

Market Mapping and Landscape Analysis of Human Rabies Biologicals in India

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Abstract

Background: Rabies vaccines and immunoglobulins are lifesaving in humans following animal exposures. These biologicals should continuously be available throughout the year to prevent and eliminate human rabies by 2030. **Objectives:** The present study aimed at assessing availability of different kinds of human rabies biologicals in the country and undertaking market mapping and landscape analysis of human rabies biologicals in India. **Methods:** The study comprising both quantitative and qualitative approach was conducted from May to November 2017 as a part of the Indian multicentric rabies survey by Association for Prevention and Control of Rabies in India. All stakeholders (agencies/personnel) associated with rabies biologicals were the study units/participants. Required data were generated through brainstorming sessions with key stakeholders; reviewing of databases/existing literature; conducting in-depth surveys; interviewing; focused group discussions, etc. **Results:** Two types of cell culture rabies vaccines are available in the country manufactured by different pharmaceutical companies; most of the vaccines are indigenously produced and the market size of the rabies vaccines is about INR 125 crores with highest sales in the northern region followed by South. Likewise, there are 2 types of immunoglobulin available, i.e., equine rabies immunoglobulins (RIGs), which are indigenously produced and human RIGs, which are imported. The market value of RIGs is about INR 83 crores. A novel rabies monoclonal antibody is also been marketed in the country from November 2017. **Conclusions:** There are many lacunas in the market availability of rabies biologicals in different parts of the country; therefore, a significant expansion/shift in focus must be considered, through rigorous strategic planning process.

Key words: Human rabies vaccines, India, landscape analysis, market mapping, rabies immunoglobulins

INTRODUCTION

Rabies is a neglected zoonotic disease, which is insufficiently addressed by the national and international community, as they affect the poor people living in remote rural areas and slums of the developing country.^[1] It is almost always fatal; globally, an estimated 59,000 human rabies deaths occur every year of which about one-third, i.e., 20,000 is from India alone.^[2] About 99% of these deaths occur following dog bites globally, and in India, it is about 97%.^[3] The disease is preventable by early and complete postexposure prophylaxis (PEP) for all animal bite cases using modern rabies immunobiologicals.^[4]

In India, an estimated 17.4 million animal bites occur annually and about 5 million rabies PEP are provided.^[5] In rabies-endemic country like India, where every animal bite is potentially suspected as rabid exposure, the exposed individuals should seek early and proper health care; simultaneously, PEP

should be started immediately at the healthcare facility.^[6] The PEP consisting of immediate wound toilet, administration of rabies immunoglobulins (RIGs) in severe exposures, and a full course of anti-rabies vaccination (ARV) is lifesaving. Unfortunately, availability, accessibility, and usage to PEP are limited, where rabies is endemic, and the incidence of dog bites is high.^[7]

In this background, Government of India has launched National Rabies Control Programme in 12th Five-Year Plan with the objectives to reduce human deaths due to rabies and

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to implement a consensus strategy for control of rabies in dogs to cut down the transmission of rabies.^[8] One of the important human component is to ensure regular supply of ARV and RIG at all anti-rabies clinics/centers (ARCs) in their states.^[9]

Global rabies conference held in Geneva, December 2015, under the auspices of World Health Organization (WHO), World Organization for Animal Health, Food and Agriculture Organization, and Global Alliance for Rabies Control has set a goal of eliminating dog-mediated human rabies by 2030. WHO through its Strategic Advisory Group of Experts working group on rabies was tasked with reviewing the current policies, availability, and distribution of ARV and RIGs; the experience and evidence from India is extremely important toward achieving the global goal of eliminating dog-mediated human rabies to which India is contributing to one-third of human rabies mortality.^[10] Likewise, there is a potential Global Alliance for Vaccines and Immunization (GAVI) investment into ARV, and it has rallied its partners and countries to build the evidence base to help and inform this investment decision process.^[11]

In this background, market mapping and landscape analysis involve identifying the key players in a field and classifying them by relevant characteristics (e.g., type of organization and target beneficiaries). This helps to understand the broader context in which they are operating and design their strategy accordingly maximizing their impact. It also allows identifying which approaches or beneficiaries are well served by existing situation, as well as any lacunae where no organization is currently active. Market mapping is especially useful for considering significant expansion or shifts in focus, through rigorous strategic planning process. It is also a key part of setting up a collective impact collaboration.^[12]

In this context, this study formed a part of the Indian multicentric rabies survey (IMRS) that was conducted by Association for Prevention and Control of rabies in India with the technical and operational support of WHO, to provide new evidence on rabies vaccination policies, feasibility and impact of improving access and coverage to PEP and experience on market availability and delivery mechanisms of rabies immunobiologicals throughout the country with the objectives to enlist different kinds of human rabies biologicals available in the country and to undertake market mapping and landscape analysis of human rabies biologicals in India.

MATERIALS AND METHODS

This targeted research was conducted from May to November 2017 which included both quantitative and qualitative approach. Primary study units/participants were all stakeholders (agencies/organizations/entrepreneurs and key personnel) at the various level of the country associated with production, distribution, sales, use, and policy decisions regarding rabies biologicals. All such stakeholders were identified and requested to participate in the study. Various research methods included brainstorming with key stakeholders for understanding production, demand,

and supply of rabies biological; reviewing databases/records and existing literature to describe market value and size of rabies biological; conducting surveys/interviewing field level stakeholders to synthesize information for understanding the geographic distribution and trends of sale of rabies biologicals; thereby providing a clear landscape of the field.

All the stakeholders were requested to provide the necessary data. The national marketing heads/directors were personally met/telephonically informed, and structured pretested survey schedules were provided (in person/soft copy by E-mail) to obtain the data. As the data requested was related to their business, some who were reluctant/hesitant had to be explained in detail and assured about maintaining anonymity and prevailed on personally to provide the requested data. The business offices of Indian Immunologicals Ltd./Human Biologicals Institute (HBI), Bharath Biotech International Limited and VINS Bio Pharma, Hyderabad were visited by the project team, and necessary data were collected through the survey schedules from the marketing teams at the headquarters of the pharma houses. Focused group discussions were also held with these marketing teams that consisted of senior level marketing managers such as general managers, managing directors, and others to explore relevant information. Some data that could not be readily provided by the pharma houses was later received electronically. The data received were cross validated as practically feasible with the information that was obtained from the seven surveyed states under the IMRS, i.e., Himachal Pradesh, Bihar, West Bengal, Manipur, Kerala, Madhya Pradesh, and Gujarat.

Finally, the data, that was on an excel sheet, were analyzed using descriptive statistics like frequency and percentages for obtaining a detailed market mapping and landscape analysis of human rabies biologicals.

RESULTS

The research results are presented under the following headings, separately for rabies vaccines and RIG.

Anti-rabies vaccines

Availability, market mapping, and landscape analysis.

Availability of rabies vaccines

Most of the available vaccines are indigenously produced in the country; one from the cooperative sector (Indian Immunologicals Ltd./HBI) and five from the private sector. There is very little vaccine produced in the State/Government sector. A very small quantity of rabies vaccine is occasionally imported, mostly from China and that is more during exigencies and for profit reasons. All vaccines are cell culture derived, and no embryonated egg rabies vaccines or nerve tissue-derived vaccines are produced/available in the country.

Types of vaccines: Two types of cell culture rabies vaccines are available in the country.

1. Purified Chick Embryo Cell Vaccine: Rabipur and Vaxirab-N

2. Purified Verocell Rabies Vaccine: Abhayrab, Rabivax-S, Indirab, Zoonovac V, BeRab, SureRab, and XP-Rab.

Production capacities of rabies vaccines

The volume of production depends on the demand that is generated from the users, i.e., Government institutions and private hospitals/practitioners. The detailed information on production capacity, demand, and supply was obtained from Central Bureau of Health Intelligence, National Health Profile, Government of India, and the vaccine producers [Table 1].^[13]

The installed capacity for human rabies vaccines in the public sector was 22.2% as compared to 77.8% of the private sector; the vaccine production against the installed capacity was 55% in the public sector and 32% in the private sector.

Market mapping of rabies vaccines

Since ARV are under drug price control, the cost of each vial is almost the same for all the brands, i.e., <Rs. 340.

The market value and size

The market in terms of its value and size for different rabies vaccines are presented in detail in Table 2.

The market size of the rabies vaccines was about INR 125 crores as per the pharmaceutical market research agencies, namely PHARMATRAC/AWACS (August 2017).^[14] There

was a degrowth, due to severe product shortages resulting in Rabipur GlaxoSmithKline (GSK) vaccine, thereby losing the number one status. The market was dominated by Abhayrab (48% market share) followed by Rabipur (24%). The dispensing market is a significant portion of the market, and it is generally the preferred target by the pharma houses. The rabies vaccines were procured by the state governments; the scenario of their availability varied from 24 × 7 availability in Gujarat and Kerala to occasional supplies in Manipur and Bihar. The information about the tender business was kept confidential and not easily shared.

Besides, the rabies vaccines were exported to countries of Asia and Africa and the proportion varied from 2% to 16% (of their production) depending on the producer. However, all the producers did not share the information despite many attempts.

Market trends in sale of different brands of rabies vaccines

The all time market leader Rabipur (GSK/Chiron Vaccines) showed a decline, due to issues in vaccine production; whereas, there was a gradual ascend of Abhayrab, produced by HBI that is established by National Dairy Development Board, a Government of India initiative. Due to a general shortage of some leading brands of vaccine, namely Rabipur and Vaxirab N, other and newer brands of rabies vaccines were gaining foothold in the market.

Table 1: Production, demand, and supply of rabies vaccines in India: 2014-2016

Institution (year)	Installed capacity (doses)	Production (doses)		Demand (doses)		Supply (doses)		Demand achieved in (%)	
		2014-2015	2015-2016	2014-2015	2015-2016	2014-2015	2015-2016	2014-2015	2015-2016
Public sector									
PII, Coonoor	2	Nil	Nil	Nil	Nil	Nil	Nil	NA	NA
HBI	120	54.22	66.7	NA	-	65.6	60.50	NA	NA
Private sector									
Chiron behring	150	72.36	87.18	73.12	86.99	73.12	86.99	100	100
Sanofi pasteur	20	06.66	06.66	10.44	10.44	10.44	10.44	100	100
Bharat biotech	120	90.00	90.00	35.20	35.20	35.20	35.20	100	100
Cadila health	84	18.77	42.00	18.25	14.51	18.25	14.51	100	100
SIIL	40	04.60	04.60	NA	NA	NA	NA	NA	NA
Total	536	246.61	297.14	137.01	147.14	202.61	207.64	-	-

All the figures are in 100,000 doses of anti-rabies vaccines. Source: Government of India, Central Bureau of Health Intelligence, National Health Profile, March, 2017, Nirman Bhawan, New Delhi plus individual Pharma houses. HBI: Human Biologicals Institute, PII: Pasteur Institute of India, SIIL: Serum Institute of India Limited, NA: Not available

Table 2: Market value and size of rabies vaccines in India: 2016-2017

Brand	Type	Company	Market Value	Market Value	Market Value GR	Market Unit	Market Unit	Market Unit GR
			August 16	August 17	August 17	August 16	August 17	August 17
Abhayrab 0.5 and 1 (mL)	PVRV	IIL	29.2	59.0	102.0	1121.6	2272.3	102.6
Rabipur 1 (mL)	PCEC	GSK LTD.	103.2	30.1	-70.8	3684.7	1144.9	-68.9
Vaxirab 1 (mL)	PCEC	Zyodus Cadila	7.5	16.3	189.2	281.3	659.4	222.0
Zoonovac-V 0.5 (mL)	PVRV	BSVL	1.2	9.7	723.0	43.2	376.9	771.8
Xprab 0.5 (mL)	PVRV	Sun Pharma	13.0	8.8	-32	504.5	368.2	-27.0
Indirab 0.5 (mL)	PVRV	BBIL	0.2	0.5	180.4	7.4	20.8	181.0
Total market			154.3	124.4	-19.7	5667.0	4842.8	-14.5

Market value in Rupees in crores; Units in 000s. PVRV: Purified verocell rabies vaccine, PCEC: Purified chick embryo cell vaccine, GR: Growth rate as compared to previous year, BBIL: Bharath Biotech International Limited

Geographical distribution/sales of rabies vaccines

The state wise distribution/sales of rabies vaccine vials were as follows: Delhi (15,460), Haryana (95,710), Punjab (170,100), Uttar Pradesh and Uttarakhand (170,800), Bihar (41,300), Chhattisgarh (33,110), Jharkhand (22,030), Odisha (6160), West Bengal (115,980), North Eastern states (134,630), Madhya Pradesh (76,180), Vidarbha (13,820), Gujarat (57,000), Maharashtra (107,080), Rajasthan (43,090), Karnataka (230,770), Kerala (10,110), Tamil Nadu (25,060), Andhra Pradesh (13,760), and Telangana (17,130). This showed that the sales of ARV were highest in the northern region followed by South and other regions.

Likewise, the rabies vaccines procurement in 2017 (as of 11th December) according to the route of administration were 34% for intramuscular (IM) route (mostly private), 34% for intradermal (ID) route (only Government), and 32% for both IM and ID (Government/Private).

Landscape analysis

A landscape analysis of rabies vaccine market showed the following:

Type of rabies vaccine market:

The market is broadly categorized as follows:

- Prescription market – Comprising of General Practitioners (GPs) (MBBS and Others); Physicians in Government and private Corporate Hospitals
- Dispensing market – GPs; Pediatricians and doctors in Government hospitals, nursing homes, specialized ARCs, corporate hospitals and others
- Tender market – Government hospitals and some/large private hospitals.

The vaccines are mostly administered free of cost by ID route in Government sector; and in private sector, it is by IM route for a fee payable by the patient. The approximate cost/charges vary from INR 400/to INR 600/dose (USD 6–9 approximate).

The prescription market constitutes the largest market share and the stake holders are diverse. The main segments include GPs, pediatricians, physicians, surgeons, doctors in both private and some government hospitals/health centers where vaccines are not stocked/not available.

Pediatricians

Many pediatricians dispense rabies vaccines or order from a nearby stockist/distributor/chemist/drug shop when a case of animal bites reports. As the rapport of the pediatricians with the parents of the children is good, now, the pharmaceutical companies are targeting them to promote preexposure rabies vaccination/prophylaxis (PrEP).

General practitioners

As dog bites results in wounds, the victim invariably reports to a GP. The GPs usually stock the rabies vaccines or procure from a nearby drug/chemist shop depending on the number of cases seen, affordability of the patients, facility to keep a refrigerator, etc. The GPs are generally targeted by the

pharmaceutical companies for promoting the rabies vaccines in both urban and rural areas.

Private/corporate hospitals/nursing homes

In the metro and large cities, corporate and private hospitals are now a popular and growing segment for emergency medical care for convenience and invariably have an in-house chemist storing rabies vaccines. In the smaller cities, the nursing homes (smaller private hospitals owned and run by a doctor) offer antirabies treatment.

Government hospitals

They procure the rabies vaccines through tenders and during exigencies purchase from the local market. The state government procures the vaccines for all the government hospitals through an agency specially created for procuring drugs, vaccines, devices, etc., known as drugs logistics society/corporation/medical services corporation, etc. This constitutes a significant portion of the market share for the pharmaceutical companies.

Rabies immunoglobulins

Availability, market mapping and landscape analysis.

Availability of rabies immunoglobulins

The currently available RIGs are of two types:

- i. Equine rabies immunoglobulin (ERIG) (indigenously produced): Equirab, VINRIG, AbhayRig, Premirab, and ARS
- ii. Human rabies immunoglobulin (HRIG) (all imported): Berirab-P and Plasmarab.

All ERIGs (5) are indigenously produced; whereas all HRIGs (2) are imported. The indigenously produced ERIGs are also exported. The current scenario of ERIG production is as follows [Table 3]: Installed capacity and the production in Government sector were 3.2% and 2.3%, respectively, showing a poor performance in this area.

ERIGs are provided mostly free of cost in the government hospitals, and their usage in the private sector is limited due to time-consuming skin sensitivity test, fear of anaphylaxis among medical professionals, cumbersome procedure of infiltrating the wounds, and hence, in many instances, the cases are referred to the government hospitals.

The HRIGs are mostly provided mostly in private hospitals for a fee (HRIG cost plus administration charges) which is beyond

Table 3: Current scenario of indigenous production of equine rabies immunoglobulin in India: 2016-2017

Product/company	Installed capacity (vials)/year	Current production (vials)/year
Equirab (BSVL)	1,400,000	572,001 (2016)
Premirab (Premium Serums)	300,000	294,636 (2017)
VinRiG (VINS Biopharma)	2,500,000	600,000 (2017)
Abhay RIG (HBI)*	100,000	12,738 (2017)
ARS (CRI, Kasauli, HP)*	40,000	22,955 (2017)
Total	4,340,000	1,502,330

*Government. ERIG: Equine rabies immunoglobulin

the reach of even the middle-income group and only the rich can afford. Only in the survey state of Gujarat, HRIG was provided free of cost in the Government hospitals and also in a limited way in cases of Adverse Drug Events to ERIG in Kerala state. This is a product that is mostly used in the corporate hospitals and private hospitals that are visited by the rich and high-income group.

Market mapping of rabies immunoglobulins

Market size and value: The market share of RIGs in India is presented in Table 4.

Landscape analysis

Types of market

The market is broadly classified into three types:

- Prescription market: Physicians/surgeons/doctors in government and private hospitals
- Dispensing market: ARCs; corporate hospitals and private hospitals
- Tender market: Government and Private Hospitals.

Pediatricians

Though competent many are reluctant to use ERIGs. Some use HRIGs in those who can afford and when the number of wounds is few and easy to infiltrate.

General practitioners

They are not very clear about the concept of use of RIGs and mostly confine to vaccines. Some refer their cases for RIG to speciality ARCs in metro and large cities.^[4]

Government hospitals

The maximum use of ERIGs takes place here as it is provided free of cost/nominal cost to the patient. Hence, the doctors from the private sector and from the peripheral rural health centers refer the dog bite cases to government hospitals after administering the vaccine.

Corporate/private hospitals

As these are visited by those from higher income group, the HRIGs are mostly used here.

Nursing homes

In smaller cities and in the suburbs of bigger cities, RIGs are used based on the affordability of the patient and the professional competence of the medical doctor.

The prescription market has a great share and like for vaccines the stake holders are diverse.

The ERIG market was about 80%–90% and 10%–20% in Government and Private sectors respectively. The current market value is about INR 83 crores. However, these figures do not include the supplies to the government that is not shared easily. However, there are frequent stock outs both in private and government sectors. The manufacturers blame the medical profession for not raising the demand in the government supplies for the drug logistics corporations to call for tenders. The demand in the private sector is limited mostly due to fear of reactions and the tedious process of wound infiltration. Besides, the ERIGs are exported and its share/quantum range from 1% to 50% between the producers.

Rabies monoclonal human antibody

Serum Institute of India private limited, Pune, launched the first global rabies monoclonal antibody (RMAb) (Rabishield) in November, 2017 in India. The product was developed in association with Massachusetts Biologicals Ltd., USA. The RMAb is expected to make inroads into the RIG segment. Serum Institute of India has an installed production capacity of 4 million RMAb vials/year.

Market demand and forecasting

The forecasting of the vaccine and RIG as per the demands is done in the government and procurement of vaccine is done by the respective state governments, mostly through drug logistics societies established for the purpose. The procurement of ERIG is irregular, occasional, and done by only a few states on continual basis. The HRIG is procured for selective/limited/restricted use by some state governments. The forecasting of vaccine demand is usually/mostly based on the current consumption levels plus 10% buffer stock in the Government.

In the private sector, the marketing personnel of the vaccine/ERIG producer/HRIG importer periodically provide to the manufacturer, an estimate of the market demand that is accordingly supplied to the C and F agents for further downward distribution up to retailer level. The stock outs of rabies vaccines and RIGs, in the government was more due to issues of logistics management; in the private sector, it was

Table 4: Market value and size of rabies immunoglobulins in India: 2016-2017

Brand	Type	Company	Market value	Market value	Market value GR	Market unit	Market unit	Market unit GR
			August 16	August 17	August 17	August 16	August 17	August 17
Berirab P; 300 IU; 2 mL	HRIG	BSVL	4.7	4.9	5.7	9.5	10.6	11.3
PlasmaRab; 300IU; 2 mL	HRIG	Plasmagen	NA	NA	NA	NA	NA	NA
Equirab; 1500 IU; 5 mL	ERIG	BSVL	1.1	2.1	98.0	30.0	58.7	95.9
AbhayRig; 1500 IU; 5 mL	ERIG	HBI	2.0	0.5	-73.9	42.1	10.8	-74.5
Berirab P; 300 IU; 2 mL	HRIG	Zyodus Cadila	1.0	0.7	-34.4	2.0	1.5	-27.2
Premirab; 1500 IU; 5 mL	ERIG	Premium Serums	NA	NA	NA	NA	NA	NA
VINRIG; 1500 IU; 5 mL	ERIG	VINS Biopharma	NA	NA	NA	NA	NA	NA
Total market	RIG	ALL	8.8	8.2	-6.2	83.6	81.6	-2.6

(Market Value in INR crores, Units in 000s) (Source: PHARMATRAC, August '17) HRIG: Human rabies immunoglobulin, ERIG: Equine rabies Immunoglobulin, NA: Not available

mostly due to issues related to vaccine/RIG production. The stock outs in the private sector for rabies vaccines was rare; for ERIG and HRIG, it was occasional.

DISCUSSION

Rabies biologicals, i.e., vaccines and immunoglobulins are life saving for humans in all rabid animal exposures. These biologicals should be continuously available throughout the year, in the entire country to prevent and ultimately eliminate human rabies by 2030.^[15] Market mapping and landscaping helps to understand the broader context in which these biologicals are available and design the strategy accordingly, to maximize their impact. Market mapping is especially useful for considering significant expansion or shifts in focus, through rigorous strategic planning process.

The present study showed that most of the available vaccines are indigenously produced in the country mainly by the private pharmaceutical companies and only one from the cooperative sector (HBI). There was very little vaccine produced in the Government sector. The market size of the rabies vaccines was about INR 125 crores; prescription market constituted the largest market share and the stake holders were diverse. The main segments include GPs, pediatricians, physicians, surgeons, doctors in the both private and some government hospitals/health centres where vaccines are not stocked/not available.

Findings/observations in relation to rabies vaccines in India if interpreted through the principles of SWOT analysis, major highlights were as follows:

Strengths: Indigenous production; capacity to upscale and good logistics.

Weakness: Except one producer (Rabipur), none have WHO prequalification (recently in 2019, two Indian vaccines [Rabivax-S and Vaxirab-N] were WHO prequalified); research and development and total absence of vaccine production in the Government sector.

Opportunity: To promote pre-exposure vaccination for special groups and inclusion of PrEP under national immunization schedule in the future.

Threats: Profitability of export market leading to neglect of domestic need/demand.

Dependence on private sector

Such SWOT analyses at the individual company level are also regularly being done and might be contributing toward overall improvement in ensuring rabies vaccines in the country.

In the global context, it is important that the companies go in for WHO prequalification that guarantees international quality and entitles them for supplying to United Nations agencies like the United Nations Children's Fund and others like GAVI, etc.^[16]

All ERIGs (5) are indigenously produced whereas all HRIGs (2) are imported. The ERIGs are also exported. The

ERIG market is about 80%–90% to 10%–20% in Government to Private sectors respectively. The current market value is about INR 83 crores. However, these figures do not include the supplies to the government that information was not shared. However, there are frequent stock outs both in private and government sectors. The manufacturers blame the medical profession for not raising the demand in the government supplies for the drug logistics corporations to call for tenders. The demand in the private sector is limited mostly due to fear of reactions and the tedious process of wound infiltration. Besides, the ERIGs are exported and its share/quantum range from 1% to 50% between the producers.

The SWOT analysis for RIG in the country highlighted the following major aspects:

Strengths: Indigenous production (ERIG); capacity to upscale and good logistics, i.e., transport, cold chain, communications, etc.

Weakness: Import dependent (HRIG); Short shelf life and frequent stock outs (HRIG).

Opportunity: Creating professional awareness about complete PEP, including RIG in all category III exposures, as a lifesaving measure.

Threats: Export of ERIG Vis-a-Vis national vaccine security; Stoppage of import of HRIG that is lifesaving and preferred by the high-income group/rich.

The RMAb is just launched and expected to make inroads into the RIG segment. The SWOT analysis for RMAb highlighted the following issues:

Strengths: The indigenous production of world's first human RMAb; capacity to upscale; good logistics, i.e., transport, cold chain, communications, etc., and proven safety and efficacy in Indian individuals.

Weakness: Not a cocktail of MABs as is the popular demand; costlier than equine RIGs; virtual lack of awareness among medical profession; as a new product, there will be natural hesitation to accept quickly.

Opportunity: Potential to replace the HRIGs and thus prevent their import; growing demand stimulates up scaling and industrial scale of production.

Threats: Some more brands of RMAb are due for launch and low-cost highly purified ERIGs. The findings of the present study suggests that there is a scope and need for improvement in production, supply, and distribution of all the rabies biologicals, more so, indigenously, since, the demand is always increasing as the awareness among public has drastically improved from past decade.

Likewise, a global survey^[17] was conducted by involving all the manufacturers of rabies biologicals, to find out the manufacturing capacity and product characteristics of rabies biologics. 23 of 42 manufacturers, responded, giving a market capacity for 2017 of 90 million vials for human vaccines, 2.5

million vials for RIGs, 2 million vials for monoclonal antibodies, and 181 million vials for dog vaccines. The survey response rate was 55% with, 13, 7, and 10 manufacturers producing human vaccines, immunoglobulins (RIGs and mAbs), and animal vaccines, respectively. Six manufacturers produced more than one rabies biologic type. Most manufacturing sites were in South East Asia (SEARO; 10 respondents) and Europe (EURO, 8 respondents). Using the survey data, 22.5 million patients could complete PEP, assuming a four visit with a 0.5/1 ml dose per visit IM regimen. With a 65% market expansion, a further 14.6 million PEP courses could be available. ID regimens with human vaccine vial sharing increases this value by up to 5-fold, assuming 0.2 ml dose per visit. The study also revealed that, market expansion was possible within 5 years for 8, 6, and 9 manufacturers with a mean potential increase of 65%, 90%–68% for human vaccines, immunoglobulins (including mAbs) and animal vaccines, respectively. The study concluded that, the production capacity could be increased by many manufacturers but was limited by country demand, lack of long-term planning, and restricted market expansion.^[17]

Should countries implement national rabies elimination programs where biologic needs are forecasted and production lead times respected, manufacturers can meet future supply needs toward global elimination of human dog-mediated rabies deaths.^[18] The world has all the tools needed to prevent human deaths from rabies. These tools need to be on hand where and when people are exposed.^[19]

Limitation

Effort was made to gather as extensive data as possible; even then, few inherent limitations related to the stakeholders could not be avoided. In general, pharma houses shared the information only pertaining to their businesses that could be in public domain.

CONCLUSIONS

Market mapping and landscape analysis showed many lacunas in the market availability of rabies biologicals in different parts of the country; therefore, a significant expansion/shifts in focus should be considered, through rigorous strategic planning process to make rabies biologicals available in all the states throughout the year, in view of eliminating human rabies by 2030.

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Conflicts of interest

There are no conflicts of interest.

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