PROJECT REPORT
(March 2019)

CONSOLIDATING CAPACITIES AND CONVERSATIONS ON ACCESS TO MEDICINES

Supported by-TIDES Foundation

SAMA RESOURCE GROUP FOR WOMEN AND HEALTH

www.samawomenshealth.in

This project was built on Sama's past initiatives and engagements in the field of access to medicines and ethical aspects in clinical trials to pose the questions on accessibility and affordability of medicines to people in India through two studies. The study on patentability and its implication on access and affordability was undertaken. The second study drawing on from the important findings of its report 'Circle of Medicines' that showed the profiteering and market based drive within the global clinical trial sector with regard to the determination of focus on non-communicable diseases (NCDs) related trials, further analysis was undertaken through an-in depth study of NCDs related clinical trials in India.

Discussion points and policy level recommendations emerging from these series of studies were then instrumental in holding conversations with civil society members, groups, health activists, policy makers and authorities. Sama actively participated in policy level discourses in this duration, including providing comments and inputs towards clinical trials draft rules released by the government of India. Strategic outreach with media was also established at determined opportunities towards public dissemination of some of the key points and issues related to clinical trials and access to medicines. The policy brief on patents & access to medicines were widely used in capacity building of different stakeholders and translated into a regional language for wider outreach.

Sama being an active member of global and national health networks and groups- Medico Friend Circle, Peoples Health Movement (PHM), World Bioethics and National Bioethics Conferences and Jan Swasthya Abhiyan (JSA) did wider dissemination of key discussion points on patents, access to medicines, clinical trials etc. These disseminations were able to reach out to both national and international audience. Further, Sama also continued its sustained endeavor towards capacity building of young scholars, students, health professionals, ethics committee members as part of this initiative. Short courses were organized by Sama covering the topics of access to medicines, right to healthcare, newer frontiers within clinical research and emerging issues, larger ethical considerations and contestations within clinical research and trials.

I. RESEARCH RELATED TO ACCESS TO MEDICINES AND CLINICAL TRIALS IN INDIA

Two research studies were conducted during this period. The first study focussed on Study on '**Patently Unaffordable: Medicines, Patents and Access**-looking into the patent status of the medicines that were approved in India after going through the clinical trials in the country. The previous study 'Circle of medicines: Development to Access - Study on accessibility and affordability of medicines that underwent clinical trials in India' had found a list of drugs that were approved for marketing in India, after having gone through the clinical trials in India. The present study explored the patent, and patentability scenario of some of those drugs to ascertain

the role of patents and its linkages with the affordability of the drugs in the context of Indian population.

The second study built an in-depth inquiry into the clinical trial scenario with regard to certain non-communicable disease (NCDs) in the overall discourse of clinical trials in the context of India. Drawing on the phase three clinical trial database built for 2005-2010 during the previous study, the current study extended this data collection until 2015, and focused its analysis on certain indicators for NCDs-diabetes, cancer and cardiovascular diseases.

I.a Patently Unaffordable: Medicines, Patents and Access

Access to medicines is an integral component of right to health. The Constitution of India obliges the State to protect the right to health of people in India. However, international trade agreements which mandate changes in the domestic law and policy impact the accessibility and affordability of medicines. India witnessed such a change in 2005 when it became compliant with the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement and made changes in law and policies in terms of intellectual property rights and regulatory laws regarding pharmaceuticals in India. The Patents Act, 1970 was amended to re-introduce product patents in all fields of technology, including pharmaceuticals for a term of 20 years to comply with TRIPS Agreement. Drugs and Cosmetics Act 1940, and Rules 1945, were amended to 'facilitate' global clinical trials in India without a phase lag as a policy change.Indian patent however ensured certain safeguards and used flexibilities of the TRIPS Agreement in the Patents Act, 1970 to prevent patents on medicines that are not truly inventive or are forms of known substances (Section 3(d)) or do not involve an inventive step (Section 2(1)(ja)) or are mere admixtures(Section 3(e)).The study locates this background for two broad concerns-drugs that undergo clinical trial are inaccessible and unaffordable to majority of people living in India; and product patents on pharmaceuticals, could allow patent holder to set monopolistic prices and unfortunately, prices of patented drugs are not regulated in India, which makes access difficult and almost impossible at times. The study presents the findings of the affordability and patentability of selected few drugs that were approved in India after undergoing clinical trials.

Methodology- Data collection involved retrieving information on patent status and pricing of drugs through relevant secondary sources. 28 drugs across eight therapeutic areas-immunological/allergic conditions, diabetes, cardiovascular disorders, hypertension, neurological disorders, cancer, hematological conditions, idiopathic pulmonary fibrosis (IPF); were identified for the data collection.

(a) Patents listed on Orange Book and Health Canada website were obtained, (b)PCT application number was obtained through different relevant website sources-Google Patents, Espacenet and USPTO (c) PCT applications were retrieved from Patent scope- WIPO website (d) Indian patent

application number was retrieved by looking up the relevant national phase, (e) Patent information collected from Indian Patent Office (IPO) website
Certain interviews with Indian pharma companies were also held to develop anecdotal references within this issue.

Findings- Both primary and secondary patent claims were identified for various drugs. Primary claims include a general formula or basic scaffold and various substituents to the formula, or a group of compounds. Primary claims could include a New Chemical Entity (NCE) and New Medical Entity (NME). Secondary claims pertain to minor modification to existing molecule,and it could include claims relating to polymorphs, ester, salts, prodrug and enantiomers, combinations, claims of drugs claimed earlier for one disease and later claimed again for use in treatment of another disease, etc.

The broad framework of analysis included- (a) To see if secondary patents claims are being filed in India to extend the monopoly beyond the original patent term, (b) implementation of key public health safeguards such as section 3(d), section 3(e) and section 3(i) of *The Patents Act, 1970* to effectively prevent evergreening, (c) interlinkages between patents, pricing and affordability of the drug, (d) working of patents[1] in India.

Of the 28 drugs that were included in the study, 16 of them had clinical trials sponsored by foreign MNCs, 11 had Indian companies as clinical trials sponsors while data was not available for one. 19 drugs were found to have one or more patents, while 9 drugs had no patent on them which were all pre 1995 drugs. Overall 11 of the drugs were pre 1995, but two were found to have patents. Diabetes, cardiovascular disorder, hypertension and cancer related drugs had maximum number of patents granted to them. Overall 42 patents were identified for the concerned 19 drugs; wherein 14 patents were granted between the years 2006-2008, 13 patents were granted between the years 2009-2011, 5 patents were granted between the years 2012-2014, and 10 patents were granted between the years 2015-2017.Of the 19 drugs, 2 drugs did not have relevant documents uploaded on the patent office website. So, the analysis on secondary patents could only be done for 17 drugs in the study. Of the 17 drugs, 9 drugs had only one patent- T1h mAb (Itolizumab), Empagliflozin (BI 10773), Insulin degludec/ Insulin aspart (NN5401), Insulin glargine (HOE901), Cabazitaxel (XRP6258) (RPR116258), 13-valent Pneumococcal Conjugate Vaccine, AzilsartanMedoxomil, Bevacizumab, Nintedanib. Out of 17 drugs 8 drugs had only secondary patents granted on them-Dronedarone, nintedanib, insulin glargine, insulin degludec/insulin aspart, HPV-16/18/AS04 vaccine, azilsartanmedoxomil, 13-valent Pneumococcal Conjugate Vaccine; while 7 drugs had both primary and secondary patents

[1] Working of patent means examining whether patents granted for the selected drugs and whether the drug is available at affordable cost. This study looks into the statement of working (Form 27) filed by the patent holder and examined the averments made therein.

granted on them- Linagliptin, eltrombopag, dulaglutide, dabigatran etexilate, cabazitaxel, apixaban and alogliptin. In total, 30 secondary patents were identified for the study.

While assessing the years of monopoly, the study revealed that secondary patents granted for drugs leads to the extension of time period of monopoly of the drug manufacturer for that particular drug. The study revealed that the secondary patents would provide an average of 3-4 years of extended monopoly. Several pending patent applications were also identified during the sudy-Apixaban (30 patent applications), dabigatran etexilate (28 patent applications) and dronedarone (23 patent applications) were amongst the highest number of secondary patent applications pending before the patent offices in India. These were again closely followed by diabetes and cancer related drugs.

The computed cost of treatment of the studied drugs ranged widely from 49 INR to 2 Lakh INR. In terms of affordability, only 3 drugs were found to be affordable to all the quintiles out of which 2 were the pre 1995 drugs and not patented while one was post 1995 and patented. 14 out of the 19 patented drugs in the study were found unaffordable to all the income quintiles in India, majority of these drugs were the ones having secondary patents to them. For the 15 drugs with secondary patents, the cost of treatment ranged between 1400 INR to 2 Lakh INR. The impact of secondary patents on affordability of medicines was clearly observed, as most of them were found to be unaffordable.

Status of affordability of the drugs	**Name of the drug**
Affordability to all quintiles	Acrivastine, Empagliflozin, Insugen N
Affordability to quintiles 4 and 5 only	Armodafinil, Asenapine, Emagliflozin N, Opipramol
Affordability to quintiles 3 and above	Armodafinil, Asenapine, Emagliflozin N, Opipramol
Affordability to none of the quintiles	13-valent Pneumococcal Conjugate Vaccine, Apaxiban, Bevacizumab, Cabazitaxel, Dabigatran etexilate, Dronedarone, Dulaglutide, Eltrombopag, Epoetin, Etanercept, Filgrastim, HPV-16/18 VLP/AS04 Vaccine, Insulin degludec/Insulin aspart, Insulin glargine, Interferon beta-1a (biosimilar), Itolizumab, linagliptin, Nintedanib

With regard to generic substitution and competition, of the 28 drugs, 16 drugs had generic substitution; of the 19 patented drugs-8 drugs had generic substitution while 11 had no generics.

With regard to the patent examination process-of the 19 drugs with patents, 51 patent applications were found out of which 6 such applications had no document uploaded on the website. So, the this enquiry could only be undertaken with the available documents for 45 patent applications out of which 37 patent applications were granted and 8 patent applications were refused by the Patent Office. On analyzing the FER (first examination report), 41

applications out of 45 patent applications raised inventive step objection;38 patent applications out of 45 patent applications raised section 3 objection. The most common response of the patent applicant (14 responses to FER) was to amend claims and not to address the inventive step objection raised in the FER. In certain cases (about 12 responses to FER) by the applicant was to distinguish prior art from present application but gave no comparative data. About 5 responses to FER were mere statements without any substantive reply. About 7 responses to the FER distinguished the invention from prior art documents and indicated towards examples or data provided in the specification. In 2 instances, the applicant contended that the invention is said to inventive and novel by the International Preliminary Examination Report and argued for waiving the inventive step objection.

With regard to the requirement of working of patents, the relevant form 27 was looked into. While looking at drug-wise compliance of Form 27, we found that of the 19 drugs, form 27 has not been filed for four drugs and remaining 15 drugs have at least one form 27 filed by the patentee since the date of grant. The issue of irregular submission of form 27 emerged during this analysis. For example, Apixaban has 2 patents that have been granted in 2010 and 2011. For the first patent (patent No.243917) granted in 2010, the patentee should have filed 7 Form 27 (from 2010 to 2016), whereas only 4 forms 27 have been filed with varied averments. The patentee was found to have declared that the patent had worked in the year 2013, 2014,2016 and that it has not worked in 2015, without any justification for its not working suddenly for one year.

Conclusion and Recommendations- While the patent process of pharmaceutical products is laden with several complex and technical details; the externalised impact on the accessibility and affordability of medicines needs critical attention. This brings up the aspect of regulatory mechanisms, bridging the existing gaps and strengthening the implementation of the key safeguards as kept within the legal and policy framework for patents in India. For example, frivolous claims granted to packaging materials and containers of drug must be avoided until such claims satisfy the test of patentability criteria. Accordingly, some of the key recommendations based on the findings of this study are noted below,

- The Indian Patent Office (IPO) must streamline its scrutinising process of the pharmaceutical patent applications and ensure the application of the patentability criteria to assess the inventive step and section 3 of the Patents Act, 1970.
- IPO should emphasize on evidence for satisfying inventive step and section 3 of the Patents Act, 1970.
- IPO should develop, in consultation with health authorities- clear guidelines to examine such applications so as to ensure the patents are only granted where genuine contributions to the state of the art are made.
- Patent claims relating to formulations or compositions, salts, ethers, esters and combinations should be allowed in narrowly defined and should be granted only on

satisfaction of section 3, the Patents Act, 1970. Polymorphs and isomers should not be patentable. Claims on method of treatment should not be entertained.

- Patent laws should include effective pre-grant and post-grant opposition mechanisms.
- Even if section 3 is satisfied, the Patent Examiner ought to ensure that the application satisfies inventive step criteria.
- The Government of India (GoI) should ensure provision of all medicines free of cost in public health systems and make them affordable to people who buy from private sector.
- The government should take steps to issue compulsory license to one or more generics, to bring down the high cost of drugs.
- In order to improve the transparency of the patent system, the international non-proprietary name (INN) of drugs, when known at the time of filing of a patent application, should be mandatorily disclosed in its title and abstract.
- National Pharmaceutical Pricing Authority (NPPA) must undertake regular monitoring of the prices of all patented drugs in India.
- NPPA should take steps towards regulating the prices of such patented drugs which are largely unaffordable to the Indian population.
- International organizations such as World Health Organisation (WHO) also have a role to play towards encouraging and supporting its member state like India for using TRIPS flexibilities, price control of patented drugs, compulsory licensing to promote access to medicines.
- Lastly, the civil society and health movements in this regard need to build and strengthen their dialogues with policy makers, generic pharmaceuticals, parliamentarians for promotion of access to medicines, and regulation of the prices of patented drugs and issuance of compulsory license towards public safeguard and protection against the profit parlance of pharmaceutical companies.

I.b Clinical Trials in Non-communicable diseases (NCDs)

This study was conceptualized based on the previous study by Sama which looked at all phase three clinical trials that were conducted in India from 2005-2010 as well as the availability and affordability of those drugs in India. 'Circle of Medicines' report by Sama from its previous study amongst several things clearly highlighted the dominant focus of pharmaceutical multinational companies on NCDs. In the backdrop of these findings, the current study focused to look in-depth into the three NCDs categories related trials-diabetes, cardiovascular and cancer. Sama's previous study showed clear priority being given to diabetes, cardiovascular diseases, and cancer related trials by the multinational pharmaceutical companies. As per the study, around 43 percent of clinical trials were found related to these three disease conditions.

Similarly, another study also supports this picture as it found that highest number of trials in India as per therapeutic area was related to cancer, cardiovascular diseases and diabetes.[2]

Methodology- The phase three clinical trial database was extended till 2015 for the identified cancer, diabetes, and cardiovascular disorders related drugs that had undergone clinical trials in India. The database of 2005-2010 phase three clinical trials from the previous study was screened by disease category wise to take out diabetes, cancer, and cardiovascular disorders related trials. Database was then collated for 2005-2015 and a master sheet was made for further analysis and findings.

Findings- Over 360 phase three clinical trials conducted in India were found to be associated with diabetes, CVD, and cancer (NCDs) during 2005-2015. The highest number of trials was found for diabetes (160) related health conditions closely followed by cancer (108) and CVD (100). An important highlight was to see that these trials in each of these NCD categories actually represented varied range of conditions associated with a particular category. The health conditions studied in these trials are not merely these diseases by themselves, but rather multiple health conditions associated with these disease categories. Whether it was the trial for diabetic neuropathic pain, chemotherapy induced mucostitis, obese patients with type 2 diabetes or post stroke spasticity of the upper limb; an exhaustive focus on these disease categories seems to be trending within the clinical trial sector. Several instances of interlinked health conditions within these disease categories were also found in the trials, particularly the linkages between CVD and diabetes for instance trials looking at obesity and diabetes together, or dyslipidemia and diabetes together and so on.

A total of 162 NCDs drugs were identified related to these 368 trials. Several drugs had multiple trials; 16 drugs were identified having more than five trials each which overall accounted for 33 per cent of total trials in the study. Sponsors related with these multiple trials for 16 drugs were found to be all MNCs- Novo Novordisk, Novartis, Sanofi, Boehringer Ingelheim amongst others. Another finding on terminated or failed trials showed there were 20 trials that were terminated for various reasons ranging from efficacy to business purpose. However, it raised an important ethical aspect with regard to the number of participants from India who were enrolled in these trials that later turned out be unsuccessful. 2,406 patients were found to be associated with these terminated trials across diabetes, cardiovascular disease and cancer disease categories. Interestingly, the terminated trials were mainly the ones sponsored by multinational pharmaceutical companies (MNCs). Eleven sponsors were identified for these twenty terminated trials, out of which only one was an Indian (domestic) sponsor- Wockhardt limited.

[2]Chaturvedi M, Gogtay NJ, Thatte UM. Do clinical trials conducted in India match its healthcare needs? An audit of the Clinical Trials Registry of India. Perspect Clin Res [serial online] 2017 [cited 2018 Sep 29];8:172-5. Available from: http://www.picronline.org/text.asp?2017/8/4/172/215970

A total of 92 different sponsors identified for the 368 trials forming part of this study. The largest numbers of sponsors are the multinational pharmaceutical companies (MNCs), while a smaller yet significant proportion of Indian sponsors were also seen in the conduct of NCDs trials. While MNCs formed 68 per cent of sponsors, 32 per cent sponsors were Indian pharmaceutical companies. On an average, this study found one sponsor for almost every four trials. Within these three NCDs, high number of diabetes related trials was seen against few sponsors, most of whom were large MNCs such as Novo Nordisk, Astra Zeneca, Boehringer, etc. This also appears in consistency with the leading companies share in the global diabetes therapeutics market, wherein these three sponsors are amongst the top six companies with Novo Nordisk at top with around 15 billion USD.[3] Unlike diabetes, there was not high number of trials being done by one sponsor rather varied sponsors were involved with one or two trials.

With regard to trial sites, almost 80 per cent trials were global, and 20 per cent were Indian only. With regard to sponsors, it was evident that Indian sponsors lacked the global footprint while MNCs are conducting a lot of NCDs studies across countries, including the Indian population. The location of the trials varied across different states. Altogether, there were 21 Indian states and union territories which formed trial sites as identified in this study- Andhra Pradesh (including now Telangana), Assam, Bihar, Chandigarh, Chhattisgarh, Delhi, Goa, Gujarat, Haryana, Jharkhand, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Odisha, Punjab, Rajasthan, Tamil Nadu, Uttar Pradesh, Uttarakhand, and West Bengal. Maharashtra led the number of trial sites with 995 sites, followed by Karnataka, Tamil Nadu, Andhra Pradesh, Gujarat and others.

Conclusion and Recommendations- Currently, a paper is being developed drawn out of these and other related findings from the study. The paper is conceived to share the findings while reflect on them from a public health perspective and ethical perspective to further build the clinical trials related discourses in the public domain.
Some of the key recommendations points that emerge primarily are-

- The government authorities need to look into the clinical trials being conducted in India from the public health perspective-including the gaps in trials vis-à-vis health needs of the country, rights of clinical trial participants in India.
- Post-trial analysis should be undertaken by the government following up on the NCDs trials in the country-relevance of the specified drugs in the context of NCD burden in India, its availability and accessibility by the treatment/healthcare seeking population across the country.
- While the National Health Policy (NHP) 2017 mentions about strengthening regulatory framework for clinical trials in India, and talks about '*Clear and transparent guidelines, with independent monitoring mechanisms, are the ways forward to foster a progressive and innovative research environment, while safeguarding the rights and health of the*

[3] https://www.igeahub.com/2018/05/19/top-10-pharmaceutical-companies-2018-diabetes/

trial participants'; the policy mentions no estimated timeline commitment for achieving the same. The draft rules on Clinical Trials were released by government of India, but they still remain to be finalized and the concerns with dilution of rights of clinical trial participants have remained forefront meanwhile.

- The Clinical Trial Registry of India (CTRI) needs to streamline its data repository of clinical trials particularly the missing data of actual number of participants recruited, terminated trials in India etc. Information details of method of recruitment of trial participants must be included in specific trials database.
- A system needs to be put in place to prevent unnecessary multiple trials being conducted for one drug.
- The authorities need to develop a system for equitable access to clinical trials, and build infrastructure for conducting clinical trials in rural, tribal and urban areas, so as to capture the diversity and ethnicity of the results of the trial drugs.
- The authorities need to properly scrutinize the types and kind of trials being proposed to be conducted, and weigh the pros and cons in granting permissions for placebo and open label trials.
- Drugs being tested in terminated trials ought not to be given drug approval. Such drugs should be further investigated into, prior to be given any kind of approvals.

II. ADVOCACY EFFORTS TOWARDS POLICY ENGAGEMENT

Sama actively engaged towards policy level advocacy on the issue of ethics and rights in clinical trials and access to medicines, vaccines, drawing on from both the studies from previous project and the current project as part of this initiative.
Following is a brief description of capturing various aspects of overall advocacy efforts in this regard.

II.a With Policy Makers and Officials

Sama continued its advocacy efforts by exploring avenues and participating in the policy level discussions with the government.

Sama team provided comments to the Draft Drugs and Cosmetics Rules (Draft Clinical Trial Rules, 2018) released by the government of India. The team deliberated on compensation, role of ethics committee in deciding compensation and post-trial access to treatment.

Meetings with Drug Controller General of India (DCGI)

Sama participated in the meetings called by DCGI on 5th and 22nd November, 2018 seeking discussions on the clinical trial draft rules. Sama shared its earlier written submissions to the government with DCGI and reiterated some of the key points including compensation for clinical trial injuries and clarity on different definitions in the draft to make them more comprehensive.

The point on making all the comments available in public domain was also flagged by Sama and other civil society members present during the meeting. DCGI agreed to work towards making available a comprehensive table with details of what comments were included and what were rejected and reasons etc.

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Letter to DCGI and MoHFW resisting dilution of compensation clause in the clinical trial draft rules

Sarojini N and Adsa from Sama along with others worked on drafting a statement on retaining compensation related provision in Clinical Trial Draft Rules. This was done in response to a news item that was carried by LIVEMINT published[4] on January 11, 2019 which reported that the Government of India (GOI) has decided to remove one of the compensation related provision for clinical trial participants in the Draft 'New Drugs and Clinical Trials Rules-2018'.

The draft rules had a clause stating that, "If a trial subject suffered from permanent disability or died during a clinical trial or bioavailability study or bioequivalence study, the sponsor would have to pay 60% of the compensation within 15 days of the opinion of ethics committee". This provision of upfront 60% compensation amount was welcomed by various civil society groups as it respects the dignity of participants taking part in clinical trials. The reported news of its dilution by the government came as a blow to the rights of clinical trial participants in India who were promised such a support.

The drafted statement was sent as a letter to the DCGI and the Undersecretary, MoHFW by the signatories. It was also shared with the different press/media contacts for wider public dissemination of the same. Some of the media platforms like 'The Wire' did cover this issue[5] as well. The full statement can be read here as published on the IJME website.

Participation in discussions on competition issues in healthcare and pharmaceutical Sector in India, 28-29 August, 2018

The Competition Commission held a workshop on issues affecting competition in healthcare and pharmaceutical sector. There was a session on Industry Practices Choking Competition; speakers were from healthcare sector including doctors, activists and journalists. The focus of the session was to discuss the impact of various practices in the healthcare industry on consumers. In the meeting Highlighting the need to place a cap on MRP for medicines, devices and diagnostics, the speakers spoke that there are many costing models that being developed to protect consumer/patients and promote healthy competition.

[4] https://www.livemint.com/Industry/jynrYOOYtSik55JzbDsYNL/Govt-to-tweak-solatium-clause-in-clinical-trials.html

[5] https://thewire.in/health/compensation-clause-for-clinical-trial-participants-should-remain-health-observers

Sama contributed the point on the need for regulations of conduct of clinical trial for ensuring ethical conduct and rights of participants and such a regulatory aspect could not be considered to be the factor for hindering competition.

III. NATIONAL SEMINAR ON NEW VACCINES FOR ALL, 20-21 OCTOBER 2016

Sama co-organised a national seminar on '*New Vaccines For All: Why, Which, When?'* along with Jan Swasthya Sahyog (JSS), Forum for Medical Ethics Society (FMES) and National Medical Journal of India (NMJI). Ms. Sarojini N from Sama, Dr. Yogesh Jain, and Dr. Amar Jesani, were the members of the organising committee of the seminar. As then members of the Mission Steering Group (MSG) of the National Health Mission (NHM), the organizing committee members paved ways for involving policy makers and stakeholders from relevant authorities to lead this discussion.

The national seminar sought to facilitate a dialogue on 'New Vaccines' in the true spirit of public health, and of a high scientific quality towards building perspectives and consensus, where possible, on these issues. It was successful in mobilising participation of representatives from the Ministry of Health and Family Welfare (MOHFW), Indian Council of Medical Research (ICMR), World Health Organisation (WHO), Institute of Economic Growth, public health institutions, civil society organisations, academic institutions, premium medical colleges, such as AIIMS, CMC Vellore, and research institutions, etc.

A full report of this seminar and it can be accessed here at Sama's website.

NATIONAL SEMINAR ON VACCINES AND POLICY DIALOGUES				
Title of the Meeting	**Place**	**Date**	**Any Collaboration in organising**	**Total No. of participants**
National Seminar on "New Vaccines – why, which,when"	NIHFW, New Delhi	20-21 October, 2016	JSS, NMJI and FMES	45

Affiliations of participants involved:

PNG, Indian Institute of Technology Madras, International Budget Partnership (IBP), State Health Resource Centre (SHRC), EKJUT, Jawaharlal Nehru University (JNU), Initiative for Health, Equity and Society (IHES)/ All India Drug action Network (AIDAN), Maulana Azad Medical College (MAMC), NarotamSekhsarai Foundation, Centre for Health and Social Justice (CHSJ), Council of Social Development (CSD), Tata Institute of Social Sciences (TISS), Mission Steering Group (MSG), Jan Swasthya Abhiyan (JSA), Guru Gobind Singh Indraprastha University (GGSIPU), NISTADS, Forum For Medical Ethics Society (FMES)/ Indian Journal of Medical Ethics (IJME), All India Institute of Medical Sciences (AIIMS), LOCOST, NHSRC, World Health Organisation (WHO-INDIA), Institute of Economic Growth (IEG), Courtyard Attorney, Centre for Technology and Policy (CTaP), Indian Institute of Technology (IIT Madras), Christian Medical College and Hospital (CMC Vellore), St. Stephen's Hospital (SSH Delhi), SATHI- Centre for Enquiry into Health and Allied Themes (CEHAT), Ministry of Health and Family Welfare (MoHFW), Immunization Technical Support Unit (ITSU), Public Health Foundation of India (PHFi), Indian Council of Medical Research (ICMR), Public Health Resource Network(PHRN), Delhi Science Forum (DSF), Third World Network (TWN), Max Hospital, Calcutta School of Tropical Medicine (CSTM Kolkata)

IV. DISSEMINATION AND PRESENTATIONS ON ACCESS TO MEDICINES ISSUES TOWARDS PUBLIC ENGAGEMENT

Dissemination of key aspects and issues emerging from the studies and their relationship with contemporary policy discourses and on the same, and other related issues were undertaken during this period through various platforms. Instead of having a single dissemination meeting, Sama has disseminated the findings through presentations, interventions at various conferences, meetings and Assemblies such as the National Health Assembly (NHA) organized by Jan Swasthya Abhiyan (JSA), People's Health Assembly (PHA) organized by global Peoples Health Movement (PHM), and World Congress of Bioethics (WCB) to which Sama was a co-organiser as well. This was done through Sama team facilitating workshops at these avenues as well as through participation in meetings and conferences being organized there.

III.a Dissemination meeting for the Patent Study, 11th October 2018

Sama organized a day-long dissemination meeting to share the findings of the study on drugs, patents and affordability-*'Patently Unaffordable: Medicines, Patents and Access'* on the 11th October 2018 at India International Centre, New Delhi. Sama presented the patent study findings and later two panel discussions raised a broader discussion on the issue of patents and access to medicines. The meeting also discussed advocacy and ways of moving forward on the issues of clinical trials and access to medicines. Sama has invited similar kind of presentations from other experts on 'Grant of pharmaceutical patents, working of patents and access to medicines', "the requirement of law to work the patents granted in India and patent holder's obligation", "Pricing of Patented Drugs and Affordability", and "regulatory aspects related to prices of patented medicines in India. India's section 3(d)". The experts include, Dr. Feroz Ali Khader (Department of Industry Policy and Promotion, Ministry of Commerce and IIT Madras, Priya Lizmary Cherian Lawyers Collective, Dr. Santanu Tripathi from School of Tropical Medicine, Kolkata, Jyotsna Singh (Medicines Sans Frontiers) and Dr. James J. Nedumpara (Centre for Trade and Investment Law)

The meeting concluded with a way forward session. It was suggested that avenues for building pressure by countries to demand public health safeguards, adhering to sovereign laws on patent regime, use of TRIPS flexibilities etc need to be strategically discussed. Lastly, there is need for synergy between campaigns; campaigns have to go beyond national and be made into a global campaign.

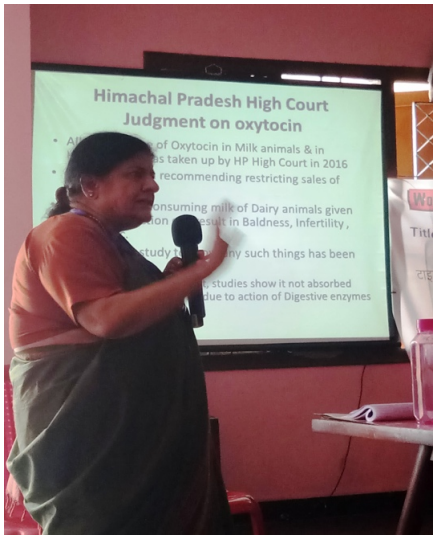
III.b Presentations at the Third National Health Assembly, Raipur

Sama along with Third World Network (TWN), co-organized a workshop on 23 September, 2018 on '**Affordable medicines and medical devices: A national imperative; reflecting on the context of India**' at the Third National Health Assembly held on 22-23 September at Raipur,

Chhattisgarh. The presentations and discussions at the workshop were largely done in Hindi language considering the language preference amongst the participants. The workshop was attended by around 30 participants mainly health activists from different states who were attending the assembly. The workshop had four presentations including two presentations by Sama and the other two by health activists from All India Drug Action Network (AIDAN and Drug Action Forum Karnataka moderated Dr. Chandrakanth Lahariya from WHO

The first presentation was from Sama focused on how multiple patents on a drug could increase the cost, leading to a prolonged monopoly and ultimately impacting the accessibility of medicines for the people. It pointed out that medicines and their high prices are an issue of serious concern and often we forget the multiple reasons involved for such high prices. The presentation therefore introduced the aspect of patents and argued how it is related to the higher prices of medicines. Before talking about patents, it was highlighted that how it is imperative to remember that health is our fundamental right supported by the mandates enshrined in the Constitution of India; which thereby makes it a corresponding duty on the part of the government to provide medicines for the people who live in India free of cost in public sector and at low prices in private sector.

The second presentation by Sama focused on the recent trends in research and development and its impact on access to medicines. The presentation highlighted that the clinical trials conducted in India are not often focused on the diseases prevalent in India. The focus of clinical trial was found on non-communicable diseases. HIV and TB had only one clinical trial respectively as per the study. The study also looked at the sponsors of the clinical trials. About 70% of the sponsors were multinational companies and they had conducted 73% of the trials. The focus of research and development should be based on public health needs of the country. The presentation was concluded flagging the note that presently market forces decide the research and development, wherein the companies decide based on profit motive and is reflected in high prices of the drugs.



The next presentation by Dr Mira Shiva discussed the issue of the recent ban on manufacture and sale of oxytocin and its impact on maternal health. She pointed out that Oxytocin is included in WHO Essential Drug List. Oxytocin Included in National List of Essential Medicine 2011, 2015. As per the Ministry protocol, Oxytocin is to be used for induction of labour, augmentation of labour, prevention of Post Partum Haemorrhage PPH and active Management of Third Stage of Labour (AMTL) Management Treatment of PPH. Access to Oxytocin has saved lives of thousands of young mothers. The government has banned the private manufacture and sale of this important medication. AIDAN has filed a PIL challenging the ban.

The fourth presentation by Dr. Gopal Dabade (AIDAN) was on snake bite and anti-venom, its availability and related issues. Snakebites in India kills annually 50,000 people. This staggering high number of deaths is perhaps the highest in the world and is of much paramount importance because all these deaths are preventable. He pointed out that unfortunately the government figures regarding deaths by snakebites are almost thirty times less as they take into account deaths that have occurred only in government hospitals. There is a need to involve experts from diverse sector like herpetologists, wild life sanctuary, researchers from the field of genetics, epidemiologists, health economists and behavioural change makers including clinicians, anti-venom manufacturers, drug regulatory authorities, traditional healers, snake rescue organisations and medicine procuring authorities.

III.c Presentation at the 14th World Congress of Bioethics: '*Ethical concerns regarding Clinical Trials in India*'

Sama made a presentation on the ethical concerns, issues and reflections related to clinical trials in India, as part of one of the parallel session organized during the congress. The session was on 'Pharmaceuticals and Access to Medicines' chaired by Mr. Sridhar Venkatapuram. It was held on 6 December, 2018 at Forensic Medicine Demonstration Room 1 in St. Johns Medical College and Hospital, Bengaluru. Based on Sama's initiative and engagement in the area of ethics in clinical trials; this presentation discussed the issues of post trial access including the availability and affordability of newer drugs for Indian population, gaps in the disease burden of India and the therapeutic areas of innovation focused by the pharmaceutical companies, and lack of monitoring mechanisms in public domain to understand better the implementation of clinical trials across varied regions and states in India. Drawing on reference from Sama's study looking at phase three clinical trials in India between 2005-2010, this presentation flagged designs and other related aspects with trials while underlining the issue of how market based model of research and development of new drugs particularly dominated by large multinational pharmaceutical companies (MNCs) plays out in the context of India and what implications then it would hold from a rights and ethics based perspective.

III.d. Medico Friend Circle annual meet on NCDs of the poor: Sama presented the role of pharmaceutical industry in clinical trials on NCDs drawing from Circle of Medicines study.

III.e Participation in Forum for Ethics Review Committees in India Conference; November 2016

Sama was invited to present a talk on the Role of the Social Scientist member in Bio-medical Research Ethics Committees, as a part of the 4th National Conference & International Colloquium Forum for Ethics Review Committees in India (FERCICON). The conference was organized by Department of Clinical & Experimental Pharmacology, Calcutta School of Tropical Medicine, Kolkata in collaboration with Bioequivalence Centre, Jadavpur University, Kolkata and Society of Topical Medicine & Infectious Diseases in India, Kolkata. The conference was held at Jadavpur University, Kolkata.

The theme of the Conference was 'Research Collaboration and Special Ethical Issues', and it was attended by members of clinical research ethics committees, expert clinicians, clinical trial investigators, pharmacologists, pharmacists, industry representatives and other stakeholders of clinical research including bioethicists and legal experts.

Sarojini from Sama was invited as a guest faculty for the panel on 'Functioning of the Ethics Committee and Role of Different Category members'. Sama's talk was on 'Commitment of the Social Scientist in Clinical Research Ethics Committee' and highlighted the points on protection of vulnerable groups, potential conflict of interests within the ethics committee, and scrutinizing the research proposal while focusing on the rights of the participants.

III.f. Meeting of the Civil Society was held on Promote health, keep the world safe, serve the vulnerable HIV, Viral Hepatitis, STIs and Universal Health Coverage on 22-23 March 2018 at WHO in Geneva. The main objective was to orient key civil society partners to organizational and strategic shifts at WHO; identify opportunities to strengthen HIV, Hepatitis and STI integration across the health system in the context of UHC and the WHO GPW 2019-2023. Sama raised many important issues related to availability and affordability of medicines and gave inputs in the recommendations.

III.g. The Prince Mahidol Award Conference 2019 was on the theme **"**The Political Economy of NCDs: A Whole of Society Approach". Sama has attended the Conference in January 2019

The list of meetings/conference/seminars/include:

LIST OF MEETINGS ATTENDED			
S. No.	**Meeting/Presentation**	**Date and Place**	**Meeting details**
1	Participation in Forum for Ethics Review Committees in India Conference Presentation on Role of Ethics Committees in specific regard to vulnerable groups	3-4th November 2016 Jadavpur University, Kolkata	Conference was organized by Department of Clinical & Experimental Pharmacology, Calcutta School of Tropical Medicine, Kolkata in collaboration with Bioequivalence Centre, Jadavpur University, Kolkata and Society of Topical Medicine & Infectious Diseases in India, Kolkata
2	6th National Bioethics Conference Paper presentation on Clinical trials in India drawing on from Sama's study Circle of Medicines	13-15 January 2017 Pune	Conference was organized by NBC
3	Medico Friend Circle annual meet on NCDs theme- 'Non Communicable Diseases (NCDs) of the poor' Presentation on role of pharmaceutical industry in clinical trials on NCDs drawing from Circle of Medicines study	27-29 January 2017 Jan Swasthya Sahyog, Ganiyari, Bilaspur, Chhattisgarh	MFC is an all-India group of socially conscious individuals from diverse backgrounds, who have come together with a common concern for health
4	Participation in Public conference on clinical drug trials International conference on to discuss debates on ethical challenges and lack of transparency around clinical trials	30th September 2016 Geneva, Switzerland	Organised by Health Action International (HAI) and Public Eye
5	Round table on Snakebites	7th August 2018	Meeting was organized by MSF, discussion on snakebite related issues
6	Consultation of a Working group for inputs to Niti Ayog in the Health Sector	Niti Ayog, New Delhi 13th October 2017	
7	WHO and Civil Society Meeting on HIV, Viral Hepatitis, Tuberculosis, STIs and Universal Health Coverage,	22-23 March 2018WHO, Geneva, Switzerland,	
8	Workshop on Access to Medicines at Third National Health Assembly	22-23 September 2018 Raipur, Chhattisgarh	Co-organised by Sama Resource Group for Women and Health and Third World Network as part of Third National Health Assembly by JSA
9	Participation in Meeting on TB: Communities, Rights and Gender Assessment Discussions on Social determinants which cause certain populations to be categorized as more vulnerable than others; Analyzing TB through the gender lens (particularly women); Legal environment of Tuberculosis	14th September 2019 Delhi	Organised by Resource Group for Education and Advocacy for Community Health (REACH). They provide support, care and treatment for TB patients, research, advocacy, public education and communication. They work with a range of partners including the RNTCP, local government officials, private hospitals, community-based providers and private practitioners among others.
10	Prince Mahidol Award Conference 2019 on NCDs	29th January to 3rd February 2019 Bangkok, Thailand	Participated in the discussions on UHC, NCDs
11	Consultation on Rajasthan Draft Public Health Act		Giving inputs on Right to Health act draft and on access to medicines, social determinants of health etc

V. CAPACITY BUILDING ACTIVITES

Sama continued its sustained capacity building efforts with students, research scholars, health professionals, ethics committee members, scientists, medical professionals through institutes organized by Sama.

Title of the Meeting	Place	Date	Total No. of participants
Short Course on Challenges to Access to Medicines - Patents, Pricing and Drug Research in India	Sanskriti Kendra, New Delhi	16th-18th August 2017	30
Course on Ethical and Legal Issues in 'New Frontier' in Bio-Medical Research,	Hotel Basera, Secunderabad	July 13-15, 2018	22

V.a Course on Challenges to Access to Medicines: Patents, Pricing and Drug Research

Sama organized a three-day short course on Challenges to Access to Medicines: Patents, Pricing and Drug Research in Delhi from 16th to 18th August 2017. This short course provided key inputs on some of the most critical issues in the domain of access to medicines in India

The short course broadly covered the following issues:

a) Access to Medicines in the framework of Public Health and Human Rights: Focus on the access to medicines as a key component of the right to health; health as a human right
b) Ethical Issues in the context of Access to Medicines and Drug Research: The significance of ethics in the conduct of health research; the national and international standards and regulations for research involving human participants

c) Access to Medicines - Connecting with ground realities; sharing experienced realities of the systems of health delivery / access to medicines; costs to access medicines/healthcare incurred by patients
d) Access to Medicines and Drug Research: The shift in research and development of medicines from synthetic/chemical to bio-therapeutic products; technological, intellectual property and regulatory barrier in accessing bio-therapeutic products
e) Access to Medicines and Drug Pricing: Historical overview of pricing policy for medicines in India; links between the essential drugs list and the pricing policy; recent changes in the national pharmaceutical pricing policy in India
f) Access to Medicines and Patents: Overview of international legal frameworks and national regulations on patents and its impact on access to medicines

Full report of this course can be seen here at Sama's website.

V.b Course on Ethical and Legal issues in 'New Frontiers' in Bio-medical Research; 13-15 July 2018

In continuation of this Sama conducted its fifth Institute on ethical conduct in biomedical research, post trial access to medicines, regulation and Law. A three day course titled "Ethical and Legal issues in 'New Frontiers' in Bio-medical Research" was organized on 13-15 July, 2018, at Basera Hotel, Secunderabad.

In a neoliberal paradigm, the aspects of globalized clinical trials, controversies and courts cases on rights of trial participants, and increasing international pressure to dilute the regulatory laws paves a complex background in the context of India. Given this background, Sama's course focused on questions regarding the responsibility of ensuring the rights of participants and compensation while looking at the newer frontiers emerging like CHIM studies within the bio-medical research paradigm; ethical review of trials, public health impact of newer studies to be introduced in India. The course focused on two aspects-revisiting the basics of ethics in biomedical research and discussions on newer studies, new rules on clinical trials, and compensation to trial participants along with other regulatory aspects.

Experts from varied backgrounds pertaining to the areas of health and bio-medical research, bio-ethics, laws and policies - formed the faculties of this course. The course had six resource persons included Dr. Anant Bhan, Adjunct Visiting Professor at Yenepoya University, Mangalore; Dr Amar Jesani, Editor of Indian Journal of Medical Ethics; Dr. Vijayaprasad Gopichandran, Department of Community Medicine, ESIC Medical College and Post Graduate Institute of Medical Science and Research; Dr. Santanu Tripathi, Professor, Calcutta School of Tropical Medicine, Kolkata; Mr. S (Chinu) Srinivasan, Health activist with All India Drug Action Network (AIDAN) and Low Cost Standard Therapeutics (LOCOST); Adv. Veena Johari, Courtyard Attorneys legal firm working on public interest issues, legal research, access to medicines.

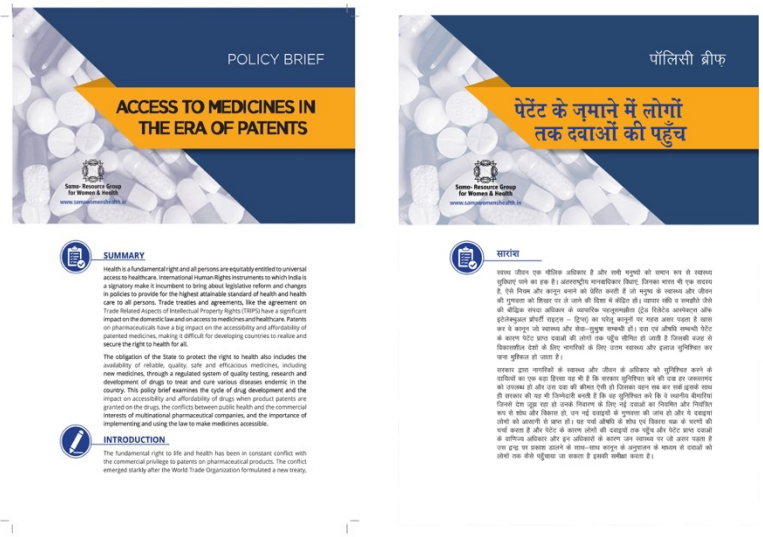
The three-day course plan had five technical sessions to be facilitated by resource persons, in addition to introductory and feedback sessions. The sessions methodology comprised a mix of presentations, open discussions, participatory group work and presentation by participants, and panel discussion. Technical sessions included themes and topics on-Research and Ethics: introduction to role of ethics in research; Recent developments in biomedical research in India: CHIM; Clinical Trials: Introduction and current scenario; Issues of Rights in Biomedical research: When rights meet ethics; Clinical Trial Regulations: Critical review and understanding.

VI. KNOWLEDGE CREATION

Sama contributed towards knowledge creation on the access to medicines and clinical trial themes through outreach of its research reports-Circle of Medicines and Compensation in Clinical Trials and information kits and a poster. Study reports were circulated amongst participants of different meetings and workshops reaching out to as many as 400 persons directly (seminars/workshops/MFC meeting) and larger outreach inversely with up to 2000 persons. Sama also contributed articles on the issue.

Patent Policy Brief by Sama

Sama published a policy brief on patents titled 'Access to Medicines in the Era of Patents' developed during this period.



The policy brief presents to its readers the overall cycle of drug development and the impact of product patent on accessibility and affordability of drugs, the conflicting terrain of public health with the commercial interests of the multinational pharmaceutical companies, and the importance of implementing and using the existing laws for making medicines accessible. A Hindi translated version of this policy brief was also published by Sama. A wide dissemination of the policy brief through social media and other forms of communications was initiated. It was disseminated widely at various relevant Seminars, meetings, conferences and study circles. And also at the IPHU is a week long course conducted by Peoples Health Movement (PHM). The latest course on 'Struggle for Health access to medicines, gender and health' was organized by PHM along with Sama and TWN in Savar, Bangladesh from 6th to 13th November, 2018 preceding to the Fourth People's Health Assembly held in Dhaka.

IPHU: Struggle for Health Course	PHA Bhawan, Savar, Bangladesh	6-13 November, 2018	PHM, TWN	60
Countries representation: South Africa, Bangladesh, Nepal, India, Philippines, Spain, Kenya, Palestine				

Sama is planning to hold a brief conversation and dissemination of patent policy briefs with the health activists coming from southern regional states of India-Tamil Nadu, Karnataka, Kerala, and Andhra Pradesh. A group of 30-40 activists are expected to be gathered for the same.