

# Pharma & Healthcare Update

March 29, 2019

## KEY DEVELOPMENTS OF 2018 THAT WILL SHAPE 2019 AND BEYOND

### INTRODUCTION

The pharmaceuticals and life sciences industry experienced an eventful 2018 because of numerous significant legal, regulatory and policy measures announced by the government in course of the year. Some of these developments, in particular, are expected become industry milestones. In this piece, we have revisited these developments with the benefit of hind-sight and discussed their potential impact.

We hope you enjoy reading it!

### REVISED DRAFT OF GOOD MANUFACTURING PRACTICES PUBLISHED

In October of 2018, the Ministry of Health and Family Welfare had published draft rules to amend the Good Manufacturing Practices (“GMP”) listed in Schedule M of the Drugs & Cosmetics Rules 1945 (“D&C Rules”). The GMP are a set of rules under the Drugs and Cosmetics Act, 1940, which lay down mandatory best practices to be followed for manufacturing a drug that is to be sold in India.<sup>1</sup> The draft rules emphasize testing of the drug at all stages of manufacturing and not just the finished product. Moreover, the draft rules put in place a mechanism for drug recall in case a product is known or suspected to be defective.

Broadly speaking, the draft rules aim to bring India’s extant GMP on par with the World Health Organization-Good Manufacturing Practices (“WHO-GMP”). Majority of Indian drug manufacturers comply with the extant GMP, however, only 20% of manufacturers are WHO-GMP compliant, leading to dual standards of quality.<sup>2</sup>

The proposal to revise the GMP is in line with the Indian Government’s goal of joining the Pharmaceutical Inspection Cooperation Scheme (“PICS”), a global mechanism to improve cooperation in GMPs between regulators.<sup>3</sup> The draft rules are expected to give impetus to drug exports from India as most countries, including the United States of America, accept imports from manufacturing facilities that are WHO-GMP compliant.<sup>4</sup>

The draft rules were published for public consultation. The government may now release an updated version of the draft rules in light of the feedback received after public consultation, or may fix a date from which the draft rules will come into effect. That update is awaited from the government.

### DRAFT GUIDELINES FOR GOOD DISTRIBUTION PRACTICES OF PHARMACEUTICAL PRODUCTS RELEASED

In September of 2018, the Central Drugs Standard Control Organization (“CDSCO”) released the draft Guidelines on Good Distribution Practices for Pharmaceutical Products (“GDP Guidelines”) to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process.<sup>5</sup> The GDP Guidelines cover principles and measures for ensuring quality and identity through the supply chain and other aspects of the distribution process, including procurement, purchasing, storage distribution, transportation, documentation and record keeping practices in the chain from the manufacturing plant to the medical stores.

At present, India does not have standard GDP Guidelines. Therefore, the publication of the draft GDP Guidelines is very timely.

The proposal for coming up with the GDP Guidelines was initially deliberated in a meeting of the Drug Consultative Committee (a statutory body constituted to advice the Government on technical matters), where it was recommended that necessary provisions be made to incorporate the GDP Guidelines as a Schedule to the Drug & Cosmetics Rules, 1945, (a set of rules under the Drugs and Cosmetics Act, 1940, which regulates the manufacture, import and sale of drugs in India) thereby giving it the force of law and ability to penalize non-compliances.<sup>6</sup> If that is the case, then the GDP Guidelines will have to be notified separately for them to take effect of law.

### DRAFT RULES TO REGULATE E-PHARMACIES PUBLISHED

The Ministry of Health and Family Welfare (“Health Ministry”) has proposed an amendment to the Drugs and Cosmetics Rules, 1945 (“D&C Rules”) (a set of rules under the Drugs and Cosmetics Act, 1940, which regulates the manufacture, import and sale of drugs in India) to regulate e-pharmacies in the country.<sup>7</sup> The D&C Rules currently do not have specific provisions to regulate the operation of e-pharmacies, as the licensing system is focused on regulation of brick-and-mortar setups. The proposed amendment will introduce a licensing system for e-pharmacies and permit them to function on par with traditional pharmacies by granting them legal recognition. It also imposes conditions on e-pharmacies, such as requiring them to maintain a confidential record of prescriptions as well as details of the drugs. E-pharmacies are also required to establish a 24/7 customer support and grievance redressal mechanism, in order to address consumer complaints. Consumers are empowered to submit complaints with the regulator for violation of the license requirements (including with respect to the quality of drugs dispensed). The regulator can cancel the license of the e-pharmacy if a violation is found, in addition to other penalties prescribed.

After the release of the draft rules, both the Madras and Delhi High Court had passed orders banning online sale of

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medicines. However, the Madras High Court has since then lifted the ban and directed the Government to notify the draft rules by January 31, 2019.<sup>8</sup>

e-Pharmacies have been at the center of controversy in India since 2015, with regulators being asked to keep a strict watch on all players in the market until the expert committee, headed by ex-Maharashtra Food and Drug Commissioner Harshdeep Kamble examined the issues in the sector. The committee had later submitted its recommendations<sup>9</sup> to the Drugs Controller General of India, who had reportedly examined the report and forwarded his recommendations to the Health Ministry.

It is not clear whether the draft rules will be revised and date from which the rules will take effect.

#### INDIAN GOVERNMENT PUBLISHES DRAFT LAW TO SEPARATELY REGULATE COSMETICS

The Ministry of Health and Family Welfare has proposed to introduce a new set of rules to create a separate regulatory framework for cosmetics in India (“**Draft Cosmetic Rules**”).<sup>10</sup> The Draft Cosmetic Rules will de-link the regulation of cosmetics from the current set of rules that regulate both drugs and cosmetics. The Draft Cosmetic Rules aim to increase scrutiny on the Indian cosmetic industry as well as the safety and efficacy of cosmetics available to Indian consumers. The Draft Cosmetic Rules introduces a regulatory regime for ‘new cosmetics’ – a cosmetic containing ingredients which have not generally been regarded as safe by the Indian or foreign regulator, or in standard texts relating to safety of such ingredients. Manufacturers and importers of new cosmetics would be required to submit data on safety and effectiveness of the cosmetic, prior to being issued a license.

Under the Draft Cosmetic Rules, manufacturers would also be required to comply with labeling requirements as prescribed by the Bureau of Indian Standards, in addition to the requirements under the rules. The proposed amendment also contains provisions allowing applicants to apply online for procuring and renewing their import and manufacturing licenses. The government is yet to confirm whether the Draft Cosmetic Rules are final or not.

#### PATENTED NEW DRUGS AND ORPHAN DRUGS OUT OF PRICE CONTROL IN INDIA

The Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) through an government order has exempted manufacturers, importers and marketers (“**Manufacturers**”) of new drugs patented in India for a period of five years beginning from the commencement of commercial marketing of such drug in India (“**New Drug Exemption**”).<sup>11</sup> Earlier, only new drugs patented in India and (i) developed through indigenous (local) research and development and (ii) not produced elsewhere were granted exemption from price control. The Order has removed all localization requirements for claiming price control exemption. Therefore, drugs developed abroad or drugs developed by indigenously but produced abroad are now exempt from price control.

The Order also exempts drugs used for treating orphan (rare) diseases if the Ministry of Health and Family Welfare (“**Health Ministry**”) decides to do so (“**Orphan Drug Exemption**”). However, it is unclear what criteria the Health Ministry will apply when deciding whether a disease can be categorized as an orphan disease. We understand that due to the absence of prevalence data this might be a tough task for the Health Ministry.<sup>12</sup>

The Order is expected to encourage foreign pharmaceutical companies to market their drugs in India by granting them price control exemption. The Order is also expected to give impetus to Indian pharmaceutical companies to conduct research into drugs used for treatment of orphan diseases. To learn more about the Order read our hotline on the subject [here](#).

#### INDIAN GOVERNMENT PROPOSES TO AMEND REGULATORY FRAMEWORK FOR BLOOD BANKS

The Ministry of Health and Family Welfare has proposed an amendment to the Drugs and Cosmetics Rules 1945 (“**D&C Rules**”) - a set of rules under the Drugs and Cosmetics Act, 1940, which regulates the manufacture, import and sale of drugs in India - to tighten existing regulations under it for blood banks and streamline the blood donation process.<sup>13</sup> The draft rules rename blood banks to blood centres, revise the licensing procedure for blood centres, stipulate new qualification requirements for technicians working at blood centres and specify norms regarding who can and cannot donate blood. Under the draft rules, licenses for operating blood centres can be granted and renewed only if such blood centres are approved by the Blood Transfusion Council of the State or Union Territory as per the procedure laid down by the National Blood Transfusion Council. The draft rules also specify eligibility criteria for potential donors. The criteria include age limits, minimum weight requirements and medical history. With the addition of these criteria, the draft rules bring uniformity to the blood donation procedure across India.

The government is yet to confirm whether the draft rules will be revised or not, and has not yet communicated a date from which the rules will take effect.

#### TECHNICAL COMMITTEE ACCEPTS PROPOSAL TO HOLD DRUG MARKETING COMPANIES RESPONSIBLE FOR DRUG QUALITY ALONG WITH THE MANUFACTURER

The Drugs Technical Advisory Board (“**DTAB**”) - the highest statutory decision-making body on technical matters related to drugs in India accepted the proposal in May 2018 to amend the Drugs and Cosmetics Act, 1940 (“**D&C Act**”) to hold drug marketing companies (companies that do not have manufacturing capabilities but avail of the manufacturing facilities of a third party) liable for manufacturing deficiencies, in addition to the manufacturer of the drug.<sup>14</sup> For the purpose of the D&C Act, the DTAB has stated that the marketing company should be treated as an agent of the manufacturer, and that defenses prescribed under the D&C Act should not be applicable to the marketer for the deficiencies.

It is a common practice for companies to outsource the manufacturing of drugs to third parties and only market the drug as a means of limiting liability. Currently, the liability for the sale of unapproved, spurious or poor quality drugs falls mainly on the manufacturer of the drug.

#### THE FIXED DOSE COMBINATION DRUG BAN SAGA

The government’s controversial decision to ban 349 Fixed Dose Combination (“**FDC**”) drugs in 2016 after protracted litigation culminated into a notification issued by the Ministry of Health and Family Welfare (“**Health Ministry**”) in September 2018 prohibiting the sale of 328 FDCs in India.

As a background, the Health Ministry, in 2016 prohibited the sale of 349 FDCs for being unsafe and irrational (“**Original Decision**”).<sup>15</sup> The Original Decision was challenged in the Delhi High Court which quashed the Original Decision by restrictively interpreting the scope of government’s power to ban sale of a drug in India.<sup>16</sup> On appeal, the Supreme Court did not agree with the High Court, but refrained from re-introducing the ban. Instead, the Supreme Court in its verdict referred the matter to the Drugs Technical Advisory Board (“**DTAB**”), which is the statutory body that advises the government on technical

matters pertaining to drugs, to review the safety, efficacy and therapeutic justification of said 349 FDC drugs.<sup>17</sup>

Pursuant to the Supreme Court verdict in December 2017, the DTAB constituted a sub-committee of experts who heard the petitioners/appellants who appeared before the High Court and Supreme Court.<sup>18</sup> The sub-committee deliberated on whether the said FDC drugs (a) were likely to involve any risk to human beings or animals; (b) did not have the therapeutic value claimed for them or to be claimed for them; or (c) contained ingredients in such quantity for which there is no therapeutic justification. The sub-committee also looked at the larger public interest for regulating, restricting, and manufacturing such FDC drugs. The sub-committee submitted the report in July 2018 to the Health Ministry recommended a ban on 343 FDCs and restricting 6 FDCs for specific indications or quantities.<sup>19</sup> On the basis of the sub-committee report the Health Ministry prohibited the sale of 328 FDCs for being unsafe and irrational, and the safety and efficacy of which were unable to be proved.<sup>20</sup>

However, the Supreme Court, based on pleas made before it by certain pharmaceutical companies and associations, has allowed the sale of 3 of the 328 FDCs, as they were licensed for sale prior to 1988 – the year that statutory requirements to prove the safety and efficacy of FDCs were first introduced.

#### **DELHI HIGH COURT ORDERS THAT MEDICINES DEVELOPED THROUGH INCREMENTAL INNOVATION OR NOVEL DRUG DELIVERY SYSTEMS MUST BE TREATED DIFFERENTLY FOR THE PURPOSE OF PRICING**

The Delhi High Court has enforced a provision of law that keeps medicines developed through incremental innovation or that use novel drug delivery systems out of the purview of price fixation.<sup>21</sup>

As a background, the National Pharmaceutical Pricing Authority (“NPPA”), the regulator responsible for fixing prices of medicine, had fixed the price of Tramadol and applied it to Tramadol manufactured by Modi-Mundi Pharma (“Company”) as well. However, the Company claimed that the Tramadol manufactured by it used an innovative drug delivery system called Continuous Controlled Release Dual Mechanism Drug Delivery System, unlike Tramadol manufactured by third parties which used conventional drug delivery systems. Therefore, the Company argued that its medicine should not have been clubbed with other medicines for the purpose of price control. The Company first sought a review of the NPPA's order on the ground that the law itself provides that medicines which have novel drug delivery systems should be priced differently. The review application was rejected. An appeal against the order was also met with the same fate. However, in a petition, the Delhi High Court agreed with the position adopted by the Company.

This is an important decision for all importers and manufacturers of medicines whose products have been developed by incremental innovation or which use novel drug delivery systems. Where the NPPA has already fixed prices of such products, they may approach a Court and have the order fixing prices of their product quashed. For those who are planning to manufacture such products or import such products for the first time, this judgement provides reassurance that the prices of their products will not be fixed by the government.

#### **THE NATIONAL MEDICAL COMMISSION BILL, 2017 CONTROVERSY**

The National Medical Commission Bill, 2017 (“NMC”) – a legislation proposed to replace the extant Medical Council of India (the apex body regulating the practice of medicine in India) and reform the medical education sector was introduced in the lower house of the Indian Parliament amid much controversy. Following widespread protests from the medical fraternity opposing the bill, the NMC was referred by the lower house to the Parliamentary Standing Committee, in January 2018, with directions to issue recommendations before the close of the budget session of the Parliament.<sup>22</sup> In March 2018, The Standing Committee submitted its report on the NMC.

The NMC focuses on effective and efficient regulation of medical education in India. It introduced certain reforms to medical education, such as the National Licentiate Examination which is required to be cleared by medical graduates in order to obtain a license to practice, as well as regulating fees of 40 per cent of the seats in private medical colleges to ensure access of medical seats to meritorious students. The NMC was drafted by a four-member committee of the Niti Aayog – a policy think tank of the Indian government – after multiple allegations of corruption in the current body regulating the practice of medicine – the Medical Council of India.<sup>23</sup> Earlier, the Supreme Court of India had directed that a panel be set up in order to oversee the functioning of the Medical Council of India.

The panel headed by Professor Ram Gopal Yadav tabled its report in Parliament on March 20, 2018 after deliberating with various academicians, medical education experts and professionals representing modern and indigenous systems of medicine.<sup>24</sup> Various changes have been proposed, significant ones being (a) total strength of the National Medical Commission to be increased from 25 to 29 members, comprising of 6 ex-officio members, 9 members to be elected amongst registered medical practitioners, the States and Union Territories to have 10 members, 3 part-time members appointed from among persons having special knowledge and professional experience; (b) the bridge course approval which attracted various protests last year, was also objected to by the panel with regards to making it mandatory. The panel wants the state governments to take measures that would increase the number of healthcare professionals practicing in rural areas; (c) the original proposal for regulation of fee of 40 per cent seats in private medical colleges is recommended to be increased to 50 per cent, with colleges being allowed to decide fee for the remaining seats.

#### **DRAFT OF LAW TO REGULATE PERSONAL HEALTH DATA IN ELECTRONIC FORM PUBLISHED**

The Ministry of Health and Family Welfare published a draft of the proposed legislation called the Digital Information Security in Healthcare Act (“DISHA”) for comments by public.<sup>25</sup> DISHA is expected to improve the existing data protection regime for personal health data in electronic form (“Digital Health Data”) by introducing new provisions for privacy, confidentiality, security and standardization of Digital Health Data, and provides for the establishment of a National Digital Health Authority, a standard setting body, as well as Health Information Exchanges, which will act as a public repository of Digital Health Data.

At present, Digital Health Data is protected as “sensitive data” under the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011. Any person who collects, handles, stores, discloses or transfers Digital Health Data is bound to follow the procedure laid down in law which, in essence, requires the person to obtain written permission from the owner of the Digital Health Data with respect to use of his/her information and use such information for legitimate business purposes for only as long as may be necessary to achieve the purpose.

DISHA introduces additional layers of protection for Digital Health Data. For example, it grants (i) the right to know the entities who may have access to the Digital Health Data and the recipients to whom the data is transmitted or disclosed; (ii) the right to require the individual's explicit prior permission for each instance of transmission or use of the Digital Health Data; and (iii) the right to seek compensation for any damages caused by violation of the right. It also limits ability of businesses to

DISHA also regulates how businesses can use Digital Health Data. This has not found favor with some businesses who believe that the proposed law is excessive and imposes unreasonable restrictions on their ability to conduct their own businesses.

## WORLD'S LARGEST STATE-FUNDED INSURANCE SCHEME LAUNCHED IN INDIA

Ayushman Bharat-Pradhan Mantri Jan Aarogya Yojna (AB-PMJAY) a comprehensive healthcare scheme to provide health insurance to over 500 million citizens was launched on September 23 2018.<sup>26</sup> The AB-PMJAY was structured to implement the recommendations of the National Health Policy released in 2017 and aims to provide cashless and paperless access to medical services for the beneficiary right at the point of service. The scheme aims to assist in reduction of hospitalization expenditures for citizens, specifically those who are below the poverty line. The scheme issues an insurance cover of up to INR 500,000 per family each year, for secondary and tertiary care hospitalization. AB-PMJAY also intends to set up 150,000 health and wellness centres as part of the scheme, in order to increase healthcare access for the population.

Over 9,000 hospitals have already been empaneled as part of the scheme. Most states and Union territories have signed Memoranda of Understanding with the Central Government to implement the programme. Certain states and union territories have however not adopted AB-PMJAY, as the government of each state/union territory has the discretion to adopt a healthcare related subject initiated by the Central Government.

## CONCLUSION

Looking back, there is no doubt that 2018 was an exciting year for the pharmaceutical and life sciences industry. New clinical trial rules, which were announced last year, have now been notified with immediate effect. Our detailed analysis on the impact of the new clinical trial rules will be published soon. The other developments discussed above, such as draft GMP standards, draft GDP Guidelines and new Draft Cosmetics Rules, have the potential to alter the way business is done in the industry and could also be enforced soon. Landmark policy decisions such as pan-India roll-out of the Ayushman Bharat scheme also have the potential to give a fillip to the industry.

It is important to realize that these legal, regulatory and policy measures when implemented will bring unique legal and regulatory challenges. Therefore, it is important to be aware of these developments and be prepared for the challenges in advance.

On that note, 2019 promises to be nothing short of thrilling!

— Anay Shukla, Darren Punnen & Dr.Milind Antani

You can direct your queries or comments to the authors

<sup>1</sup> Draft Rules to amend Good Manufacturing Practices under the Drugs and Cosmetics Rules 1945 available at: <http://egazette.nic.in/WriteReadData/2018/190663.pdf> (last checked January 28, 2019).

<sup>2</sup> News Article on revised Good Manufacturing Practices available at: [https://www.business-standard.com/article/economy-policy/soon-uniform-inspection-norms-for-pharma-units-govt-to-form-advisory-body-118091901066\\_1.html](https://www.business-standard.com/article/economy-policy/soon-uniform-inspection-norms-for-pharma-units-govt-to-form-advisory-body-118091901066_1.html) (last checked January 28, 2019).

<sup>3</sup> News article on revised Good Manufacturing Practices available at: <http://pharmabiz.com/ArticleDetails.aspx?aid=111683&sid=1> (last checked January 28, 2019).

<sup>4</sup> News Article on India joining the Pharmaceutical Inspection Cooperation Scheme available at: <https://www.financialexpress.com/opinion/larger-picture-joining-pics-a-big-boost-for-drug-quality/1325399/> (last checked January 28, 2019).

<sup>5</sup> Draft Guidelines on Good Distribution Practices for pharmaceutical products available at: [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTk3MA](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTk3MA) (last checked January 28, 2019).

<sup>6</sup> Minutes of Meeting 54<sup>th</sup> Meeting of the Drugs Consultative Committee available at: [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common\\_download.jsp?num\\_id\\_pk=NjY1](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=NjY1) (last checked January 28, 2019).

<sup>7</sup> Draft Rules on e-pharmacies available at: [http://www.cdsco.nic.in/writereaddata/2018\\_08\\_28\\_Draft%20GSR%20817\(E\)\\_Sale%20of%20Drugs%20by%20E-Pharmacy.pdf](http://www.cdsco.nic.in/writereaddata/2018_08_28_Draft%20GSR%20817(E)_Sale%20of%20Drugs%20by%20E-Pharmacy.pdf) (last checked January 28, 2019).

<sup>8</sup> News Article on the Madras High Court banning the online sale of drugs available at: <https://www.ndtv.com/tamil-nadu-news/madras-high-court-lifts-ban-on-online-sale-of-medicines-1971672> (last checked January 28, 2019).

<sup>9</sup> Report of Sub-Committee constituted by the Drugs Consultative Committee to examine the issue of regulating the sale of drugs over the internet under the Drugs And Cosmetics Rules, 1945 available at: <http://www.cdsco.nic.in/writereaddata/Sub-Committee%20Report%20on%20e-pharmacy.pdf> (last checked January 28, 2019).

<sup>10</sup> Draft Cosmetic Rules available at: <http://egazette.nic.in/WriteReadData/2018/193442.pdf> (last checked January 28, 2019).

<sup>11</sup> Order by Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) available at: [http://pharmaceuticals.gov.in/sites/default/files/Gazette%20Notification\\_DPCO.pdf](http://pharmaceuticals.gov.in/sites/default/files/Gazette%20Notification_DPCO.pdf) (last checked January 28, 2019).

<sup>12</sup> National Policy for Treatment of Rare Diseases available at: <https://HealthMinistry.gov.in/sites/default/files/Rare%20Diseases%20Policy%20FINAL.pdf> (last checked January 28, 2019).

<sup>13</sup> Draft Rules to amend regulatory framework for blood banks available at: <http://egazette.nic.in/WriteReadData/2018/193445.pdf> (last checked January 28, 2019).

<sup>14</sup> Minutes of the 79<sup>th</sup> Meeting of the Drugs Technical Advisory Board available at: [http://www.cdsco.nic.in/writereaddata/Final%20Minutes%20for%2079th%20DTAB%20meeting%20held%20on%2016\\_05\\_2018\(1\).pdf](http://www.cdsco.nic.in/writereaddata/Final%20Minutes%20for%2079th%20DTAB%20meeting%20held%20on%2016_05_2018(1).pdf) (last checked January 28, 2019).

<sup>15</sup> Complete list of 344 drugs banned by the Ministry of Health Family Welfare available at: [https://www.nhp.gov.in/Complete-list-of-344-drugs-banned-by-the-Ministry-of-Health-Family-welfare\\_pg](https://www.nhp.gov.in/Complete-list-of-344-drugs-banned-by-the-Ministry-of-Health-Family-welfare_pg) (last checked January 28, 2019); Notification by Ministry of Health and Family Welfare banning FDCs available at: <http://egazette.nic.in/WriteReadData/2016/168502.pdf> (last checked January 28, 2019).

<sup>16</sup> Order of the Delhi High Court in Pfizer Limited & Anr. v. Union of India & Anr. available at: <http://lobis.nic.in/ddir/dhc/RSE/judgement/01-12-2016/RSE01122016CW22122016.pdf> (last checked January 28, 2019).

<sup>17</sup> Order of the Supreme Court in Union of India & Anr. V. Pfizer Limited & Ors. available at: [https://www.sci.gov.in/supremecourt/2017/3271/3271\\_2017\\_Judgement\\_15-Dec-2017.pdf](https://www.sci.gov.in/supremecourt/2017/3271/3271_2017_Judgement_15-Dec-2017.pdf) (last checked January 28, 2019).

<sup>18</sup> Agenda No.2, Minutes of the 78<sup>th</sup> Meeting of Drugs Technical Advisory Board available at: [http://cdsco.nic.in/writereaddata/Minutes%20of%2078th%20DTAB%20Meeting%20held%20on%2012\\_02\\_2018.pdf](http://cdsco.nic.in/writereaddata/Minutes%20of%2078th%20DTAB%20Meeting%20held%20on%2012_02_2018.pdf) (last checked January 28, 2019).

<sup>19</sup> Report of the Sub-Committee constituted by the Drugs Technical Advisory Board available at: [https://cdsco.gov.in/opencms/export/sites/CDSCO\\_WEB/Pdf-documents/Committee/dtab\\_sub\\_report.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/Committee/dtab_sub_report.pdf) (last checked January 28, 2019).

<sup>20</sup> Notifications by the Ministry of Health and Family Welfare banning 328 Fixed Dose Combination drugs available at: [http://www.cdsco.nic.in/writereaddata/2018\\_09\\_07\\_S\\_O\\_%204379\(E\)%20to.pdf](http://www.cdsco.nic.in/writereaddata/2018_09_07_S_O_%204379(E)%20to.pdf) (last checked January 28, 2019).

<sup>21</sup> Order of the Delhi High Court in Modi-Mundipharma Pvt. Ltd. v. Union of India & Ors. available at: <http://lobis.nic.in/ddir/dhc/VIB/judgement/19-07-2018/VIB17072018CW118022016.pdf> (last checked January 28, 2019).

<sup>22</sup> News article on National Medical Commission Bill sent to Standing Committee available at: <https://www.thehindu.com/news/national/nmc-bill-sent-to-standing-committee/article22351803.ece> (last checked January 28, 2019).

<sup>23</sup> Parliamentary Standing Committee Report on the Functioning of Medical Council of India available at: <http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Health%20and%20Family%20Welfare/92.pdf> (last checked January 28, 2019).

<sup>24</sup> Parliamentary Standing Committee Report on the National Medical Commission Bill 2017 available at: <http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Health%20and%20Family%20Welfare/109.pdf> (last checked January 28, 2019).

<sup>25</sup> Draft of Digital Information Security in Healthcare Act 2018 available at: <https://Health.Ministry.gov.in/newshighlights/comments-draft-digital-information-security-health-care-actdisha> (last checked January 28, 2019).

<sup>26</sup> Press Information Bureau press release *PM launches Ayushman Bharat - PMJAY at Ranchi* available at: <http://pib.nic.in/newsite/PrintRelease.aspx?relid=183635> (last checked January 28, 2019).

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