International regulatory activities based on PMDA International Strategic Plan 2015

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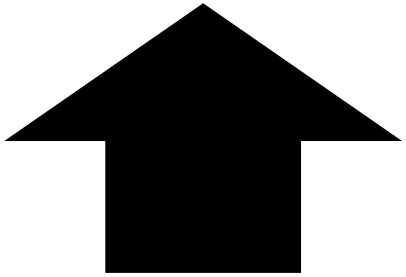
pmda

3rd 5-year plan for PMDA's activities (FY2014 - 2018)

[Goals]

1. Extending health and life span of Japanese people
2. Contribution to global medicine
3. Activation of industries



Development of
Japan-original innovative products

[Major Challenges]

1. Shortening the time from early development to approval
2. High quality review/consultation services
3. Enhancing safety measures
4. **<u>Globalization</u>**

Announcement of PMDA's International Strategic Plan 2015 on 26 June 2015

Structure - PMDA's International Strategic Plan 2015

Vision - PMDA's International Strategic Plan 2015

1. To contribute to the world through regulatory innovation

   PMDA will, based on regulatory science, promote public health globally by communicating the outcomes of its first-in-the-world product reviews, safety measures, and relief services

2. To maximize the common health benefits to other countries/regions

   PMDA will, in order to realize quicker access to more effective and safer medical products for patients around the globe, communicate more closely with countries around the world to promote regulatory harmonization and collaboration

3. To share the wisdom with other countries/regions

   PMDA will, by fully utilizing the accumulated knowledge and experience, contribute to the public health of partner countries/regions through provision of information and training that are essential for building regulatory capacity in those countries

Highlights of Strategy - PMDA's International Strategic Plan 2015 (1/2)

1. Taking the lead, and disseminating the information around the globe
   - **a.** **Establish the "Regulatory Science Center"** to provide consultations, conduct product review, and implement safety measures based on the latest science (by end of FY 2018)
   - b. Proactively **publicize globally the knowledge and experience** of PMDA

2. Promoting international regulatory harmonization and global cooperation
   - **a.** **Expand the range of collaborative activities** between regulatory authorities in Japan and EU, US etc.
   - b. Further expedite **harmonization of the Japanese Pharmacopeia, EP and USP** through the activities of the Pharmacopoeial Discussion Group (PDG)

Highlights of Strategy - PMDA's International Strategic Plan 2015 (2/2)

3. Increase efficiency of inspections that may lead to future international work-sharing
   a. Streamline international **collaboration in GMP/GCP inspections**

4. **Contribution to international regulatory harmonization activities**
   a. ICH, IGDRP, ICMRA etc.

5. Provision of information and training programs that are essential for building regulatory capacity in partner countries
   a. Establish the "Asian Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs"
   b. Deepen mutual understanding and trust of key ASEAN countries, China/Korea, BRICs, and other countries **through bilateral meetings and symposia**.

Positive commitment to ICH, ICMRA etc. – Example of achievements (1/3)

1. Japan took a lead in ICH in Japan in Nov. 2016 as a Vice Chair of its Assembly and Chair of its Management Committee.

2. The next Summit of Heads of Medicines Regulatory Agencies and ICMRA will be hosted by Japan in Oct. 2017.

3. 7th International Meeting of World Pharmacopoeias in Japan in Sep. 2016 resulted in the completion of Good Pharmacopoeial Practices (GPhP) and agreement of next activities.

4. Bilateral symposium with regulatory authority
   Brazil (Sep. 2015, Oct. 2016), Chinese Taipei (Nov. 2015), Thailand (Mar. 2016), India (May 2016), South Korea (Jun. 2016)

Asia Training Center – Example of achievements (2/3)

1. Established in April 2016
2. Organize training programs held in Japan and overseas
3. Exchange staff members for on-the-job training
4. Training themes:
   - Best Regulatory Practices in Product Review, Safety Info Analysis, etc.
   - ICH, IMDRF, IGDRP, ICCR, PIC/S Guidelines
   - Specific topics per request by partner country

Training held / to be held in FY2016

[PMDA-ATC Seminars]

- Pharmaceutical Review (25-29 Jul, Japan)
- Pharmaceutical Review (26-29 Sep , Thailan
- GMP Inspection (5-9 Dec, Japan) [co-hostec

[APEC-LSIF-RHSC CoE Pilot Workshop]

- Good Registration Management (15-17 Nov, Chinese Taipei)
- MRCT/GCP Inspection (23-26 Jan 2017, Japan)
- Pharmacovigilance (6-9 Feb 2017, Japan)

GMP MRA Expansion between Japan and EU – Example of achievements (3/3)

Based on close collaborative activities between GMP experts in Japan and EU, the Agreement on the Mutual Recognition (MRA) of GMP for pharmaceuticals between Japan and EC was amended to include the following competent authorities;

Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia, Bulgaria, Romania and Croatia

厚生労働省
Ministry of Health, Labour and Welfare

文字サイズの変更 標準 大 特大

テーマ別に探す | 報道・広報 | 政策について | 厚生労働省について | 統計情報・白書 | 所管の法令等

ホーム > 報道・広報 > 報道発表資料 > 2016年4月 > 医薬品GMPに関する日EU相互承認の対象国が拡大しました

平成28年4月25日
【照会先】
医薬・生活衛生局監視指導・麻薬対策課
分 析 官　工藤（内線2765）
課長補佐　日下部 哲也（内線2763）
（代表電話）03-5253-1111
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報道関係者各位

医薬品GMPに関する日EU相互承認の対象国が拡大しました

4月22日（日本時間同日）ブリュッセルにて、相互承認に関する日本国と欧州共同体との間の指定の医薬品に係る優良製造所基準（GMP）に関する分野別附属書を改正する外交上の公文の交換が行われました。
この附属書改正は、我が国のGMP要件とその実施の同等性を確認した国として、既存の15カ国※1に加えて、新たに13カ国（ブルガリア、キプロス、チェコ、クロアチア、エストニア、ハンガリー、ラトビア、リトアニア、マルタ、ポーランド、ルーマニア、スロバキア、スロベニア）を、医薬品GMPに関する相互承認の対象国とするものです。
これにより、GMP相互承認の対象医薬品※2に関して、いずれのEU加盟国との間で輸出入する場合にあっても、流通する製品の品質確保が適切に実施されるよう、
○ 日本及びEU加盟各国の規制当局が実施したGMP適合性確認結果を相互に受け入れ、
○ 輸入製品について、輸出元の外国製造業者が行った試験検査の記録を確認することをもって当該輸入製品に係る国内製造業者による試験検査に代えることができる 等、
規制当局における業務効率化、企業の負担軽減等につながることが期待されます。

※1　オーストリア、ベルギー、デンマーク、フィンランド、フランス、ドイツ、ギリシャ、アイルランド、イタリア、ルクセンブルク、オランダ、ポルトガル、スペイン、スウェーデン、英国（以上、平成16年5月から協定適用）
※2　現在のところ、化成品の非滅菌製剤（錠剤、カプセル剤等）がGMP相互承認の対象医薬品となっています。なお、今般の対象国拡大に引き続き、化成品以外も含めて具体的な対象医薬品拡大の議論を、EUの担当当局である欧州医薬品庁との間で進めているところです。

Thank you

MHLW

PMDA