Notification for Prohibition of 14 FDCs vide various Notifications- reg.

Dear Members,

We request our members to kindly peruse through the attached Notifications wherein the below mentioned 14 FDCs are prohibited :

1. Nimesulide + Paracetamol dispersible tablet
2. Amoxicillin + Bromhexine
3. Pholcodine + Promethazine
4. Chlorpheniramine maleate + Dextromethorphan + Guaiphenesin + Ammonium chloride + Menthol
5. Ammonium chloride + Bromhexine + Dextromethorphan
6. Chlorpheniramine Maleate + Codeine syrup
7. Bromhexine + Dextromethorphan + Ammonium Chloride + Menthol
8. Dextromethorphan + Chlorpheniramine Maleate + Guaiphenesin + Ammonium Chloride
9. Paracetamol + Bromhexine + Phenylephrine + Chlorpheniramine + Guaiphenesin
10. Salbutamol + Bromhexine
11. Chlorpheniramine + Codeine Phosphate + Menthol Syrup
12. Phenytoin+ Phenobarbitone sodium
13. Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol (100mg + 40mg + 2.5mg + 0.9mg), (125mg + 55mg + 4mg + 1mg), (110mg + 46mg + 3mg + 0.9mg) & (130mg + 55mg + 3mg + 0.5mg) per 5ml syrup
14. Salbutamol + Hydroxyethyltheophylline (Etofylline) + Bromhexine

Also, members are requested to note that All strengths of the aforesaid FDC's are prohibited for sale with immediate effect and only the mentioned strength of Sr. No. 13 is prohibited with immediate effect.

This is for your kind information & necessary action.

Thanks & regards,

Daara B Patel
Secretary - General

Notification

New Delhi, the 2nd June 2023

S.O. 2394(E). - Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Nimesulide+ Paracetamol dispersible tablets** vide notification number S.O.712 (E), published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia,* mentioning that in respect of 15 FDCs claimed to be approved prior to 1988, Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for this FDC and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended";

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 712 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Nimesulide + Paracetamol dispersible tablets** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2395(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Amoxicillin+ Bromhexine** vide notification number S.O. 777 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia*, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under Section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended".

And whereas on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 777 (E) dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Amoxicillin+ Bromhexine** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2396(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Pholcodine+ Promethazine** vide notification number S.O. 789 (E), published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter ali,* mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended";

And whereas on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O.789 (E) dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Pholcodine + Promethazine** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2397(E).—Whereas, the Central Government in exercise of the powers conferred by Section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Chlorpheniramine maleate + Dextromethorphan + Guaiphenesin + Ammonium Chloride + Menthol** vide notification number S.O. 869 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia,* mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee

constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended";

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 869 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Chlorpheniramine maleate + Dextromethorphan + Guaiphenesin + Ammonium Chloride + Menthol** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2398(E).— Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Chlopheniramine Maleate + Codeine Syrup** vide notification number S.O. 909 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia*, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee.

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended".

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare

(Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 909 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Chlopheniramine Maleate + Codeine Syrup** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2399(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Ammomium Chloride + Bromhexine + Dextromethorphan** vide notification number S.O 922 (E), published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia*, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee.

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under Section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended";

And whereas on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 922(E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Ammomium Chloride + Bromhexine + Dextromethorphan** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2400(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Bromhexine + Dextromethorphan + Ammonium Chloride + Menthol** vide notification number S.O. 926(E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia*, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended";

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate byway of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 926 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Bromhexine + Dextromethorphan + Ammonium Chloride + Menthol** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2401(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Dextromethorphan + Chlorpheniramine + Guaiphenesin + Ammonium Chloride** vide notification number S.O. 930 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia*, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of

1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee.

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended";

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 930 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Dextromethorphan + Chlorpheniramine + Guaiphenesin + Ammonium Chloride** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2402(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Paracetamol + Bromhexine + Phenylephrine + Chlorpheniramine + Guaiphenesin** vide notification number S.O. 977(E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia,* mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended";

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O 977 (E) dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Paracetamol + Bromhexine+ Phenylephrine + Chlorpheniramine + Guaiphenesin** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2403(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Salbutamol + Bromhexine** vide notification number S.O. 978 (E), published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia,* mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended";

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 978 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Salbutamol + Bromhexine** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2404(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Chlorpheniramine + Codeine Phosphate + Menthol Syrup** vide notification number S.O 983 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia*, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended";

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 983 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Chlorpheniramine + Codeine Phosphate + Menthol Syrup** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2405(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Phenytoin + Phenobarbitone sodium** vide notification number S.O. 1028 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia*, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the

Central Government and Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended".

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country. Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 1028 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Phenytoin + Phenobarbitone sodium** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2406(E).—Whereas, the Central Government in exercise of the powers conferred by Section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol (100mg + 40mg + 2.5mg + 0.9mg) , (125mg + 55mg + 4mg + 1mg) , (110mg + 46mg + 3mg + 0.9mg) & (130mg + 55mg + 3mg + 0.5mg) per 5ml syrup** vide notification number S.O. 4411(E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii),dated the 07th September 2018;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its order dated 14.02.2019 in the Miscellaneous application No. 600 of 2018 in Civil Appeal No.s 23405-23472 of 2017, the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for this FDC in the above mentioned strengths and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC in the above mentioned strengths under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended";

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 4411(E) dated the 07th September 2018; on the basis of the

recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol (100mg + 40mg + 2.5mg + 0.9mg) , (125mg + 55mg + 4mg + 1mg) , (110mg + 46mg + 3mg + 0.9mg) & (130mg + 55mg + 3mg + 0.5mg) per 5ml syrup** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2407(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Salbutamol + Hydroxyethyltheophylline (Etofylline) + Bromhexine** vide notification number S.O. 4687(E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 07th September 2018;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its order dated 14.02.2019 in the Miscellaneous application No.600 of 2018 in Civil Appeal No.s 23405-23472 of 2017, the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended";

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide S.O. number 4687(E), dated the 07th September 2018; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Salbutamol + Hydroxyethyltheophylline (Etofylline) + Bromhexine** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

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