



Accredited Consultants Pvt. Ltd.
AN ISO 10002:2004 & ISO 9001:2008 CERTIFIED COMPANY



ACPL TIMES

A MONTHLY INTERNAL
NEWSLETTER OF ACPL



CS Prasad (MD)

Dear Colleagues,

As we stand at the threshold of Christmas and prepare to welcome the New Year 2026, I would like to take a moment to reflect, appreciate, and look ahead—together.

The year drawing to a close has been one of learning, resilience, and steady progress. In a world marked by constant change, your commitment, adaptability, and teamwork have been the true strength of our organization. Every milestone achieved this year carries the imprint of your dedication and collective effort.

Christmas reminds us of the values that matter most—gratitude, compassion, and togetherness. It is a time to pause, reconnect with our loved ones, and appreciate the simple joys that bring meaning to our lives. As an organization, these same values guide how we work, collaborate, and grow with purpose.



Looking ahead to 2026, we do so with optimism and confidence. New opportunities await us, along with fresh challenges that will call for innovation, courage, and unity. I am confident that with our shared vision and strong culture, we will continue to move forward—stronger and more inspired than ever.

On behalf of the leadership team, I extend my heartfelt thanks to each one of you for your hard work, integrity, and commitment. May the festive season bring you peace, good health, and happiness, and may the New Year open doors to new successes, both professionally and personally.

Wishing you and your families a joyful Christmas and a prosperous, fulfilling New Year 2026.

With warm regards
C S Prasad. (MD)



1. Overview of the Indian Medical Devices Sector

The Indian medical devices industry is one of the fastest-growing healthcare markets globally. It is projected to reach USD 50 billion by 2030, driven by rising healthcare demand, supportive government policies, and increased domestic manufacturing.

The sector includes:

- Diagnostic imaging equipment
- Surgical instruments
- Consumables and disposables
- Orthopedic and rehabilitation devices
- Cardiac and critical-care devices
- In-vitro diagnostics (IVD)

2. Market Drivers

a. Increasing Healthcare Demand

- Growing population with higher life expectancy
- Rising burden of non-communicable diseases (diabetes, CVD, cancer)
- Expanding insurance coverage and government health schemes

b. Government Initiatives

- Production-Linked Incentive (PLI) Scheme for medical devices
- Medical Devices Rules (MDR) 2017 with risk-based classification
- Establishment of Medical Device Parks (Andhra Pradesh, Telangana, Tamil Nadu, Himachal Pradesh)
- Higher import duties to encourage domestic manufacturing

c. Improving Infrastructure

- Expansion of hospitals, diagnostics centers, and telemedicine
- Digital health initiatives (eSanjeevani, Ayushman Bharat Digital Mission)



3. Market Challenges

- High dependence on imports (approx. 70-75%)
- Complex regulatory pathways for high-risk devices
- Limited R&D capacity and skilled workforce
- Pricing pressure due to National Pharmaceutical Pricing Authority (NPPA) regulations on essential devices

4. Investment Opportunities

a. Domestic Manufacturing

High-potential categories for Make in India:

- Low-cost diagnostic equipment
- Catheters, stents, implants
- Home-care and wearable devices
- Surgical consumables

b. R&D and Innovation

- AI/ML-based diagnostics
- IoT-enabled medical devices
- Personalized implants and 3D-printing technologies

c. Export Potential

India can become a competitive export hub for:

- Orthopedic implants
- Disposables (syringes, IV sets, gloves)
- Dental equipment
- Low-cost imaging devices



5. Regulatory Landscape

Class	Risk Level	Examples
A	Low	Thermometers, Surgical Masks
B	Low - moderate	Suction Pumps, IV Cannulas
C	Moderate-high	Ventilators, Infusion Pumps
D	High	Heart Valves, Implantable devices

Registration requirements include:

- Device Master File (DMF)
- Quality Management System (ISO 13485)
- Clinical evidence (depending on device class)
- Import License or Manufacturing License

6. Future Outlook

The Indian medical device industry is expected to grow at a CAGR of 15–20%, driven by:

- Increased localization of manufacturing
- Digitalization and AI-driven devices
- Demand for affordable solutions in emerging markets
- Rising investment from global manufacturers

7. Conclusion

India presents a high-growth, high-potential environment for medical devices with strong government support, expanding healthcare needs, and increasing domestic capabilities. While regulatory and import-dependence issues remain, the long-term outlook is strongly positive.

Cosmetovigilance is the system for monitoring, evaluating, and preventing adverse effects linked to the use of cosmetic products. It is similar to pharmacovigilance but applies specifically to cosmetics (e.g., skincare, makeup, hair products, perfumes, etc.).

Definition

Cosmetovigilance is a public health surveillance system aimed at identifying and assessing undesirable effects (UEs) and serious undesirable effects (SUEs) resulting from cosmetic product use.



Objectives

1. Detect adverse reactions (allergies, irritations, burns, etc.).
2. Evaluate their severity and causality.
3. Prevent recurrence through corrective actions (product reformulation, withdrawal, updated usage instructions).
4. Ensure consumer safety and regulatory compliance.

Key Concepts

Undesirable Effect (UE)

A harmful reaction occurring under normal or reasonably foreseeable use of a cosmetic product.

Serious Undesirable Effect (SUE)

A reaction leading to:

- Hospitalization
- Permanent functional incapacity
- Life-threatening situation
- Death
- Congenital anomalies
- Immediate medical intervention to avoid such outcomes

SUEs must be reported to authorities.



Examples of reported effects

- Contact dermatitis
- Irritant dermatitis
- Allergic reactions (e.g., fragrances, preservatives)
- Burns or depigmentation (chemicals, depilatories, hair dyes)
- Infections (contaminated products)
- Photosensitivity reactions

Reporting Process

1. Consumer or healthcare professional notices an adverse event.

2. Information is reported to:

- Manufacturer
- Responsible Person
- National health authority (for SUEs)

3. Case evaluation:

- Clinical description
- Product history
- Exposure details
- Laboratory tests if needed

4. Corrective actions



Why cosmetovigilance is important

- Cosmetics are widely used daily.
- Many contain potential allergens or sensitizers.
- Ensures ongoing safety monitoring even after products enter the market.

MOST GREAT PEOPLE HAVE ACHIEVED THEIR GREATEST SUCCESS JUST ONE STEP BEYOND THEIR GREATEST FAILURE. - NAPOLEON HILL



Below is a clear and concise list of common winter climate-related diseases and the precautions you can take to prevent them.

1. Common Cold

- Caused by various viruses (rhinovirus most common).
- Symptoms: sneezing, runny nose, sore throat, mild fever.

2. Influenza (Flu)

- More severe than the common cold.
- Symptoms: high fever, body aches, extreme fatigue, cough.

3. Pneumonia

- Infection of the lungs caused by bacteria, viruses, or fungi.
- Symptoms: chest pain, high fever, cough with phlegm, difficulty breathing.

4. Asthma Exacerbations

- Cold air can trigger bronchial tightening.
- Symptoms: wheezing, shortness of breath, chest tightness.

5. Bronchitis

- Inflammation of bronchial tubes.
- Symptoms: persistent cough, mucus, chest congestion.

6. Strep Throat

- Bacterial throat infection (Streptococcus).
- Symptoms: severe sore throat, fever, swollen tonsils.

7. Norovirus / Stomach Flu

- Spreads more easily in winter due to indoor crowding.
- Symptoms: vomiting, diarrhea, stomach cramps.

8. Hypothermia

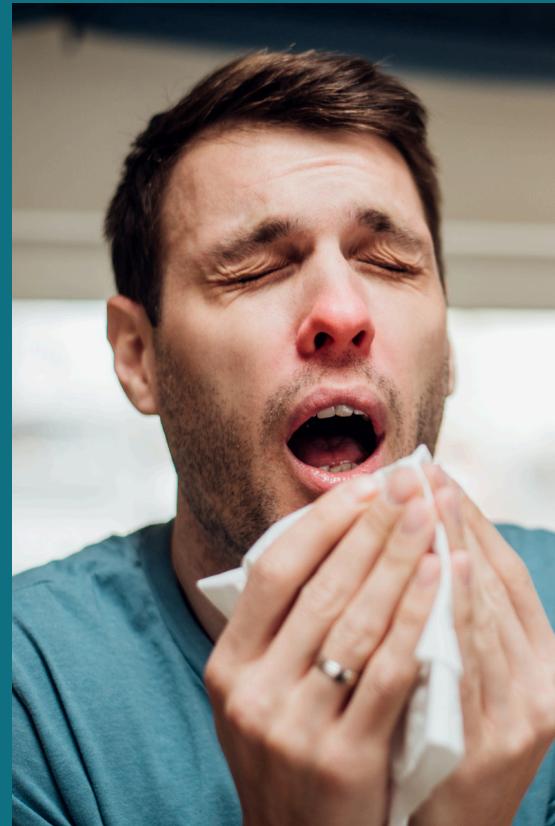
- Body temperature drops dangerously low due to cold exposure.
- Symptoms: shivering, confusion, slurred speech.

9. Frostbite

- Damage to skin/tissues due to freezing temperatures.
- Symptoms: numbness, pale/blue skin, hard or waxy appearance.

10. Seasonal Affective Disorder (SAD)

- Caused by reduced sunlight exposure.
- Symptoms: low mood, fatigue, sleep disturbances.



INDIA ENTRY STRATEGY



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Enter the Indian Market with Confidence

Expand Your Business in India with the Right Partner

Looking to enter the Indian market smoothly and compliantly?

Accredited Consultants (ACPL) is your trusted India entry partner with 25+ years of proven expertise.

We support global companies across:

- ✓ Medical Devices
- ✓ Cosmetics
- ✓ In Vitro Diagnostics (IVD)
- ✓ Active Pharmaceutical Ingredients (API)
- ✓ Pharmaceuticals

Please email us at info@acplgroupindia.co.in for knowledgeable advice. Check out all of our offerings at www.acplgroupindia.co.in



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End-to-End India Entry Support by ACPL

How ACPL Helps You Succeed in India

✓ Incorporation & Legal Setup

Subsidiary | JV | Authorized Agent | FDI compliance

✓ Regulatory Approvals

CDSCO | BIS | DCGI | Product registration & licensing

✓ Market Intelligence

Industry analysis | Competitive positioning

✓ Customer & Market Research

Demographic, geographic & cultural insights

✓ Go-to-Market Strategy

Pricing, distribution & sales planning

✓ Partnerships & Networking

Distributors, agents & strategic alliances

✓ Risk Analysis & Localization

Operational risk planning | Product & packaging alignment

1. Strengthen Immunity

- Eat vitamin-rich foods (Vitamin C, D, zinc).
- Include warm soups, leafy greens, citrus fruits, nuts.

2. Stay Hydrated

- Drink warm water/herbal teas.
- Humidify indoor air to prevent dryness.

3. Dress Properly

- Layer clothing.
- Cover head, ears, hands, and feet.
- Use thermal wear in extreme cold.

4. Maintain Hygiene

- Wash hands frequently.
- Avoid touching face.
- Use sanitizer in public places.

5. Boost Indoor Ventilation

- Avoid staying in closed, crowded rooms.
- Let in fresh air for a short time daily.

6. Get Vaccinated

- Annual flu shot.
- Pneumococcal vaccine for high-risk groups.

7. Protect Respiratory Health

- Wear masks in crowded or polluted areas.
- Use steam inhalation if congested.

8. Stay Warm Outdoors

- Limit exposure during extreme cold.
- Keep emergency warm clothing in vehicles.

9. Manage Chronic Conditions

- Asthma: keep inhalers accessible.
- Heart patients: avoid sudden exposure to cold.

10. Mental Health Care

- Get morning sunlight.
- Exercise regularly.
- Maintain a consistent sleep schedule.



THE ONLY PERSON YOU ARE DESTINED TO BECOME IS THE PERSON
YOU DECIDE TO BE. - RALPH WALDO EMERSON

Once upon a time, two monks – one old and one young – were walking along a mountain road after the rain. The path was muddy and slippery.

They came to a river where the water was flowing fast. On the bank stood a young woman. Her clothes were neat, but one of her legs was injured, so she walked with a limp and did not dare step into the water.

She looked at the two monks and said softly:

“Dear masters, my leg is hurt. I’m afraid to cross the river alone. Could you please help me?”

The young monk felt uncomfortable. He thought:

“I am a monk... how can I touch a young woman?”

But the old monk did not say a word. He gently bent down, lifted the girl onto his back, and carefully walked across the river, trying not to let water splash onto her injured leg.

When they reached the other side, he put her down. The girl bowed in gratitude and limped away on the path.

The two monks continued their journey. They walked for a long time.



The young monk still looked upset and tense. Finally, he could not hold it in anymore and said:

“Master, we are monks... How could you carry a young woman like that?”

The old monk answered calmly:

“I put her down by the river a long time ago. Why are you still carrying her in your mind?”

In that moment, the young monk suddenly understood:

Very often, the real burden is not what we carry on our back, but what we refuse to put down in our heart.

Lesson 1: Many things in life are already over, but we keep suffering because we replay them again and again in our mind.

Lesson 2: Attachment and judgment in our thoughts are sometimes heavier than the actual situation.

Lesson 3: When we learn to let go inside, the road ahead becomes lighter, even if nothing outside has changed.



AN AFRICAN PROVERB

THE PLANT GOD FAVORS WILL GROW EVEN WITHOUT RAIN.

MEANING : DESPITE EXTERNAL CIRCUMSTANCES WHAT IS MEANT FOR YOU WILL BE RECEIVED.

Cultural Roots of secret santa does not come from one single inventor or country. It evolved from older traditions of anonymous giving, mainly in Europe.

Saint Nicholas (4th century, present-day Turkey) known for giving gifts secretly to people in need. This idea of anonymous generosity is the spiritual foundation of Secret Santa.

Christian charity traditions. In medieval Europe, anonymous gift-giving was encouraged as a moral virtue, especially during Christmas.

Scandinavian Influence (Northern Europe)

One of the clearest ancestors of Secret Santa is the Scandinavian tradition:

“Julklapp” (Sweden, Norway, Finland)

- A gift is secretly delivered
- Often anonymously
- Sometimes with playful clues or jokes
- This strongly resembles modern Secret Santa.

Modern Secret Santa (19th–20th Century)

The modern version of Secret Santa developed much later.

- United States & Western Europe (late 1800s-early 1900s)
- Became popular in:
 - Schools
 - Churches
 - Offices



Why so popular ?

- Growing workplace communities.
- Need for a way to:
 - Include everyone
 - Keep gifts affordable
 - Avoid social pressure to buy gifts for many people

Secret Santa solved this by:

- One gift per person
- Equal spending
- Random name selection

Global Spread

Secret Santa spread worldwide through:

- Christian Christmas traditions
- Colonial influence
- Global workplaces
- Media & pop culture
- Internet & online name generators

Today, it's common in:

- North & South America
- Europe
- Australia & New Zealand
- Parts of Asia & Africa (especially multinational offices)

Even in non-Christian countries, it's often practiced as a secular, fun game, not a religious ritual.

Why It Became So Popular Worldwide

Secret Santa works globally because it is:

- Simple
- Inclusive
- Low-cost
- Social
- Fun and suspenseful



Core universal idea:

Give joy anonymously without obligation or competition.

In One Line

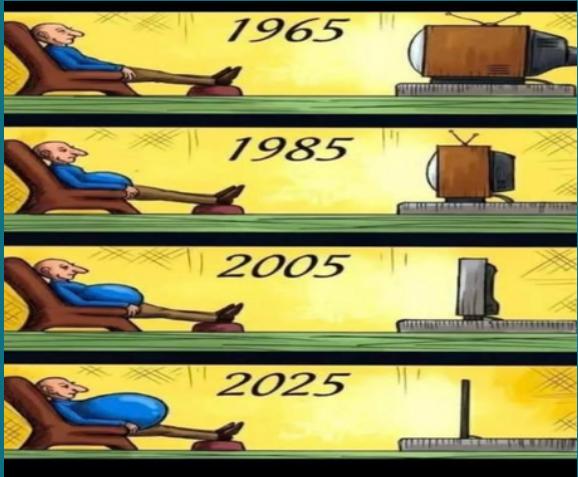
Secret Santa evolved from ancient anonymous charity (Saint Nicholas), blended with European winter traditions, and was modernized in workplaces in the 20th century—then spread globally through culture and commerce.

CDSCO has issued a circular on 5th December 2025 regarding new provision of Risk Classification of Medical Devices on the CDSCO online system for Medical Devices.

CDSCO has put a Gazette notification on 15th December 2025 on Draft Notification for amendment in Medical Device Rule 2017.

CDSCO issued a public notice on 5th December 2025 on MedTech Mitra's In-Vitro Diagnostic Innovators Handbook.

CDSCO issue a public notice on 10th December 2025 with list of Ethics Committees cancelled by CLA.



Laugh It Out

Einstein was right. Energy (and mass) is never created or destroyed, but only transferred

Thank you for reading

Please connect any exceptional achievements, new initiatives , specific information related to ACPL Group of companies or any other individual contributions like poems, stories ,Jokes etc to hr@acplgroupindia.co.in for incorporating the same in the upcoming editions of ACPL times.