The long pending demand of pharmacy professionals for inclusion of Pharmacy subjects in the Indian Administrative Examination (IAS) has been ignored by the concerned authority, creating dissension amongst the pharmacy community. In India most of the students pursuing professional courses like Medical, Engineering etc are getting an advantage in the examination to be qualified for IAS. Pharmacy students are not getting this advantage as Pharmacy subjects are not included in the said examination. Resolutions have been taken in this respect on several occasions by the IPCA in the past but result is yet to be positive. Similar situation is prevailing in case of examination for selecting Patent Examiners in which Pharmacy subject is not included though thirteen subjects like Chemistry, Chemical Engineering, Electric Engineering have been included. It may be noted that patent application on Pharmaceuticals have a major share on the total number of patent application in India. This issue has been raised by a certain quarter before the concerned authority but no positive results are yet visible. In India most of the decisions are taken and executed by the bureaucrats, where the opinions of the technocrats are mostly ignored, absence of bureaucrats with pharmaceutical background is a disadvantage in taking decision in the matter of Pharmaceuticals. These are two issues amongst several such that are deterrent to the development of the profession in our country. Policy makers require think over proper utilization of the huge manpower in pharmaceutical profession in India. IPA is trying its best by submitting memorandum to the concerned authorities and trying to pursue the matter continuously, but expected result is yet to be achieved. Therefore, it is high time for taking up these issues by all of the pharmaceutical professional organizations jointly.
Every API (bulk drug) manufactured or imported in India shall bear QR code effective from 1st Jan 2023

MINISTRY OF HEALTH AND FAMILY WELFARE
(Deartment of Health and Family Welfare)

NOTIFICATION

New Delhi, the 18th January, 2022

G.S.R. 20(E).— Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published as required under sub-section(1) of section 12 and sub-section(1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 567(E), dated the 8th August, 2019, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 10th August, 2019;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred under sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

1. (1) These rules may be called the Drugs (Amendment) Rules, 2022.

   (2) They shall come into force on the first day of January, 2023.

2. In the Drugs Rules, 1945, in rule 96, after sub-rule (4), following sub-rule shall be inserted, namely:—

   “(5) Every active pharmaceutical ingredient (bulk drug) manufactured or imported in India shall bear Quick Response code on its label at each level packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the following minimum particulars, namely:—

   (i) Unique product identification code,
   (ii) Name of the API,
   (iii) Brand name (if any),
   (iv) Name and address of the manufacturer,
   (v) Batch no.,
   (vi) Batch size,
   (vii) Date of manufacturing,
   (viii) Date of expiry or retesting,
   (ix) Serial shipping container code,
   (x) Manufacturing licence no. or import licence no.
   (xi) Special storage conditions required (if any).”.

[F.No.X.1101/14/17/2019—DR]

Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note:— The principal rules were published in the Official Gazette vide notification number F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R.848(E), dated the 9th December, 2021.

New Drug: Carbetocin
Duratocin (Ferring) ampoules containing 100 microgram/mL
Approved indication: prevention of uterine atony after Caesarian section

Oxytocin is a hormone released from the posterior pituitary. As it stimulates rhythmic contractions of uterine smooth muscle, synthetic preparations can be used to induce or augment labour. Oxytocin can also be used to prevent postpartum haemorrhage.
Carbetocin is a synthetic analogue of oxytocin, with a longer half-life (41 minutes after intravenous injection vs 1–5 minutes). It stimulates a prolonged uterine response lasting about an hour.

The approved indications reflect the largest published trial of carbetocin. This involved 694 women who were having elective Caesarian sections under regional anaesthesia. The women were randomised to receive, after delivery, a bolus dose of oxytocin followed by an infusion, or a bolus dose of carbetocin followed by an infusion of placebo. In the oxytocin group, 10% of the women needed additional treatment to maintain the uterine contraction in the 48 hours after delivery. Only 6.3% of the women given carbetocin needed additional treatment.\(^1\)

The adverse effects of carbetocin resemble those of oxytocin. They include abdominal pain, nausea, flushing and headache. Nearly half the patients may complain of itching.

While a single dose of carbetocin may be preferable to an infusion of oxytocin, after Caesarian section, it may not reduce blood loss more than oxytocin. In the main trial, the fall in postoperative haemoglobin was similar in both groups. Two women in each group had a postpartum haemorrhage.\(^1\)

Carbetocin has not been studied after vaginal delivery or in women with a high risk of postpartum haemorrhage after Caesarian section. More research, including patient safety and economic evaluations, will therefore be needed before it can replace oxytocin as the first drug to use in the active management of the third stage of labour.

References:


Indian situation: Carbetocin bulk and Carbetocin injection 100 mcg/ml approved by CDSCO with indication Prevention of postpartum haemorrhage due to uterine atony on 21.09.2020 and it is available in Indian market.

Minister of State for Health Bharati Pravin Pawar informed the Lok Sabha that 167 deaths have been reported as Adverse Events Following Immunization (AEFI) after the second dose of the COVID-19 vaccine in the country.

The highest number of 43 fatalities has been reported as AEFI from Kerala, followed by 15 from Maharashtra, 14 from West Bengal and 12 each from Madhya Pradesh and Odisha, according to data provided by the minister in response to a written question.

Further, Mr. Pawar said 1,53,26,714 precaution doses have been administered to eligible beneficiaries, of which 37,00,573 doses went to healthcare workers, 48,84,424 doses to frontline workers and 67,41,717 doses to people aged 60 years and above having comorbidities.

Adequate COVID-19 vaccine doses have been made available to states and union territories to vaccinate all eligible beneficiaries with the first, second and the precaution dose as on February 8, 2022, Mr. Pawar said in the reply.

The administration of precaution doses to healthcare workers, frontline workers and persons aged 60 years and above has started under the National COVID-19 Vaccination Programme from January 10.

**COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) 1: Risk of capillary leak syndrome (CLS)**

The Pharmacovigilance Risk Assessment Committee (PRAC) has concluded that people who have previously had capillary leak syndrome (CLS) must not be vaccinated with COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) (Vaxzevria®) and that CLS should be added to the product information as a new adverse drug reaction. CLS is a very rare, serious condition that causes fluid leakage from small blood vessels, resulting in swelling in the arms and legs, low blood pressure and low albumin level. COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) is a vaccine for preventing COVID19 in people aged 18 years and older. The PRAC carried out an in depth review of six cases of CLS in people who had received the vaccine. Health-care professionals should be aware of the signs and symptoms of CLS and of its risk of recurrence in people who have previously been diagnosed with the...
condition. People who have been vaccinated with the vaccine should seek immediate medical assistance if they experience rapid swelling of the arms and legs or sudden weight gain in the days following vaccination.


2. Risk of Guillain-Barre syndrome (GBS)
The PRAC has recommended a change to the product information for COVID19 vaccine NRVV Ad (ChAdOx1 nCoV-19) (Vaxzevria®) to include a warning on Guillain-Barre syndrome (GBS). The PRAC has assessed all the available evidence including cases reported and data from the scientific literature, but at this stage the data neither confirms nor rules out a possible association with the vaccine. Health-care professionals should be alert to signs and symptom of GBS to allow early diagnosis and supportive care and treatment. People taking the vaccine are advised to seek immediate medical attention if they develop weakness and paralysis that can progress to the chest and face.


COVID-19 vaccine NRVV Ad26 (JNJ 78436735)
Risk of capillary leak syndrome (CLS)
The PRAC has recommended that people who have previously had CLS must not be vaccinated with COVID19 vaccine NRVV Ad26 (JNJ 78436735) (COVID-19 vaccine Janssen®) and that CLS should be added to the product information as a new adverse drug reaction. COVID-19 vaccine NRVV Ad26 (JNJ 78436735) is indicated for preventing COVID-19 in people aged 18 years and older. The PRAC reviewed three cases of CLS in people who have had the vaccine. Health-care professionals should be aware of the signs and symptoms of CLS and of its risk of recurrence in people who have previously been diagnosed with the condition. Also, health-care professionals should tell people receiving the vaccine that they must seek medical attention if they experience rapid swelling of the arms and legs or sudden weight gain in the days following vaccination.

Reference: EMA, 9 July 2021

Reader’s Column
Dear Dr. Mandal,

Very good editorial and also the asterisks on the Monthly Drug Safety Alerts that point out that Ems rarely mentioned in this list.

Prof. Krisantha Weerasurya
Sri Lanka

Dear Dr. Mandal,

Thanks for sharing. Thanks to Govt. to control drug price by controlling freebies.
But I don’t think it will be enforced.
Please recall in 2004 in IPC at Kolkata Union Health Minister Dr. Radoss spoke to control. But till today nobody can control.

We have to suffer.
Dr. R. N. Gupta

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