*

Underlined agents: New class

Note - This data does not include bedaquiline and delamanid, two new drugs to treat MDR-TB that are currently in Phase 3 trials, but have already received conditional marketing approval.

There is a serious lack of treatment options for multidrug- and extensively drug-resistant M. tuberculosis and gram-negative pathogens which can cause severe and often deadly infections that pose a significant threat in hospitals and nursing homes. There are also very few oral antibiotics in the pipeline, yet these are essential formulations for treating infections outside hospitals or in resource-limited settings.

To combat this threat, WHO along with Drugs for Neglected Diseases Initiative (DNDi) has set up the Global Antibiotic Research and Development Partnership (GARDP). On September 4, 2017, Germany, Luxembourg, the Netherlands, South Africa, Switzerland and the United Kingdom of Great Britain and Northern Ireland and the Wellcome Trust pledged more than €56 million for this work. WHO is also working with countries and partners to improve infection prevention and control and to foster appropriate use of existing and future antibiotics. WHO is also developing guidance for the responsible use of antibiotics in the human, animal and agricultural sectors[29].

29 http://www.who.int/mediacentre/news/releases/2017/running-out-antibiotics/en/

EUROPEAN MEDICINES AGENCY - MEETING HIGHLIGHTS FROM THE COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP) SEPTEMBER 11-14, 2017

On September 15, 2017, The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended thirteen medicines for approval at its September meeting[30].

Committee for Medicinal Products for Human Use is EMA's arm which is responsible for preparing the Agency's opinions on questions concerning human medicines. The CHMP plays a vital role in the authorization of medicines in the European Union (EU)[31].

The thirteen medicines recommended for approval are:

Sr. No.	Name	International non-proprietary name (INN)	Therapeutic Indication	Marketing Authorization Holder
1.	Elebrato Ellipta	Fluticasone furoate / Umeclidinium / Vilanterol	Treatment of moderate to severe chronic obstructive pulmonary disease in adults	GlaxoSmith-Kline
2.	Tremfya	Guselkumab	Treatment of plaque psoriasis	Janssen-Cilag
3.	Nyxoid	Naloxone	Treatment of opioid overdose	Mundipharma
4.	Tookad	Padeliporfin	Treatment of adenocarcinoma of the prostate	STEBA Biotech
5.	VeraSeal	Human fibrinogen/ Human thrombin	Use as a sealant during surgical operations in adults	Instituto Grifols
6.	Zejula	Niraparib	Treatment of ovarian cancer	Tesaro UK
7.	Zubsolv	Buprenorphine / Naloxone	Treatment of opioid dependence	Mundipharma
8.	Trelegy Ellipta	Fluticasone furoate / Umeclidinium / Vilanterol	Treatment of moderate to severe chronic obstructive pulmonary disease in adults	GlaxoSmith-Kline
9.	Imatinib Teva B.V.	Imatinib	Treatment of leukemia and gastrointestinal stromal tumours	Teva B.V.
10.	Miglustat Gen. Orph	Miglustat	Treatment of mild to moderate Type 1 Gaucher disease	Gen.Orph
11.	Ritonavir Mylan	Ritonavir	Treatment of HIV infection	Mylan

30 http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/09/news_detail_002809.jsp&mid=WC0b01ac058004d5c1

31 http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000094.jsp&mid=WC0b01ac0580028c79

Sr. No.	Name	International non-proprietary name (INN)	Therapeutic Indication	Marketing Authorization Holder
12.	Cyltezo	Adalimumab	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, ulcerative colitis and uveitis	Boehringer Ingeleim
13.	Ontruzant	Trastuzumab	Treatment of early and metastatic breast cancer, and metastatic gastric cancer	Samsung Bioepis

KEY RECOMMENDATIONS FOR APPROVAL

- The CHMP recommended granting marketing authorizations for two cancer medicines: Zejula (niraparib), an orphan designated medicine, and Tookad (padeliporfin), for the treatment of adenocarcinoma of the prostate.
- CHMP gave positive opinions for two medicines for people using opioids: Nyxoid (naloxone), and Zubsolv (buprenorphine / naloxone), intended for the treatment of opioid dependence. Hybrid applications were submitted for both medicines which means that the marketing authorization applications were relied in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.
- Two biosimilar medicines were recommended for approval by the Committee: Cyltezo (adalimumab) and Ontruzant (trastuzumab). Ontruzant is the first trastuzumab biosimilar recommended for approval by the CHMP.

OTHER SIGNIFICANT HIGHLIGHTS OF THE MEETING

- Extension of therapeutic Indications: Four recommendations on extensions of therapeutic indications by the Committee; recommended extensions of indications for Benlysta (belimumab), Tasigna (nilotinib), Firazyr (icatibant) and Stribild (elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil).
- Negative Opinion: The CHMP adopted a negative opinion for an extension of therapeutic indication for Raxone. Raxone is a medicine that contains the active substance idebenone; it is available as tablets (150 mg). The Committee adopted a negative opinion, recommending the refusal of a change to the marketing authorization for Raxone. The change concerned the addition of a new use of Raxone in patients with Duchenne muscular dystrophy to slow their gradual loss of breathing ability.
- Withdrawals of applications – Four applications were withdrawn; these included marketing authorizations for Fulphila (pegfilgrastim), Ogivri (trastuzumab) and Tigecycline Accord (tigecycline). An application to extend the indication of Opdivo (nivolumab) to treat liver cancer has also been withdrawn.
- Outcome of review on factor VIII - The CHMP concluded that there is no clear and consistent evidence of a difference in the incidence of inhibitor development between the two classes of factor VIII medicines: those derived from plasma and those made by recombinant DNA technology.

CDSCO APPROVES PRIVATE DRUG TESTING LABORATORIES UNDER THE DRUGS AND COSMETIC ACT, 1940

The Central Drugs Standard Control organization (CDSCO), the Central Drug Authority authorized to execute and regulate the functions of Central Government specified under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rule, 1945 made under the Act. The CDSCO is headquartered in New Delhi and has six zonal offices, five sub-zonal offices, 13 port offices and seven Central Drug Laboratories under its control.

The Drugs and Cosmetics Act, 1940 prescribes statutory requirements for grant of license, and for monitoring the manufacture, sale and distribution of drugs to ensure quality, safety and efficacy of drugs manufactured and sold in country. Moreover, the Central Government, to carry out quality control measures of Drug and Cosmetics, established a Central Drugs Laboratory under the Drugs & Cosmetics Act, 1940. At present, there are seven Central Drug Laboratories as described below:

1. Central Drugs Laboratory, Kolkata
2. Central Drugs Testing laboratory(CDTL) Mumbai
3. Central Drugs Testing Laboratory (CDTL) Chennai, Tamil Nadu
4. Central Drugs Testing Laboratory (CDTL) Hyderabad, AP
5. Regional Drugs Testing Laboratory (RDTL) Guwahati
6. Regional Drugs Testing Laboratory (RDTL) Chandigarh
7. Central Drug Laboratory, CRI Kasauli

Apart from these central laboratories, some private testing laboratories were also approved under the provision in Form 37 of Schedule A of Drugs and Cosmetics Act, 1940. The form 37 prescribes *"Approval for carrying out tests on drugs / cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs /cosmetic".* Whereas the renewal of the approval shall be granted under Form 38 of Schedule A of Drugs and Cosmetics Act, 1940.

On September 11, 2017, CDSCO, on its website, has uploaded the list of private drug testing laboratories approved in Form 37 of Schedule A of Drug and Cosmetic Act, 1940 for carrying out test of drugs /cosmetics for the benefit of all stakeholders. CDSCO has notified a total of 228 private drug testing laboratories in various zones. Further, in this regard, CDSCO has notified that if any laboratory's name is missing in the list, the approval holder may communicate to the concerned state licensing authority after vetting the same at their end.

Simultaneously, all State/U.T. Drugs Controllers are also requested to go through the list of approved Private Drugs Testing Laboratories falling under their area of jurisdiction and inform this to the Directorate via email (as mentioned in notice) in case of any discrepancy, so that laboratory data bank can be rectified accordingly[32].

CONCLUSION:

The approval of private drug testing laboratories is subject to the conditions conferred in Form 37 of the Act, and such other conditions as may be specified in the rules for the time being in force under the Act.

32 http://www.cdsco.nic.in/writereaddata/Notice%2011_09_17%20Private%20Approved%20Testing%20Labs.pdf

HEALTH MINISTRY OF INDIA LAUNCHES TWO NEW CONTRACEPTIVES

On September 5, 2017, the Ministry of Health and Family Welfare of India announced the launch of two new contraceptives, an injectable contraceptive MPA (Medroxyprogesterone acetate) under the **'Antara'** programme and a contraceptive pill, **'Chhaya'**, in the public health system to expand the basket of contraceptive choices to meet the emerging needs of couples[33]. The new contraceptives, which are available for free in Medical Colleges and District Hospitals at present, have so far been launched in 10 states that includes Maharashtra, Uttar Pradesh, Madhya Pradesh, Rajasthan, Karnataka, Haryana, West Bengal, Odisha, Delhi and Goa.

The contraceptives are safe and highly effective; the 'Antara' injectable being effective for three months and the 'Chayya' pill for one week. They will help meet the changing needs of couples and help women plan and space their pregnancies. Training of healthcare practitioners from all the states has been completed as well, with a pool of state and district level doctors and staff nurses being trained to support the roll-out.

To help improve the supply and distribution of contraceptives, the Ministry had also recently launched a new software, Family Planning Logistics Management Information System (FP-LMIS), designed to provide robust information on the demand and distribution of contraceptives to health facilities and ASHAs.

In addition, **Mission Parivar Vikas**, a central family planning initiative has also been launched by the Ministry. The key strategic focus of this initiative is on improving access to contraceptives through delivering assured services, ensuring commodity security and accelerating access to high quality family planning services.

- The mission is being implemented in 146 high focus districts with the highest total fertility rates in the country. These districts are in the seven high-focus, high Total Fertility Rates (TFR) states of Uttar Pradesh, Bihar, Madhya Pradesh, Rajasthan, Jharkhand, Chhattisgarh and Assam, which constitute 44% of the country's population.
- The main objective of the Mission Parivar Vikas family planning initiative is to bring down the Total Fertility Rate to 2.1 by the year 2025.

The Ministry of Health and Family Welfare, through its sustained family planning efforts, aims to achieve its goal of increasing modern contraceptive usage and ensure that 74% of the demand for modern contraceptives is satisfied by 2020, with continued emphasis on delivering assured services, generating demand and bridging supply gaps. The Ministry's focus remains on increasing awareness and demand through a holistic communications campaign that has simultaneously been rolled out across all states of India.

33 http://pib.nic.in/newsite/PrintRelease.aspx?relid=170537

WORLD HEALTH ORGANIZATION (WHO) LAUNCHES NEW NON-COMMUNICABLE DISEASES (NCDS) PROGRESS MONITOR 2017

On September 18, 2017, World Health Organization (WHO) launched its Non-Communicable Diseases (NCDs) Progress Monitor 2017, which listed actions by countries - to set targets, implement policies, to address four main shared and modifiable NCDs risk factors (Tobacco, Unhealthy diet, physical inactivity and harmful use of alcohol) and build capacities to reduce and treat NCDs. It also shows that progress around the world has been uneven and insufficient.

According to WHO, Noncommunicable diseases (NCDs), including heart disease, stroke, cancer, diabetes and chronic lung disease, are collectively responsible for almost 70% of all deaths worldwide. Almost three quarters of all NCD deaths, and 82% of the 16 million people who died prematurely, or before reaching 70 years of age, occur in low- and middle-income countries. The rise of NCDs has been driven by primarily four major risk factors: tobacco use, physical inactivity, the harmful use of alcohol and unhealthy diets[34].

According to this report released, on September 18, 2017, Governments must step up efforts to control Non-Communicable Diseases (NCDs) to meet globally agreed targets, including preventing the premature deaths of millions of people from these conditions. Limited national progress has been made in the fight against NCDs - primarily **cardiovascular and chronic respiratory diseases, cancers and diabetes**, which are the world's biggest killers, and claim the lives of 15 million people aged 30 to 70 years annually.

In May 2015, the WHO had published a Technical Note on how WHO will report in 2017 to the United Nations General Assembly on the progress achieved in the implementation of national commitments included in the 2011 UN Political Declaration and the 2014 UN Outcome Document on NCDs. The Technical Note was updated in September 2017 to ensure consistency with the revised set of WHO 'best-buys' and other recommended interventions for the prevention and control of non-communicable diseases which were endorsed by the World Health Assembly in May 2017. The Technical Note outlines a set of ten progress monitoring indicators intended to show the progress achieved in countries in the implementation of selected national commitments included in the 2014 Outcome Document.

The 10 NCD progress monitoring indicators are as follows[35]:

Consider setting National NCD targets for 2025:	
1	Consider setting National NCD targets for 2025:
2	Member State has a functioning system for generating reliable cause-specific mortality data on a routine basis
3	Member State conducts a STEPS survey or a comprehensive health examination survey - every 5 years
Consider developing National multi-sectoral policies and plans to achieve the National targets by 2025:	
4	Member State has an operational multi-sectoral national strategy/ action plan that integrates the major NCDs and their shared risk factors
Reduce risk factors for NCDs, building on guidance set out in the WHO Global NCD Action Plan:	

34 http://www.who.int/ncds/en/

35 http://www.who.int/mediacentre/news/releases/2017/ncds-progress-report/en/

5	Member State has implemented the following five demand-reduction measures of the WHO FCTC at the highest level of achievement:	
	5a	Reduce affordability by increasing excise taxes and prices on tobacco products
	5b	Eliminate exposure to second-hand tobacco smoke in all indoor workplaces, public places and public transport
	5c	Implement plain/standardized packaging and/or large graphic health warnings on all tobacco packages
	5d	Enact and enforce comprehensive bans on tobacco advertising, promotion and sponsorship
	5e	Implement effective mass media campaigns that educate the public about the harms of smoking/ tobacco use and second-hand smoke
6	Member State has implemented, as appropriate according to national circumstances, the following three measures to reduce the harmful use of alcohol as per the WHO Global Strategy to Reduce the Harmful Use of Alcohol:	
	6a	Enact and enforce restrictions on the physical availability of retailed alcohol (via reduced hours of sale)
	6b	Enact and enforce bans or comprehensive restrictions on exposure to alcohol advertising (across multiple types of media)
	6c	Increase excise taxes on alcoholic beverages
7	Member State has implemented the following four measures to reduce unhealthy diets:	
	7a	Adopt national policies to reduce population salt/sodium consumption
	7b	Adopt national policies that limit saturated fatty acids and virtually eliminate industrially produced trans fatty acids in the food supply
	7c	WHO set of recommendations on marketing of foods and non-alcoholic beverages to children
	7d	Legislation /regulations fully implementing the International Code of Marketing of Breast-milk Substitutes
8	Member State has implemented even one recent national public awareness, and motivational communication for physical activity, including mass media campaigns for physical activity behavioral change.	
Strengthen health systems to address NCDs through people-centered primary health care and universal health coverage, building on guidance set out in WHO Global NCD Action Plan:		
9	Member State has evidence-based national guidelines/protocols/ standards for the management of major NCDs through a primary care approach, recognized/approved by government or competent authorities	
10	Member State has provision of drug therapy, including glycemic control, and counseling for eligible persons at high risk to prevent heart attacks and strokes, with emphasis on the primary care level	

This Progress Report presents information for each country related to their achievement of the NCD progress monitoring indicators. The countries vide profiles also include information on the population, percentage and number of deaths from NCDs, and the risk of premature death from the four main NCDs (cardiovascular diseases, cancer, diabetes or chronic respiratory diseases). For example, India's Non- Communicable Diseases (NCDs) progress monitors report[36] -

36 http://apps.who.int/iris/bitstream/10665/258940/1/9789241513029-eng.pdf

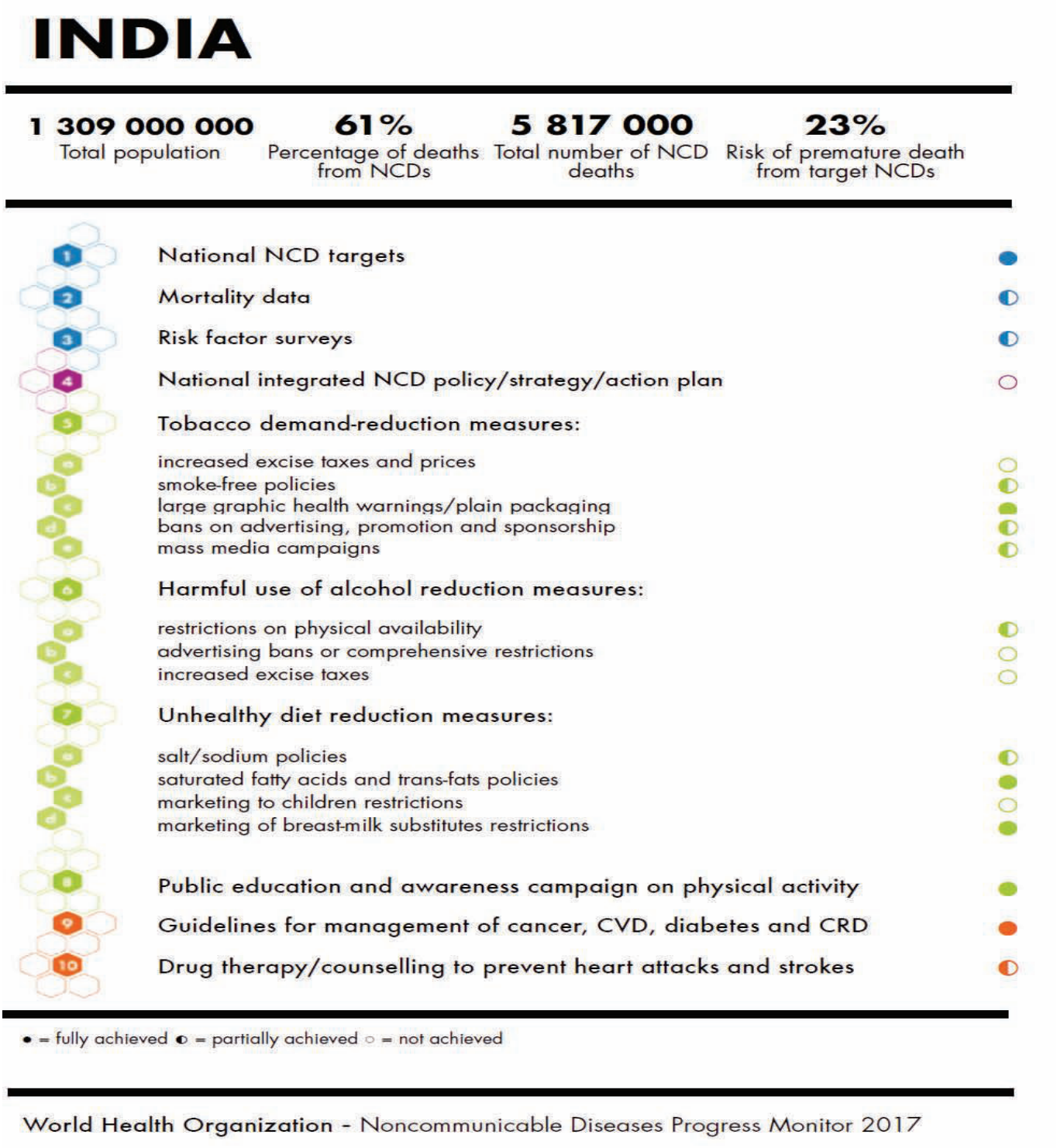

Fig 1 ***–Adapted from World Health Organization - Non-Communicable Diseases Progress Monitor 2017***

HIGHLIGHTS FROM THE EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY (ESMO) 2017 CONGRESS

The European Society for Medical Oncology (ESMO) 2017 Congress, which is organized by ESMO in conjunction with the European Association for Cancer Research, took place from September 8 – 12, 2017, in Madrid.

ESMO 2017 was a global event with nearly 24,000 participants from 131 countries. Ten countries with the highest number of delegates were the USA, France, Spain, UK, Germany, Italy, Switzerland, China, Japan, and Russia[37].

A record number of abstracts were submitted, with 1,736 selected for presentation. Groundbreaking research was revealed in 55 late breaking abstracts. ESMO 2017 research was simultaneously published in leading scientific journals including the New England Journal of Medicine (NEJM), Lancet Oncology and Annals of Oncology.

Some of the Key trials that have been touted as Practice-changing studies in the oncology domain presented at ESMO 2017 included:

- PACIFIC: New standard of care for locally advanced, unresectable stage III non-small-cell lung cancer (NSCLC).
- COMBI-AD: New adjuvant treatment option for high-risk melanoma.
- CheckMate 238: Improved adjuvant therapy for patients with surgically resected stage III/IV melanoma at high risk of relapse.
- LORELEI: Greater tumour shrinkage in estrogen receptor positive and HER2 negative early breast cancer.
- MONARCH 3: Improved outcomes with a new initial strategy for postmenopausal women with hormone receptor positive, HER2 negative advanced breast cancer.
- ARIEL 3: New maintenance therapy for recurrent ovarian cancer.
- RANGE: Promising treatment for advanced or metastatic urothelial cancer.
- CheckMate 214: Combination therapy reduces kidney cancer death risk.

THE PACIFIC TRIAL

The PACIFIC trial was a randomized, double-blinded, placebo-controlled, multi-center trial of Durvalumab as sequential treatment in unselected patients with locally-advanced, unresectable (Stage III) NSCLC who have not progressed following platinum-based chemotherapy concurrent with radiation therapy[38].

The trial being conducted in 235 centers across 26 countries involving approximately 700 patients. The primary endpoints of the trial are progression-free survival (PFS) and overall survival (OS), and secondary endpoints include landmark PFS and OS, objective response rate (ORR) and duration of response.

37 http://www.esmo.org/Press-Office/Press-Releases/Best-of-ESMO-2017-Congress?hit=ehp

38 https://www.astrazeneca.com/media-centre/press-releases/2017/astrazeneca-presents-superior-progres sion free survival-for-imfinzi-in-the-pacific-trial-of-patients-with-locally-advanced-unresectable-lung-cancer-at-esmo-2017-congress-08092017.html

Results of the PACIFIC trial, showed an improvement in PFS of more than 11 months in patients treated with Imfinzi compared to standard of care and is the first medicine to show superior PFS in this setting.
With highly favorable result from the PACIFIC trials the researchers concluded that - Immunotherapy could be the new standard of care in patients with stage III, locally advanced non-small cell lung cancer (NSCLC) who have failed chemoradiotherapy.

THE COMBI-AD TRIAL

COMBI-AD was a randomized, double-blind, placebo-controlled, phase 3 study in patients with high-risk, stage III, BRAF-V600E/K-mutant Melanoma who had not received prior anticancer therapy. Participating patients had undergone surgical resection and had been disease free for ≤12 weeks. They were randomly selected to receive either the combination of Dabrafenib 150 mg twice daily and Trametinib 2 mg once daily (n = 438) or matching placebo (n = 432). Dabrafenib and Trametinib were used at doses approved in the metastatic melanoma setting. The results showed[39]:

- The three-year relapse-free survival (RFS) rate for patients treated with the combination was 58%, compared to 39% with placebo.
- Consistent improvement in RFS observed across all pre-specified subgroups, including patients with stage III A, B and C melanoma.
- Study demonstrated clinically meaningful improvements in secondary endpoints, including overall survival (OS), distant metastasis-free survival (DMFS) and freedom from relapse (FFR).

Based on the results of the study the researchers concluded that the study will change guidelines for patients with melanoma in the adjuvant setting and provide new treatment options for these patients.

THE CHECKMATE 238 STUDY

The CheckMate 238 trial was a randomized, double-blind, phase 3 trial that included 906 patients aged 15 years or older. The patients, who had undergone complete resection for stage IIIB, IIIC, or IV melanoma, were randomly assigned to receive either Nivolumab 3 mg/kg (n = 453) every 3 weeks for four doses or Ipilimumab 10 mg/kg every 3 weeks for four doses and then once every 12 weeks (n = 453).

The results showed that treatment with Nivolumab 3 mg/kg resulted in a significant improvement in recurrence-free survival (RFS) compared to Ipilimumab 10 mg/kg in patients with stage IIIb/c or stage IV melanoma following complete surgical resection.

Adjuvant Nivolumab increased relapse-free survival by a significant 35% compared to adjuvant Ipilimumab while also reducing the rate of grade ≥3 adverse effects by approximately a third.

Based on the results of the study the researchers concluded that the significant RFS results observed with Nivolumab in CheckMate -238 are encouraging and provide physicians with new insights into the potential of Nivolumab for the management of adjuvant melanoma.

THE LORELEI STUDY

The LORELEI study enrolled 334 postmenopausal women across 85 centers and 22 countries. Women were required to have ER+/HER2– (estrogen receptor positive and HER2-negative) operable breast cancer (stage I-III), with tumors 2 cm or greater determined from breast MRI.

39 https://www.novartis.com/news/media-releases/novartis-phase-iii-study-demonstrates-adjuvant-tafinlarr-mekinistr-reduced-risk

Women were randomly assigned to receive Letrozole plus Taselisib (n = 166) or Letrozole with matching placebo (n = 168). In the subset of patients with PI3KCA mutations, 73 received Taselisib and Letrozole and 79 received Letrozole and placebo. Taselisib was given at a daily dose of 4 mg, with a schedule of 5 days on and 2 days off for 16 weeks. Surgery was performed 16 weeks after receipt of the therapy. Taselisib is an oral, potent, and selective PI3-kinase (PI3K) inhibitor with enhanced activity against PIK3CA mutant (MUT) cancer cells.

The results from the study showed that adding Taselisib to Letrozole before surgery significantly improved outcomes for patients with early breast cancer that was both estrogen receptor positive and HER2-negative (ER+/HER2-).

Based on the results of the study the researchers concluded that adding Taselisib to Letrozole before surgery significantly improved outcomes for patients with early breast cancer that was both estrogen receptor positive and HER2-negative (ER+/HER2-)[40].

THE MONARCH 3 STUDY

MONARCH 3 was a phase III randomized, double blind trial of Abemaciclib versus placebo, both on top of endocrine therapy with a non-steroidal aromatase inhibitor (Anastrozole or Letrozole), as initial therapy in postmenopausal women with hormone receptor positive, HER2 negative advanced breast cancer. The study included 493 patients from 22 countries who had never been treated for metastatic disease. The primary endpoint was progression-free survival.

Results from the study showed that when compared to single agent endocrine therapy alone, the combination of Abemaciclib and endocrine therapy significantly prolonged progression-free survival. In patients with measurable disease, the objective response rate was 59% in the Abemaciclib arm and 44% in the placebo arm.
Based on the results of the study the researchers concluded that adding the cyclin-dependent kinase (CDK) 4/6 inhibitor Abemaciclib to endocrine therapy improved progression-free survival compared to endocrine therapy alone. Abemaciclib, the third CDK4/6 inhibitor to be tested in advanced breast cancer and the MONARCH 3 trial confirms the role of this new class of agents in combination with endocrine therapy in the treatment of metastatic breast cancer[41].

THE ARIEL 3 STUDY

The ARIEL3 pivotal study of Rucaparib is a confirmatory randomized, double-blind study comparing the effects of Rucaparib against placebo to evaluate whether Rucaparib given as a maintenance treatment to platinum-sensitive ovarian cancer patients can extend the period of time for which the disease is controlled after a complete or partial response to platinum-based chemotherapy. The study enrolled 564 patients with high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. To be eligible for the study, participants had to have received at least two prior platinum-based treatment regimens, been sensitive to the penultimate platinum regimen, and achieved a complete or partial response to their most recent platinum-based regimen. Trial participants were randomized 2:1 to received 600 milligrams of Rucaparib twice daily (BID) or placebo.

Rucaparib is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3 being developed in ovarian cancer as well as several additional solid tumor indications.

The results from the ARIEL 3 study showed that Rucaparib maintenance therapy increases progression-free survival in BRCA mutant recurrent ovarian cancer by 77%.

40 http://www.esmo.org/Conferences/ESMO-2017-Congress/Press-Media/Press-Releases/LORELEI-Taselisib-Boosts-Breast- Tumor-Shrinkage

41 http://www.esmo.org/Conferences/ESMO-2017-Congress/Press-Media/Press-Releases/Abemaciclib-Initial-Therapy-Improves-Outcome-in-Endocrine-sensitive-Advanced-Breast-Cancer

Based on the results of the study the researchers concluded that Rucaparib is an exemplary member of this exciting class of drugs that can be used to treat women with recurrent ovarian cancer in the maintenance setting[42].

THE RANGE STUDY

The phase III RANGE study enrolled 530 patients with progressive advanced or metastatic urothelial carcinoma after platinum-based chemotherapy. Prior treatment with one immune checkpoint inhibitor was allowed. The investigators randomized 263 patients to Docetaxel at 75 mg/m2 plus Ramucirumab at 10 mg/kg and 267 patients to Docetaxel at the same dose plus placebo on day 1 of a 21-day cycle until disease progression or other discontinuation criteria. Radiographic assessment occurred every 6 weeks.

Beyond the primary investigator assessed PFS (Progression Free Survival) endpoint, secondary outcome measures included overall survival (OS), objective response rate (ORR), safety, and quality of life (QoL).

The results from the RANGE study showed that adding Ramucirumab to Docetaxel led to a statistically significant improvement in progression-free survival (PFS) as compared to Docetaxel plus placebo in patients with advanced or metastatic platinum refractory urothelial carcinoma. Patients treated with Ramucirumab/Docetaxel had significantly longer median PFS of 4.1 months compared to 2.8 months with Placebo/Docetaxel, HR 0.757; 95% CI 0.607, 0.943 (p = 0.0118).

Based on the results of the study the researchers concluded that Docetaxel plus Ramucirumab is the first regimen to show superior PFS over chemotherapy in a phase III trial in patients with platinum refractory advanced urothelial cancer. Ramucirumab plus Docetaxel could become a standard of care in patients with platinum-refractory advanced or metastatic urothelial cancer who have either progressed on checkpoint inhibitors or are not eligible to receive them[43].

THE CHECKMATE 214 STUDY

CheckMate 214 is a phase 3, randomized, open-label study evaluating the combination of Nivolumab plus Ipilimumab versus Sunitinib in patients with previously untreated advanced or metastatic renal cell carcinoma. Patients in the combination group received Nivolumab 3 mg/kg plus Ipilimumab 1 mg/kg every 3 weeks for 4 doses followed by Nivolumab 3 mg/kg every 2 weeks. Patients in the comparator group received Sunitinib 50 mg once daily for 4 weeks, followed by 2 weeks off before continuation of treatment. Patients were treated until progression or unacceptable toxic effects. The primary endpoints of the trial are progression-free survival (PFS). The results of the study showed that after approximately 17.5 months of follow-up, Nnivolumab plus Ipilimumab showed superior overall survival versus current standard of care of Sunitinib in intermediate- and poor-risk patients. The combination of Nivolumab and Ipilimumab also met the secondary endpoint of improved overall survival in all randomized patients.

Based on the results of CheckMate 214 trial the researchers concluded that this trial supports the use of combined Nivolumab plus Ipilimumab as a potential first-line treatment for patients with intermediate/poor risk metastatic Renal Cell Carcinoma (RCC)[44].

42 http://www.esmo.org/Conferences/ESMO-2017-Congress/Press-Media/Press-Releases/Rucaparib-Boosts-Progression-Free-Survival-BRCA-Mutant-Recurrent-Ovarian-Cancer

43 http://www.esmo.org/Conferences/ESMO-2017-Congress/News-Articles/Ramucirumab-Improves-PFS-in-Patients-with-Platinum-Refractory-Advanced-Urothelial-Carcinoma

44 http://www.esmo.org/Conferences/ESMO-2017-Congress/News-Articles/Nivolumab-Plus-Ipilimumab-versus-Sunitinib-in-First-Line-Treatment-for-Advanced-or-Metastatic-RCC

CONCLUSION:

European Society for Medical Oncology (ESMO) 2017 Congress was truly a global event with nearly 24,000 participants from 131 countries. Few landmark trials and some clinical practice changing studies were presented at the ESMO-2017 congress. Researchers also highlighted the importance of preventing cancer. "Forty percent of cancers are preventable," said Prof Josep Tabernero, ESMO President-Elect.

On the policy front, there were debates about the sustainability and cost effectiveness of cancer treatments. Biosmilars, which are new in oncology, were presented as a valid option to facilitate access to treatment and alleviate the strain on healthcare systems. Held in collaboration with the European Association for Cancer Research (EACR), the tag line for ESMO 2017 was "Integrating science into oncology for a better patient outcome".

USFDA HEMATOLOGY/ONCOLOGY (CANCER) APPROVALS & SAFETY NOTIFICATIONS: JANUARY TO SEPTEMBER 2017

The Office of Hematology and Oncology Products (OHOP) of United States Food and Drug Administration (US FDA) is accountable to ensure the availability of safe and effective drugs for cancer and hematologic conditions to the U.S. public. OHOP oversees development, approval, and regulation of therapeutic/prophylactic drug treatments for cancer and non-malignant hematologic conditions.

During the period from January 2017 to September 14, 2017 the US FDA has approved 38 hematology and oncology products so far including 4 diagnostic kits/tests for the same under Hematology/Oncology (Cancer) approvals. This periodic approval has already crossed the total number of product approvals in year 2016 (22 products)[45].

The details of approvals from January to September 2017 is being explained in below table-

Sr. No.	Drug name	Active ingredient (dose)	Date of approval	Type of approval	Approved indication	Manufacturing/ marketing company
1	VERZENIO	Abemaciclib (150 mg twice daily in combination with Fulvestrant or 200 mg twice daily as monotherapy)	September 28, 2017	Approval	Women with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.	Eli Lilly and Company
2	OPDIVO	Nivolumab (240 mg every 2 weeks)	September 22, 2017	*Accelerated approval	Hepatocellular carcinoma (HCC) in patients who have been previously treated with Sorafenib.	Bristol-Myers Squibb Co.
3	KEYTRUDA	Pembrolizumab (: 200 mg every 3 weeks)	September 22, 2017	*Accelerated approval	Patients with recurrent locally advanced or metastatic, gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1.	Merck & Co., Inc.
4	JEVTANA	Cabazitaxel (20 mg/m^2 every 3 weeks	September 14, 2017	Approval	Metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.	Sanofi-Aventis

45 https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm578081.htm

Sr. No.	Drug name	Active ingredient (dose)	Date of approval	Type of approval	Approved indication	Manufacturing/ marketing company
5	ALIQOPA	Copanlisib (Recommended 60 mg administered as a 1-hour intravenous infusion)	September 14, 2017	*Accelerated approval	Relapsed follicular lymphoma who have received at least two prior systemic therapies.	Bayer HealthCare Pharmaceuticals Inc.
6	MVASI	Bevacizumab-awwb (25mg/ml Solution for intravenous infusion)	September 14, 2017	Approval	Metastatic colorectal cancer, Non-squamous non-small cell lung cancer, Glioblastoma with progressive disease following prior therapy.	Amgen Inc.
7	MYLOTARG,	Gemtuzumab ozogamicin (4.5 mg as a lyophilized cake or powder in a single-dose vial)	September 1, 2017	Approval	Newly-diagnosed CD33-positive acute myeloid leukemia (AML) in adults and for treatment of relapsed or refractory CD33-positive AML in adults and in pediatric patients 2 years and older.	Pfizer Inc.
8	KYMRIAH	Tisagenlecleucel (A single dose unit 0.2 to 5.0 x 106 CAR-positive viable T cells per kg of body weight)	August 30, 2017	**Regular approval	Patients up to age 25 years with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.	Novartis Pharmaceuticals Corp.
9	LYNPARZA,	Olaparib tablets (300 mg taken orally twice daily)	August 17, 2017	**Regular approval	Maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy.	AstraZeneca
10	BESPONSA	Inotuzumab ozogamicin (1.8 mg/m2 per cycle)	August 17, 2017	Approval	Adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).	Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.
11	VYXEOS	Daunorubicin 44 mg and cytarabine 100 mg encapsulated together in liposomes.	August 3, 2017	**Regular approval	Adults with newly-diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC).	Jazz Pharmaceuticals, Inc.

Sr. No.	Drug name	Active ingredient (dose)	Date of approval	Type of approval	Approved indication	Manufacturing/ marketing company
12	IMBRUVICA	Ibrutinib (420 mg taken orally once daily)	August 2, 2017	Approval	Adult patients with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy.	Pharmacyclics LLC
13	IDHIFA	Enasidenib (100 mg orally once daily)	August 1, 2017	**Regular approval	Adult patients with relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase-2 (IDH2) mutation.	Celgene Corp.
14	OPDIVO	Nivolumab (240 mg every 2 weeks)	August 1, 2017	Approval	Patients 12 years and older with mismatch repair deficient (dMMR) and microsatellite instability high (MSI-H) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.	Bristol-Myers Squibb Company
15	NERLYNX	Neratinib (240 mg given orally once daily with food)	July 17, 2017	Approval	Adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.	Puma Biotechnology, Inc.
16	BLINCYTO	Blinatumomab (35 mcg of lyophilized powder in a single-dose vial)	July 11, 2017	Approval	Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.	Amgen Inc.
17	ENDARI	L-glutamine oral powder (10 - 30 gm per day taken orally)	July 7, 2017	Approval	Acute complications of sickle cell disease in adult and pediatric patients 5 years and older.	Emmaus Medical, Inc.

Sr. No.	Drug name	Active ingredient (dose)	Date of approval	Type of approval	Approved indication	Manufacturing/ marketing company
18	BEVYXXA	Betrixaban (160 mg on day 1, followed by 80 mg once daily taken for 35 to 42 days with food)	June 23, 2017	Approval	Prophylaxis of Venous Thromboembolism (VTE) in adult patients hospitalized for an acute medical illness that are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE.	Portola
19	TAFINLAR and MEKINIST	Dabrafenib and Trametinib (150 mg orally twice daily)	June 22, 2017	**Regular approval	Metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation.	Novartis Pharmaceuticals Inc.
20	RITUXAN HYCELA	Rituximab and Hyaluronidase human (1400 mg : 23,400 units, and 1600 mg : 26,800 units)	June 22, 2017	**Regular approval	Adult patients with follicular lymphoma, diffuse large B-cell lymphoma, and chronic lymphocytic leukemia.	Genentech Inc.
21	ZYKADIA	Ceritinib (750 mg orally once daily)	May 26, 2017	**Regular approval	Patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive.	Novartis Pharmaceuticals Corp.
22	KEYTRUDA	Pembrolizumab (200 mg for adults or 2 mg/kg (up to a maximum of 200 mg) for children intravenous infusion)	May 23, 2017	*Accelerated approval	Adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options.	Merck & Co.

Sr. No.	Drug name	Active ingredient (dose)	Date of approval	Type of approval	Approved indication	Manufacturing/ marketing company
23	KEYTRUDA	Pembrolizumab (200 mg as an intravenous infusion over 30 minutes every 3 weeks)	May 18, 2017	**Regular approval	Locally advanced or metastatic urothelial carcinoma in patients who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.	Merck and Co., Inc.
24	KEYTRUDA	Pembrolizumab in combination with Pemetrexed and Carboplatin (200 mg as an intravenous infusion every 3 weeks)	May 10, 2017	*Accelerated approval	Previously untreated metastatic non-squamous non-small cell lung cancer (NSCLC).	Merck and Co., Inc.
25	BAVENCIO	Avelumab (10 mg/kg as an intravenous infusion over 60 minutes every 2 weeks)	May 9, 2017	*Accelerated approval	Locally advanced or metastatic urothelial carcinoma in patients whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.	EMD Serono, Inc.
26	IMFINZI	Durvalumab (10 mg/kg, Intravenous infusion over 60 minutes every 2 weeks)	May 1, 2017	*Accelerated approval	Locally advanced or metastatic urothelial carcinoma in patients who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.	AstraZeneca UK Limited
27	ALUNBRIG	Brigatinib tablets (90 mg orally once daily for the first 7 days then, if tolerated, increase to 180 mg orally once daily)	April 28, 2017	*Accelerated approval	Metastatic anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) progressed on or are intolerant to Crizotinib.	Takeda Pharmaceutical Company Limited, through its wholly owned subsidiary ARIAD Pharmaceuticals, Inc.

Sr. No.	Drug name	Active ingredient (dose)	Date of approval	Type of approval	Approved indication	Manufacturing/ marketing company
28	RYDAPT	Midostaurin (50 mg twice daily with food)	April 28, 2017	Approval	Adult patients with newly diagnosed acute myeloid leukemia (AML) who are FLT3 mutation-positive (FLT3+).	Novartis Pharmaceuticals Corp.
29	STIVARGA	Regorafenib (160 mg (four 40 mg tablets) taken orally once daily after a low-fat meal for the first 21 days of each 28-day cycle.)	April 27, 2017	Expanded	Hepatocellular carcinoma (HCC) patients who have been previously treated with Sorafenib.	Bayer HealthCare Pharmaceuticals Inc.
30	IBRANCE	Palbociclib (125 mg capsule taken orally once daily with food for 21 consecutive days followed by 7 days off treatment)	March 31, 2017	**Regular approval	Hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy in postmenopausal women.	Pfizer Inc.
31	TAGRISSO	Osimertinib (80 mg orally once daily, with or without food)	March 30, 2017	**Regular approval	Metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC).	AstraZeneca Pharmaceuticals, LP
32	ZEJULA	Niraparib (300 mg taken once daily with or without food.)	March 27, 2017	Approval	Maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy.	Tesaro, Inc.
33	BAVENCIO	Avelumab (10 mg/kg as an intravenous infusion over 60 minutes every 2 weeks)	March 23, 2017	*Accelerated approval	Patients 12 years and older with metastatic Merkel cell carcinoma (MCC).	EMD Serono, Inc.

Sr. No.	Drug name	Active ingredient (dose)	Date of approval	Type of approval	Approved indication	Manufacturing/ marketing company
34	KEYTRUDA	Pembrolizumab (200 mg every 3 weeks for adults and 2 mg/kg (up to 200 mg) every 3 weeks for pediatric patients)	March 15, 2017	*Accelerated approval	Adult and pediatric patients with refractory classical Hodgkin lymphoma (cHL), or those who have relapsed after three or more prior lines of therapy.	Merck and Co., Inc.
35	KISQALI	Ribociclib (600 mg orally taken once daily with or without food for 21 consecutive days followed by 7 days off treatment)	March 13, 2017	Approval	Postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer	Novartis Pharmaceuticals Corp.
36	Revlimid,	Lenalidomide (10mg once daily continuously on days 1-28 of repeated 28-day cycles)	February 22, 2017	Approval	Maintenance therapy for patients with multiple myeloma following autologous stem cell transplant.	Celgene Corp.
37	OPDIVO	Nivolumab (240 mg intravenously every 2 weeks)	February 2, 2017	*Accelerated approval	Locally advanced or metastatic urothelial carcinoma patients who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with a platinum-containing chemotherapy.	Bristol-Myers Squibb Company

*Accelerated approval –Faster approval of drugs for serious clinical conditions and the drug appears to provide *benefit over available therapy* based on the surrogate endpoints. **Regular approval- Regular marketing approval of oncology drugs requires substantial evidence of efficacy from adequate and well-controlled clinical trials[46].

Underlined text - Few of the remarkable approvals so far:

- Tisagenlecleucel (KYMRIAH, Novartis Pharmaceuticals Corp.) is the first chimeric antigen receptor (CAR) T-cell immunotherapy approved by the FDA. Tisagenlecleucel consists of autologous T cells collected in a leukapheresis procedure that are genetically modified with a new gene containing a CAR protein allowing the T cells to identify and eliminate CD19-expressing normal and malignant cells.

46 https://www.fda.gov/ohrms/dockets/ac/02/briefing/3894B1_02_FDA-Team%20Leader%20Comments.htm

- Ibrutinib (Imbruvica, Pharmacyclics LLC) for the treatment of adult patients with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy. This is the first FDA-approved therapy for the treatment of cGVHD.
- Enasidenib (IDHIFA, Celgene Corp.) This is the first FDA approval for relapsed or refractory AML specifically with an IDH2 mutation. The FDA concurrently approved a companion diagnostic, the RealTime IDH2 Assay, used to detect the IDH2 mutation.
- Dabrafenib and Trametinib (TAFINLAR® and MEKINIST®, Novartis Pharmaceuticals Inc.) These are the first FDA approvals specifically for treatment of patients with BRAF V600E mutation-positive metastatic NSCLC.
- Pembrolizumab (KEYTRUDA, Merck & Co.) is the FDA's first tissue/site-agnostic approval.
- Osimertinib (TAGRISSO, AstraZeneca Pharmaceuticals, LP) In November 2015, Osimertinib received accelerated approval for the indication based on an overall response rate (ORR) of 59% among 411 patients in two single-arm clinical trials.
- Avelumab (BAVENCIO, EMD Serono, Inc.) for the treatment of patients 12 years and older with metastatic Merkel cell carcinoma (MCC). This is the first FDA-approved product to treat this type of cancer.

The approval information of diagnostic tests/kits under Hematology/Oncology (Cancer) approvals is not included in the table like -

- Marketing approval to the Praxis Extended RAS Panel (Illumina, Inc.),
- Approval of Aminolevulinic acid hydrochloride, known as ALA HCl (Gleolan, NX Development Corp.)
- Marketing approval of the Philips IntelliSite Pathology Solution (PIPS, Philips Medical Systems Nederland B.V.),
- Marketing authorization of Ipsogen JAK2 RGQ PCR Kit (QIAGEN GmbH.)

NEW PRICING AGREEMENT TO LAUNCH NEW HIGH-QUALITY ANTIRETROVIRAL THERAPY IN LOW- AND MIDDLE-INCOME COUNTRIES AT SIGNIFICANTLY REDUCED PRICE

On September 21, 2017, World Health Organization (WHO) announced[47] a breakthrough pricing agreement which will accelerate the availability of the first affordable, generic, single-pill HIV treatment regimen, containing Dolutegravir (DTG), to public sector purchasers in low- and middle-income countries (LMICs) at around US$75 per person, per year. The agreement is expected to accelerate treatment rollout as part of global efforts to reach all 36.7 million people living with HIV with high-quality antiretroviral therapy. UNAIDS estimates that in 2016, only over half (19.5 million) of all people living with HIV, had access to the lifesaving medicines.

DTG, a best-in-class integrase inhibitor, is widely used in high-income countries and is recommended by the World Health Organization (WHO) as an alternative first-line HIV regimen, as well as a preferred treatment by the U.S. Department of Health and Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents, among many others. DTG is one of several anti-retrovirals included in the "integrase inhibitor" drug class. DTG, when combined with 2 other medicines in a single fixed-dose combination pill, is considered to be among the best current treatments for HIV, but its availability has previously been limited due to high cost. DTG was approved by the U.S. Food and Drug Administration (FDA) in August 2013; by the European Commission in January 2014; by the Canadian regulatory authority Health Canada in October 2013 and by the Japanese Pharmaceuticals and Medical Devices Agency in April 2014[48].

In addition to improving treatment quality and retention, widespread use of DTG is expected to lower the cost of first-line HIV treatment regimens while also reducing the need for more expensive second- and third-line regimens.

The agreement announced by the governments of South Africa and Kenya, together with the Joint United Nations Programme on HIV/AIDS (UNAIDS), the Clinton Health Access Initiative (CHAI), the Bill & Melinda Gates Foundation (BMGF), Unitaid - the United Kingdom's Department for International Development (DFID), the United States President's Emergency Plan for AIDS Relief (PEPFAR), the U.S. Agency for International Development (USAID), and the Global Fund to Fight AIDS, Tuberculosis and Malaria, with Mylan Laboratories Limited and Aurobindo Pharma, takes an important step toward ensuring the availability of worldwide high-quality treatment for HIV.

This one pill, once-a-day generic fixed-dose combination of tenofovir disoproxil fumarate, lamivudine, and dolutegravir (TLD) was developed by Mylan and Aurobindo under licensing agreements from ViiV Healthcare, the original developer of DTG. In August 2017, Mylan and Aurobindo both received tentative approval from the U.S. Food and Drug Administration (FDA) for their products under the United States PEPFAR program[49]. Clinical studies have demonstrated that treatment regimens that use DTG result in more rapid suppression of viral load, fewer side effects, and greater potency against drug resistance than current regimens used in LMICs.

47 http://www.who.int/hiv/mediacentre/news/high-quality-arv-reduced-price/en/

48 https://www.viivhealthcare.com/our-medicines/tivicay.aspx

49 https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=reportsSearch.process&rptName=5&rep ___ortSelectMonth=8&reportSelectYear=2017&nav#navigation

The United Nations officials also welcomed this breakthrough pricing agreement terming it as a global partnership to accelerate the availability in low- and middle-income countries of the first affordable, generic, single-pill HIV treatment regimen. The agreement is expected to accelerate treatment rollout as a part of global efforts to reach, all 36.7 million people, living with HIV with high-quality antiretroviral therapy[50].

The UNAIDS Executive Director said "This agreement will improve the quality of life for millions of people living with HIV. To achieve the 90-90-90 treatment targets, newer, affordable and effective treatment options must be made available—from Baltimore to Bamako—without any delay".

The 90-90-90 is UN AIDS ambitious program which targets that by 2020, 90% of all people living with HIV will know their HIV status; by 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy; by 2020, 90% of all people receiving antiretroviral therapy will have viral suppression[51].

CONCLUSION:

This groundbreaking agreement aims to help improve the lives of millions of patients by reducing costs and increasing availability of a one pill, once daily fixed-dose-combination including dolutegravir. This drug combination is better tolerated and more effective and will lead to improved health outcomes by ensuring that fewer HIV patients develop drug resistance and that more remain ontreatment.

50 http://www.un.org/apps/news/story.asp?NewsID=57641#.Wciuz9QjGUk

51 http://www.unaids.org/en/resources/documents/2017/90-90-90

CDSCO NOTICE REGARDING STRICT REGULATORY CONTROL OVER MANUFACTURE, SALE AND DISTRIBUTION OF OXYTOCIN AND TO CURB ITS MISUSE

On September 22, 2017, The Central Drug Standard Control Organization (CDSCO) has notified to all the state drug controllers regarding strict regulatory control over manufacture, sale and distribution of Oxytocin and to curb its misuse. The CDSCO has received the letter from Ministry of Health and Family Welfare vide F.No. BD/VET/CELL/13.2014 (Pt-1) dated 09-05-2017 that the following measures are to be taken in order to comply the direction of the Hon'ble High court, Himanchal Pradesh on the subject cited above-

- Constitution of special task force in each District, of each State, to ensure that no prohibited/regulated drug including Oxytocin is freely available in each district in open market, save and except in manner prescribed.
- Concerned Drug Controllers of the States where licenses of manufacturing of Oxytocin have been issued shall examine the license of all existing manufacturers of Oxytocin to ensure that the same have been issued strictly in accordance to the Drugs and Cosmetics Act, 1940 and Rules 1945 and that the manufacturers mandatorily comply with all the conditions of the Act and rules framed there under. Immediate appropriate actions as per the statutory provisions may be taken wherever violations of the rules are found.
- The State Drug Controllers shall place on their respective websites, by 10th of each month, details of licenses issued to various manufacturers along with the monthly statement of production and sales of Oxytocin with complete particulars and details furnished by manufacturers. The manufacturer of Oxytocin shall in turn submit these details beforehand, so as to reach the office of drug Controller by 7th of every month.
- The wholesaler and retailers of all prohibited scheduled drugs including Oxytocin shall maintain records, as required under law and the same shall be produced for inspection after every quarter before the officer specifically deployed for this purpose by the drug controller.
- You may take appropriate steps of undertaking IEC activities for sensitizing public about ill effects of Oxytocin both on humans and the animals specially mulching cattle, and about penal provisions for abuse/misuse of Oxytocin[52].

ABOUT OXYTOCIN

Oxytocin, a neuro-hormone that also acts as neurotransmitter in brain, is naturally released in large amounts by the posterior pituitary gland in mammals. Oxytocin is known to induce contractions of the uterus during labour and stimulate ejection of milk during breastfeeding. It also promotes the maternal nurturing behavior along with general psychological stability in women as per various researches.

Synthetic Oxytocin is being widely administered in obstetric practice for induction of labour, control of bleeding following delivery, and for the stimulation of milk letdown reflex in human and cattle as well. However, along the way people started using Oxytocin injections unsystematically on milch animals not only during delivery of a calf,

52 http://www.cdsco.nic.in/writereaddata/notice22_9_2017.pdf

but more frequently to get benefit/profit out of that for example – a milch cattle injected 5 ml of Oxytocin twice a day just five minutes before of milking, so that milk flows fast out of the udder[53].
There have been many complaints regarding misuse of Oxytocin injection in milch cattle to increase milk production by dairy owner and also to increase the size of vegetables and fruits by farmers in the country. However, there no scientific data in support of such practices is available. The National Dairy Research Institute (NDRI) and Indian Council of Agricultural Research (ICAR) has informed that there is no scientific evidence that artificial use of Oxytocin has adversely affected progeny of cattle and buffaloes resulting in dwindling of livestock. However, continuous Oxytocin use could lead to a progressive addiction and lack of response to normal let down of milk[54].

REGULATION OF MANUFACTURE, SALE AND DISTRIBUTION OF OXYTOCIN IN RECENT YEARS

The Government of India, Ministry of Health and Family Welfare, issued a notification under Section 26A of the Drugs and Cosmetics Act, 1940 vide G.S.R. 29(E) dated January 17, 2014 restricting the manufacture and sale of Oxytocin as under:

- The manufacturers of bulk Oxytocin drug shall supply the active pharmaceutical drug only to the manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug.
- The formulations meant for veterinary use shall be sold to the veterinary hospitals only[55].

Further, the Department of Animal Husbandry, Dairying and Fisheries have also issued an Advisory to all the State Governments to comply with the provisions of the above-mentioned notification. Despite this, the continued misuse of Oxytocin injection in the country has been considered by the Drug Consultative Meeting (DCC) as well as Drug Technical Advisory Board (DTAB) in its various meetings.

In the 69th meeting of DTAB, the board opposed against Oxytocin prohibition, as it has definite use for therapeutic purposes. The problem of misuse of Oxytocin is more related to stricter control over the manufacture and sale of the drug especially through clandestine channels.[56]

Similarly, the 49th DCC meeting also raised the following recommendations to fight against the misuse of Oxytocin in the country:

- State Drug Regulatory officials must conduct raids with the assistance of Police Authorities at the suspected outlets of such drugs near the dairy farms after due surveillance to apprehend culprits red-handed.
- The manufacture and sale of Oxytocin formulations by the licensed manufacturers in the State should be monitored regularly.
- States should share information about the raids conducted and results of investigations with other concerned State Drug Control Authorities and Zonal offices for interstate coordination.
- Samples of milk may be drawn to assess the presence of Oxytocin in milk.
- Rapid test for detection of Oxytocin may be developed.

53 http://www.bwcindia.org/Web/Awareness/LearnAbout/Oxytocin.html
54 http://dahd.nic.in/sites/default/files/LS%20328.pdf
55 http://cdsco.nic.in/writereaddata/G.S.R.%2029%20(E).pdf
56 http://www.cdsco.nic.in/writereaddata/70th%20DTAB%20minutes.pdf

- The Port offices of CDSCO shall inform custom authorities that import of all peptide formulations be monitored for their use.
- The Central Government may request Police authorities of States to take cognizance of offences related to misuse of Oxytocin.
- FSSAI may be asked to explore the possibility of declaring the use of Oxytocin on animals for production of milk as an offence under the FSSAI Act.
- Each State and Central regulatory system must develop an intelligence wing for keeping close watch, sharing of information and prompt action for checking/eradicating the misuse of Oxytocin in the country[57].

CONCLUSION:

The manufacture, sale and distribution of Oxytocin is well described under the provisions of the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. However, a strict vigilance and regular monitoring/ inspection of Oxytocin misuse by Central and State drug authorities are recommended.

57 http://www.cdsco.nic.in/writereaddata/Minutes%20of%20%20DCC%20dated%2016_10_2015%20.pdf

US FDA APPROVES FIRST CONTINUOUS GLUCOSE MONITORING SYSTEM FOR ADULTS NOT REQUIRING BLOOD SAMPLE CALIBRATION

On September 27, 2017, the United States Food and Drug Administration (US-FDA) approved the FreeStyle Libre Flash Glucose Monitoring System, the first continuous glucose monitoring system that can be used by adult patients to make diabetes treatment decisions without calibration using a blood sample from the fingertip (often referred to as a "fingerstick")[58].

People with diabetes must regularly test and monitor their blood sugar to make sure it is at an appropriate level, which is often done multiple times per day by taking a fingerstick sample and testing it with a blood glucose meter. Typically, patients use results of a traditional fingerstick test to make diabetes treatment decisions; however, fingerstick testing is not needed to inform appropriate care choices or to calibrate glucose levels with this system.

The system reduces the need for fingerstick testing by using a small sensor wire inserted below the skin's surface that continuously measures and monitors glucose levels. Users can determine glucose levels by waving a dedicated, mobile reader above the sensor wire to determine if glucose levels are too high (hyperglycemia) or too low (hypoglycemia), and how glucose levels are changing. It is intended for use in people 18 years of age and older with diabetes; after a 12-hour start-up period, it can be worn for up to 10 days.

The FreeStyle Libre Flash Glucose Monitoring System is manufactured by Abbott Diabetes Care Inc.

FreeStyle Libre system measures glucose levels through a small sensor applied to the back of upper arm. The sensor, which is the size of two stacked quarters, provides real-time glucose readings for up to 10 days, both day and night. The sensor can also read glucose levels through clothes, making testing discreet and convenient. The FreeStyle Libre system provides people with diabetes, three key pieces of data with each scan: a real-time glucose result, an 8-hour historical trend, and a trend arrow showing the direction their glucose level is moving in. The touch-screen reader holds up to 90 days of data, which allows people to track their glucose levels over time[59].

According to the Centers for Disease Control and Prevention, more than 29 million people in the U.S. have diabetes. People with diabetes either do not make enough insulin (type 1 diabetes) or cannot use insulin properly (type 2 diabetes). When the body doesn't have enough insulin, or cannot use it effectively, sugar builds up in the blood. High blood sugar levels can lead to heart disease; stroke; blindness; kidney failure; and amputation of toes, feet or legs.

The FDA evaluated data from a clinical study of individuals aged 18 and older with diabetes, and reviewed the device's performance by comparing readings obtained by the FreeStyle Libre Glucose Monitoring System to those obtained by an established laboratory method used for analysis of blood glucose. Risks associated with use of the system may include hypoglycemia or hyperglycemia in cases where information provided by the device is inaccurate and used to make treatment decisions, as well as mild skin irritations around the insertion site. It does not provide real-time alerts or alarms in the absence of a user-initiated action; for example, it cannot alert users to low blood glucose levels while they are asleep.

58 https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577890.htm

59 http://www.abbott.com/corpnewsroom/product-and-innovation/welcome-freestyle-libre.html

CONCLUSION:

This revolutionary new glucose sensing technology eliminates the need for routine finger sticks and is the only personal continuous glucose monitor (CGM) that does not require finger stick calibration. It is designed to be approachable, accessible and affordable for those millions of people who suffer from diabetes.

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