Editorial:

The Education Regulations, 2020 for Diploma Course in Pharmacy published on 9th October 2020 repealing the Education Regulation 1991. This long pending issue has come out with features to meet the current need of the healthcare services. In the two years course curriculum new subjects included very judiciously like Social Pharmacy, Community Pharmacy & Management, Pharmacotherapeutics etc. Though detailed course curriculum is yet to be published experts opine that these subjects will be the driver to make the entire course contemporary.

Another grey area became transparent as it is stated that a student appeared for Part II exam is eligible to undergo practical training in an Institutions as prescribed by this ER. This ER very specifically and elaborately prescribed the infrastructure and manpower required to conduct Diploma in Pharmacy Course.

This ensured that the Diploma in Pharmacy Course (D.Pharm.) course will continue as this ER stated that “The minimum qualification required for registration as a pharmacist shall be a pass in Diploma in Pharmacy (Part-I & Part-II) and satisfactory completion of Diploma in Pharmacy (Part-III).”

Hope Pharmacy Council (PCI) will publish the detailed course after consultation with the stake holders.

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Pharmacists able to dispense COVID-19 treatments without a prescription under government protocols

Changes to legislation mean that government ministers or NHS bodies will be able to issue “pandemic treatment protocols” that authorise the “supply of prescription-only medicines without a prescription”. Community pharmacists will be able to dispense COVID-19 treatments without a prescription under government-issued protocols, following changes to the pharmacy terms of service.

Amendments to the NHS (Charges and Pharmaceutical and Local Pharmaceutical Services) Regulations 2020 will now allow government ministers or NHS bodies to issue “pandemic treatment protocols” that “can be used to authorise supply of prescription-only medicines without a prescription”.

According to the legislation’s explanatory memorandum, protocols will be issued “if a Covid-19 treatment became available that was suitable for distribution via community pharmacies” and it was not found to be necessary for an authorized prescriber to decode to treat.

The protocols will not be limited to COVID-19, extending to “treatment for other pandemic diseases” as well, the memorandum says.

Changes to the legislation will come into effect on 9 November 2020-21 days after the amendments were laid before parliament on 19 October 2020 – and from part of the essential service dispensing provisions.

The amendments also allow for “flexible provision of immunization services during the pandemic”, which enable community pharmacies to close, with the permission of NHS England, “to focus on the delivery of flu or COVID-19 vaccinations”.

Much larger numbers of patients than is usual will need to be vaccinated, and this measure will support both the expansion of the national flu vaccination programme and any future national Covid-19 vaccination programme”, the explanatory memorandum says.

For details: The Pharmaceutical Journal, 21 OCT 2020

DCGI approves Dr Reddy's request to conduct Phase 2, 3 clinical trials with Russia's Sputnik V COVID-19 vaccine

After being denied their request to conduct a phase three clinical trial with Russia's Sputnik V covid-19 vaccine and asked to submit a new request, the Controller General of Medicines of India (DCGI) has given Dr Reddy's Laboratories its approval. The big pharma will conduct Phase 2-3 clinical trials of the vaccine instead of jumping straight to Phase 3. The reason the first request was overturned was due to a lack of sufficient safety and efficacy data on the Russian vaccine.

GV Prasad, co-chairman and managing director of Dr Reddy's, said in a statement, “We are grateful for DCGI's scientific approach and support in the application process.”

"Regulatory approval provides an opportunity to initiate clinical trials in India and further supply a safe and effective vaccine to combat the pandemic,” he added.

After the first application was evaluated by the Subject Expert Committee (SEC) on COVID-19 at Central Drugs Standard Control Organisation (CDSCO), the regulator said Dr Reddy's cannot directly conduct a phase 3 trial for the COVID-19 vaccine. This, since the sample size of early human trials for the vaccine carried out in Russia, was "small", and information of its safety and the immunogenic effect was insufficient for Indian subjects.

CDSCO had asked Dr Reddy's to submit a revised application, which includes new protocols for both phase 2 and phase 3 human clinical trials instead of just phase 3. A PTI report states that the pharma giant was asked to submit additional information as well, but as to what was specified, it is unclear.

Kirill Dmitriev, CEO of the Russian Direct Investment Fund (RDIF) said in a statement, "We are delighted to be working with regulatory authorities in India and will provide data on the safety and immunogenicity of the vaccine from Phase 3 trials in Russia, in addition to data from clinical trials in India to facilitate successful Sputnik V trials in the country."

India, overlooked by Dr Reddy's will be conducting a multicenter, randomized controlled trial, which will include safety and immunogenicity trials. RDIF will also supply 100 million doses of Dr Reddy's after receiving Indian regulatory approval.
The ongoing post-registration Sputnik V vaccine trials are being conducted in Russia on 40,000 volunteers as well as in Belarus, Venezuela and the United Arab Emirates. Ref. Firstpost

ICMR Nod for IIT-Kharagpur Team’s Covid Testing Device
Researchers at IIT-Kharagpur have received validation for ‘COVIRAP’ — the diagnostic machine developed by them for its efficacy in detection of Covid — from the Indian Council of Medical Research (ICMR). Multiple commercial units have already approached the institute for technology licencing of the device that is easy to operate and affordable, and can produce results in a custom-developed app in an hour.

Education minister Ramesh Pokhriyal Nishank said this would impact lives in rural India as the device is portable, can be operated on low energy and by minimally trained rural youth. He added, “Developed at a cost of less than Rs 1,000, this has made high-quality and accurate Covid testing affordable for around Rs 500. This can be reduced through government intervention.”

V K Tewari, director of IIT-Kharagpur, said this was one of the greatest contributions in the area of virology and may replace PCR-based tests to a large extent.

Subsequent financial support for this project was provided by the IIT Foundation, USA. It was developed by a team led by Suman Chakraborty from the department of mechanical engineering and Arindam Mondal of the school of bio-science. ICMR-NICED director Shanta Dutta said, “This needs a rapid commercial scale-up.

Ref. The Times of India

IPC to Amend Blood Thinner Heparin Sodium Monograph in IP 2018
The Indian Pharmacopoeia Commission (IPC) will soon amend the heparin sodium monograph in IP 2018 following an appeal from stakeholders. The decision to this effect was taken by the IPC at a meeting held on September 23, 2020. The meet was attended by IPC officials— Dr Jai Prakash, senior secretary-cum-scientific director, Dr M Kalaivani, senior scientific officer, Dr Gaurav Pratap Singh, senior scientific officer, Anubhuti Goyal, scientific assistant, Sargam Verma, technical associate, Rajesh Verma, assistant drugs controller (biological) at CDSCO, National Institute of Biologicals (NIB) officials, Central Drug Testing Laboratory (CDTL), Mumbai officials, and Dr Ranjeet Ajmani, chief executive officer, PlasmaGen Biosciences, Bengaluru.

Heparin, a common anti-coagulant drug (that reduces blood clots from forming in the body), is used in treating COVID-19 patients. It is included in the “Guidelines on Clinical management of COVID-19”, released by the directorate general of health services, ministry of health & family welfare. The blood-thinning drug has reduced hospitalisation rates, improved recovery rates, and even reduced the rate of sudden deaths by 90 per cent.

At the meet, stakeholders requested for amendment only in heparin sodium monograph not in heparin injection monograph of IP 2018, as amendment in potency value of the bulk does not have any impact on usual strength of injection.

Currently, there are two potency value of heparin sodium mentioned in its monograph in IP 2018 i.e. a potency of not less than 180 IU per mg in parenteral preparations containing heparin sodium and a potency of not less than 120 IU per mg in non-parenteral preparations containing heparin sodium.

With the proposed amendment to heparin sodium monograph in IP 2018, a potency of not less than 150 IU per mg in parenteral preparations containing heparin sodium will be included in the monograph.

The data/supporting documents (certificate of analysis Brazilian manufacturers) submitted by Biological E Ltd and Bacto Chem. Lab. supports the potency value of not less than 150 IU/mg.

The manufacturers have expressed difficulty in achieving the potency value of not less than 180 IU/mg in parenteral preparations comprising heparin sodium, said a senior scientific official at IPC.

At present, heparin sodium monograph in IP 2018 mentions that heparin sodium intended for use in the manufacture of parenteral preparation contains not less than 180 IU per mg and heparin sodium not intended for the use in the parenteral preparation contains not less than 120 IU per mg, calculated on the dried basis.

Once the proposed amendment is introduced to heparin sodium monograph, it will read as follows, “Heparin sodium intended for use in the manufacture of parenteral preparation contains not less than 180 IU per mg for Heparin obtained
from the intestinal mucosa or other suitable tissues of domestic mammals used for food by man except bovine source. Heparin sodium intended for use in the manufacture of parenteral preparation contains not less than 150 IU per mg obtained from the intestinal mucosa or other suitable tissues of bovine and heparin sodium not intended for the use in the parenteral preparation contains not less than 120 IU per mg, calculated on the dried basis.”
At present heparin sodium monograph mentions method A to perform assay test to the bulk drug obtained from porcine/bovine sources.
For details: Pharmabiz

**Pfizer, BioNTech start combined trials of COVID-19 vaccine candidate in Japan**
Pfizer Inc PFE.N and BioNTech SE announced on 20th October the start in Japan of combined Phase I and Phase II clinical trials of their mRNA vaccine candidate against the corona virus.

The study will recruit 160 people aged from 20 to 85, the firms said in a statement. Earlier, they had agreed to supply Japan with 120 million doses of their experimental corona virus vaccine in the first half of 2021.
Pfizer, which is developing the vaccine with German partner BioNTech, has said it may confirm if the vaccine is effective as soon as this month, but also needs safety data from a global trial of 44,000 people that will not be available until next month.
Japan has pledged to secure enough vaccine supply for its entire population by the middle of 2021. In addition to Pfizer, it has struck deals on supplies with AstraZeneca Plc and other overseas makers of vaccine candidates.
Clinical trials of AstraZeneca and Oxford University’s experimental COVID-19 vaccine resumed in Japan this month after being put on hold over the illness of a British volunteer.
Ref. Reuters