厚生労働省
Ministry of Health, Labour and Welfare

pmda

JFMDA
The Japan Federation of Medical Devices Associations

Report on collaborative activities related to QSD/QMS

2nd Joint Conference of Taiwan and Japan on Medical Products Regulation

31 Oct 2014

QSD/QMS WG

Members of QSD/QMS Working Group

Taiwan Group	
Ms. Yu-wen Ruby Huang	Section Chief, TFDA, Division of Medical Device and Cosmetics
Ms. Yu-Hsuan Chen	Senior Technical Specialist, TFDA, Division of Risk Management
Ms. Fongan Lee	Senior Inspector, Industrial Technology Research Institute
Mr. Brian Lai	St. Shine Optical Co., Ltd.
Japan Group	
Ms. Naoko Sato	Office of GMP/QMS Inspection Pharmaceuticals and Medical Devices Agency (PMDA), Japan
Mr. Hideki Asai	Japan Federation of Medical Devices Associations (JFMDA) QMS Committee Hitachi High-Tech Science Corporation
Mr. Norio Yoda	Japan Federation of Medical Devices Associations (JFMDA) International Policy & Strategy Committee TERUMO CORPORATION

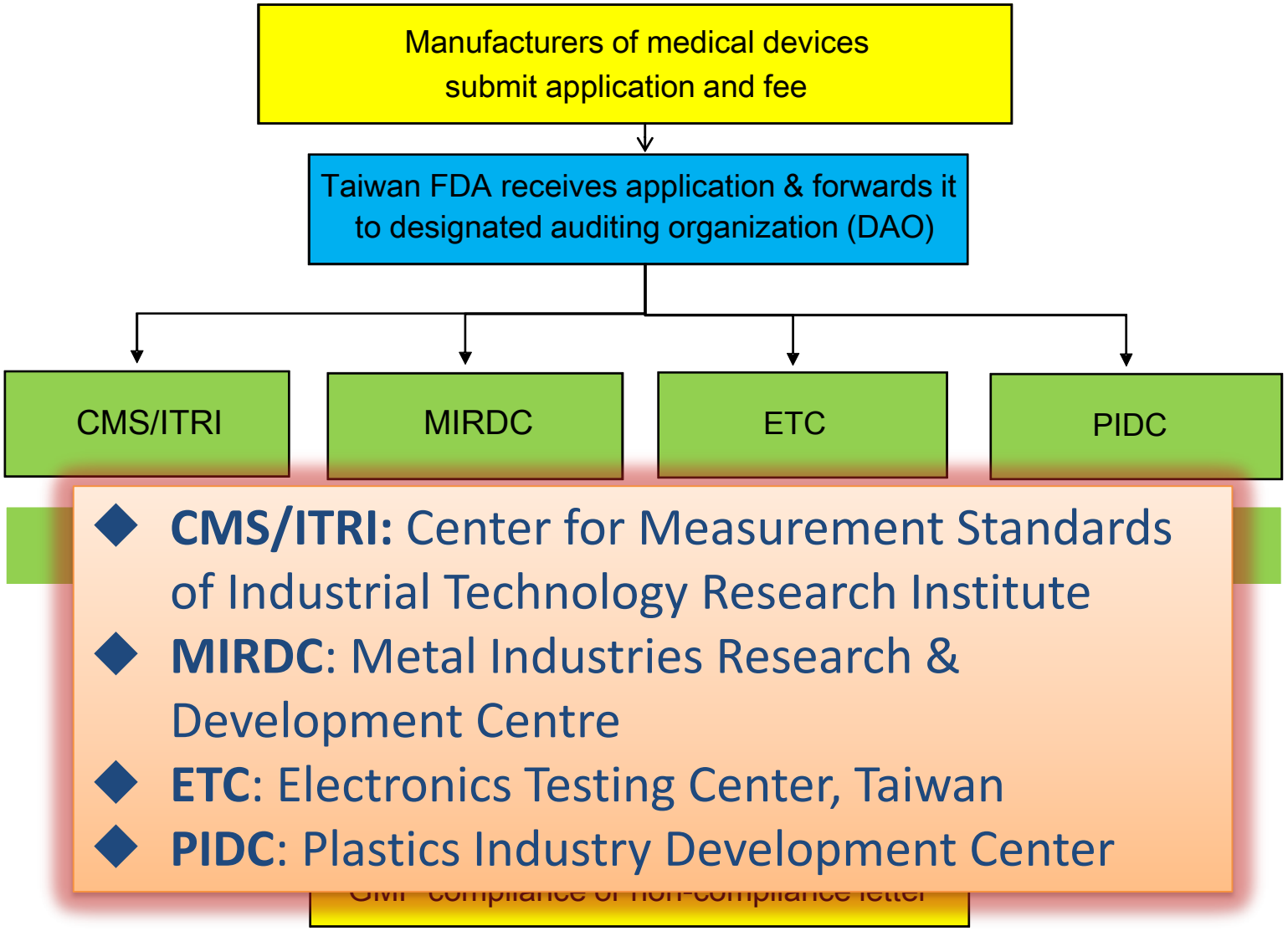
Agenda

1. Regulations on QSD in Taiwan
2. Regulations on QMS in Japan
3. Comparison of regulations between Taiwan and Japan
4. Experiences of QSD/QMS in each party
5. Current measures to utilize outside resources or materials in each party
6. Good measures taken outside both parties
7. Experiences of actual Inspection with the other party
8. Proposals for further activities

Regulations on QSD in Taiwan

- Pharmaceutical Affairs Act
  (http://law.moj.gov.tw/Eng/LawClass/LawSearchNo.aspx?PC=L0030001&DF=&SNo=14,18,57,57.1,58,71,92)
- Standards for Medicament Factory Establishments
  (http://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=L0030008)
- Pharmaceutical Good Manufacturing Practice Regulations (http://law.moj.gov.tw/Eng/LawClass/LawParaDeatil.aspx?Pcode=L0030073&LCNOS=_60_&LCC=1)
- Regulations of Medicament Manufacturer Inspection
  (http://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=L0030009)
- Regulations for the Issuance of Medicinal Products & Medical Devices Manufacturing Licenses & Evidentiary Documents for Good Manufacturing Practices
  (http://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=L0030076)

Regulations on QSD in Taiwan (2)



- **CMS/ITRI:** Center for Measurement Standards of Industrial Technology Research Institute
- **MIRDC**: Metal Industries Research & Development Centre
- **ETC**: Electronics Testing Center, Taiwan
- **PIDC**: Plastics Industry Development Center

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Regulations on QMS in Japan (1)

- Pharmaceutical Affairs Law
- QMS Ordinance
  (MHLW Ministerial Ordinance No.169)
- Q & A Regarding the relation between QMS Ordinance and ISO13485:2003
  (Administrative Notice dated May 30, 2011)
- Mutual acceptance of audit results regarding QMS inspection and surveillance inspection
  (PFSB/CND Notification No. 0401-7, PFSB/ELD/OMDE Notification No. 0401-2 dated April 1, 2011)

Regulations on QMS in Japan (2)

Authority of QMS inspection

Product		Domestic plant	Foreign plant
IVDs	・New drugs ・Radioactive drugs	PMDA	PMDA
	Products without CS*	Prefectures	PMDA
	Products with CS*	Registered certification body	Registered certification body
Medical Devices	・Class Ⅳ ・New medical devices ・Cell / Tissue-based medical devices	PMDA	PMDA
	Class Ⅲ and Class Ⅱ (without CS*)	Prefectures	PMDA
	Class Ⅱ (with CS*)	Registered certification body	Registered certification body

Regulations on QMS in Japan (3)

Authority of QMS inspection (from 25 Nov. 2014)

Product		Domestic plant	Foreign plant
IVDs	・New drugs ・Radioactive drugs	PMDA	PMDA
	Products without CS*	PMDA	PMDA
	Products with CS*	Registered certification body	Registered certification body
Medical Devices	・Class Ⅳ ・New medical devices ・Cell / Tissue-based medical devices	PMDA	PMDA
	Class Ⅲ and Class Ⅱ (without CS*)	PMDA	PMDA
	Class Ⅱ and Class Ⅲ (with CS*)	Registered certification body	Registered certification body

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Comparison of regulations between Taiwan and Japan (1)

	Taiwan	Japan
QMS Requirements	ISO 13485:2003	ISO 13485:2003+α
QMS inspection Organization	4 DAOs	PMDA and RCBs
On-site/ Off-site Documentation Inspection decision	By request, however main practice is “on-site inspection for domestic manufacturers and documentation inspection for overseas manufactures”.	Based on the complexity , risks etc. (page 16)
Accreditation of Foreign manufacturer	Included in QMS inspection (currently , most parts belong to QSD review) .	Current “Accreditation” will be changed into just “Registration” Nov. 2014.
Required documentation for documentation inspection	All of tier2 documentation should be in Chinese or English.	Not all of them should be in Japanese or English. The country’s name does not affect the volume of the countries.

Comparison of regulations between Taiwan and Japan (2)

	Taiwan	Japan
Necessity of ISO or CFG certificate	Mandatory for QSD. •ISO 13485 certificate is required for all QSD submissions. •Under agreement with bilateral cooperation, such as simplified QSD submission, Certificate for Foreign Government (CFG) is required.	Just used for the decision for on-site/documentation and/or abbreviation for the on-site period
Required product data for the Inspection	Device Master File(s) is required for QMS inspection.	As product data, the information from submission or Instruction for Usage (IFU) are almost enough. The detailed data such as the test results are not necessary.

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Development of QSD in Taiwan

- 1998/8/10: Good Manufacturing Practices (GMP) for medical devices announced based on ISO 13485:1996
- 1999/2/10: GMP implementation started and required new manufacturers to submit Quality System Documentation (others had a 5-year transition period)
- 2007/5/30: QSD application form revised and ISO 13485:2003 adopted
- 2013/3/11: GMP for medical devices revised into Part 3 of the Pharmaceutical Good Manufacturing Practice Regulations

Japan- Contents of New QMS Ordinance

Chapter 1.	General Provisions (Article 1~3)
Chapter 2.	**Medical Devices Manufacturing** (Article 4~64) **Harmonized ISO13485:2003**
Chapter 3.	**Additional Requirements** (Article 65~72-3)
Chapter 4.	**Biological-origin Medical Device, etc. Manufacturers (Domestic, Foreign)** (Article 73~79) Added Buildings and Facilities Regulation
Chapter 5.	**In-Vitro Diagnostic Radioactive Reagents Manufacturers (Domestic, Foreign)** (Article 80~81) Added Buildings and Facilities Regulation
Chapter 6.	Provisions Applied Mutatis Mutandis of Medical Device, etc. Manufacturing Sites, etc.(Article 82~84)

Experiences of QMS in Japan (1)

Complexity of manufacturing process

Risk associated with the use of products

Previous nonconformity and recall

On-Site Inspection

Desktop (Off-Site) Inspection

Certificate of ISO13485

Results of the previous on-site inspections

Experiences of QMS in Japan (2)

Examples of mandatory on-site inspections

- New medical devices
- Cell tissue derived medical devices
- Class IV medical devices

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TFDA- Technical Cooperation Program with EU

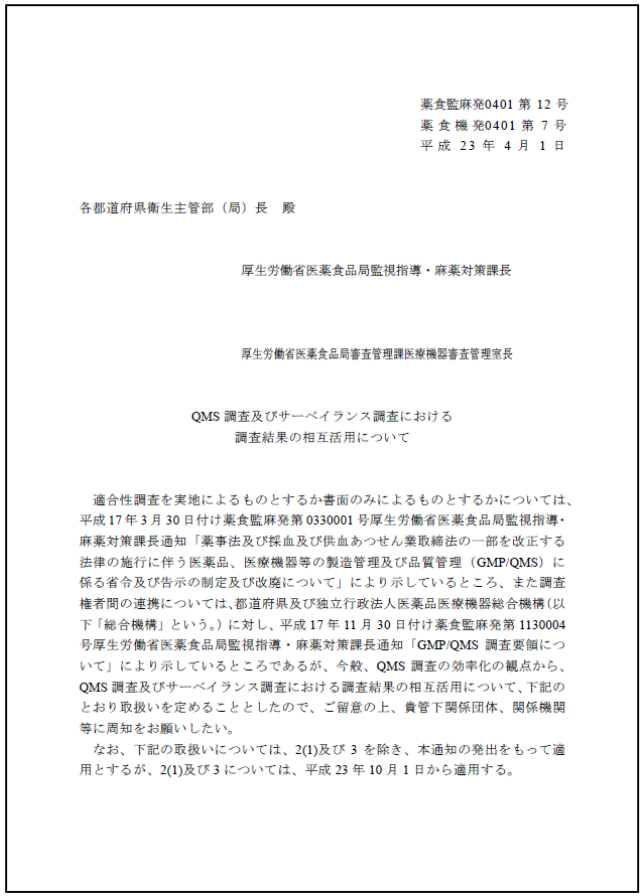
- Designated Auditing Organizations (DAOs) of Taiwan FDA have established a Technical Cooperation Program (TCP) with EU Notified Bodies to facilitate the harmonization of regulatory auditing and to reduce duplicate audits.
- Taiwan FDA recognizes audit reports issued by 11 EU Notified Bodies for use in the QSD submission (i.e., abbreviated QSD submission).
- Under the TCP, the audit report issued by EU-NB (SGS, BSI, TUVPS) that inspected by the recognized auditor of DAOs will be accepted and included as part of documentation for production registration.

TFDA- Technical Cooperation Program with EU (2)

Eleven EU Notified Bodies participate in the TCP:

- TÜV SÜD Product Service GmbH (or TUVPSG, NB0123)
- TÜV Rheinland LGA Products GmbH (NB0197)
- mdc medical device certification GmbH (NB0483)
- MEDCERT (NB0482)
- BSI (NB0086)
- SGS United Kingdom Ltd (NB0120)
- AMTAC Certification Services Ltd (NB0473)
- UL International (UK) Ltd (NB0843)
- LNE/G-MED (NB0459)
- DGM Denmark A/S (NB0543)
- DEKRA Certification B.V. (NB0344)

Utilization of audit results issued by other audit bodies (1)



薬食監麻発0401 第 12 号
薬 食 機 発0401 第 7 号
平 成 23 年 4 月 1 日

各都道府県衛生主管部（局）長　殿

厚生労働省医薬食品局監視指導・麻薬対策課長

厚生労働省医薬食品局審査管理課医療機器審査管理室長

QMS 調査及びサーベイランス調査における
調査結果の相互活用について

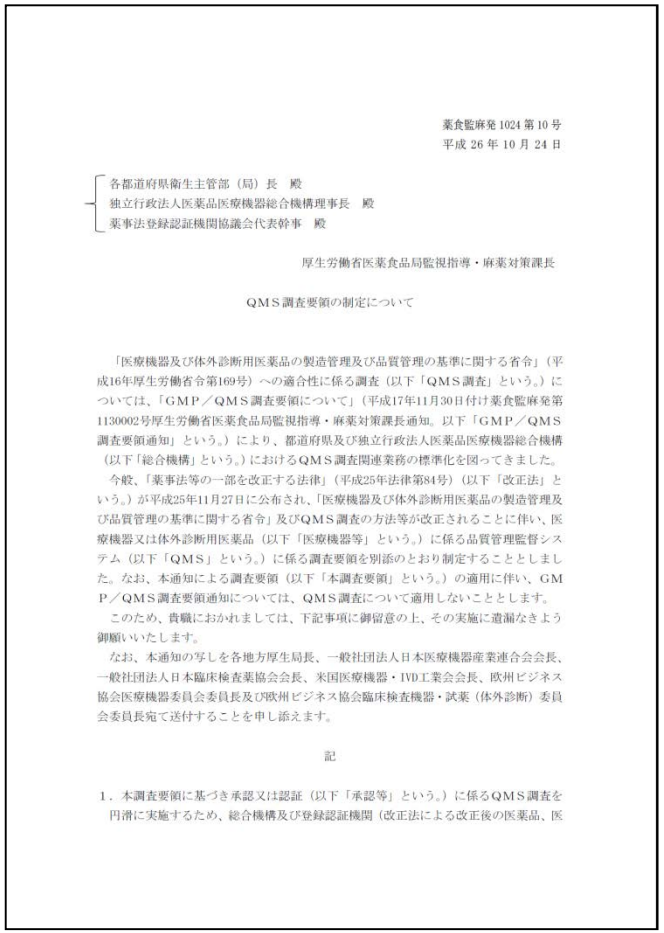
適合性調査を実地によるものとするか書面のみによるものとするかについては、平成 17 年 3 月 30 日付け薬食監麻発第 0330001 号厚生労働省医薬食品局監視指導・麻薬対策課長通知「薬事法及び採血及び供血あっせん業取締法の一部を改正する法律の施行に伴う医薬品、医療機器等の製造管理及び品質管理（GMP/QMS）に係る省令及び告示の制定及び改廃について」により示しているところ、また調査権者間の連携については、都道府県及び独立行政法人医薬品医療機器総合機構（以下「総合機構」という。）に対し、平成 17 年 11 月 30 日付け薬食監麻発第 1130004 号厚生労働省医薬食品局監視指導・麻薬対策課長通知「GMP/QMS 調査要領について」により示しているところであるが、今般、QMS 調査の効率化の観点から、QMS 調査及びサーベイランス調査における調査結果の相互活用について、下記のとおり取扱いを定めることとしたので、ご留意の上、貴管下関係団体、関係機関等に周知をお願いしたい。

なお、下記の取扱いについては、2(1)及び 3 を除き、本通知の発出をもって適用とするが、2(1)及び 3 については、平成 23 年 10 月 1 日から適用する。

PFSB/CND Notification No. 0401-7,
PFSB/ELD/OMDE Notification No. 0401-2
dated April 1, 2011

Mutual acceptance of audit results regarding QMS inspection and surveillance inspection

Utilization of audit results issued by other audit bodies (2)



薬食監麻発 1024 第 10 号
平成 26 年 10 月 24 日

各都道府県衛生主管部（局）長　殿
独立行政法人医薬品医療機器総合機構理事長　殿
薬事法登録認証機関協議会代表幹事　殿

厚生労働省医薬食品局監視指導・麻薬対策課長

QMS 調査要領の制定について

「医療機器及び体外診断用医薬品の製造管理及び品質管理の基準に関する省令」（平成16年厚生労働省令第169号）への適合性に係る調査（以下「QMS調査」という。）については、「GMP／QMS調査要領について」（平成17年11月30日付け薬食監麻発第1130002号厚生労働省医薬食品局監視指導・麻薬対策課長通知。以下「GMP／QMS調査要領通知」という。）により、都道府県及び独立行政法人医薬品医療機器総合機構（以下「総合機構」という。）におけるQMS調査関連業務の標準化を図ってきました。

今般、「薬事法等の一部を改正する法律」（平成25年法律第84号）（以下「改正法」という。）が平成25年11月27日に公布され、「医療機器及び体外診断用医薬品の製造管理及び品質管理の基準に関する省令」及びQMS調査の方法等が改正されることに伴い、医療機器又は体外診断用医薬品（以下「医療機器等」という。）に係る品質管理監督システム（以下「QMS」という。）に係る調査要領を別添のとおり制定することとしました。なお、本通知による調査要領（以下「本調査要領」という。）の適用に伴い、GMP／QMS調査要領通知については、QMS調査について適用しないこととします。

このため、貴職におかれましては、下記事項に御留意の上、その実施に遺漏なきよう御願いいたします。

なお、本通知の写しを各地方厚生局長、一般社団法人日本医療機器産業連合会会長、一般社団法人日本臨床検査薬協会会長、米国医療機器・IVD工業会会長、欧州ビジネス協会医療機器委員会委員長及び欧州ビジネス協会臨床検査機器・試薬（体外診断）委員会委員長宛て送付することを申し添えます。

記

1．本調査要領に基づき承認又は認証（以下「承認等」という。）に係るQMS調査を円滑に実施するため、総合機構及び登録認証機関（改正法による改正後の医薬品、医

PFSB/CND Notification No1024-10
dated October 24, 2014
(effective from November 25, 2014)

QMS Inspection Guidelines
Appendix 1
Decision Criteria for On-site Inspection and Desktop Inspection

- **<u>Utilize the results regarding QMS inspection by other inspection bodies for the decision of On-site inspection or Desktop Inspection</u>**

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International Arrangements of Taiwan

- Taiwan has established cooperative agreements for exchanging medical device information with:
  - United States (**E**xchange **o**f **L**etters, 1998)
  - European Union (EOL, 2001)
  - Switzerland (EOL, 2007)
  - Australia (**M**emorandum **o**f **U**nderstanding, 2010)
  - Liechtenstein (EOL, 2011)
  - UK of Great Britain & Northern Ireland (MOU, 2012)
  - Japan (MOU between 亜東交流協会and 日台交流協会, 2013)

- Mechanisms can be implemented through these agreements for mutual exchange of medical device vigilance reports and audit reports.

QMS Cooperation under EOL with Liechtenstein

- Manufacturers established in Taiwan exporting to Liechtenstein can under this EOL allow the Designated Auditing Organizations of TFDA to present appropriate audit reports to the competent authority of Liechtenstein as part of the documentation regarding access to the market.
- The Liechtenstein Office of Public Health could invite TFDA to observe the inspections of medical device manufacturers in Liechtenstein.
- The Liechtenstein Office of Public Health will recognize the accomplishment derived from TCP cooperation to eliminate duplicate inspection.

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7. Taiwan Experiences of actual Inspection as an observer
8. Proposals for further activities

TFDA Experiences of Actual Inspection

- Taiwan FDA and its DAOs have observed quality system inspection of medical device manufacturer in Belgium.
- Under the TCP, Taiwan FDA's DAOs have conducted audits and prepared audit reports for evaluation by EU Notified Bodies (e.g., TUVPSG, BSI, SGS) as part of the ISO 13485 certification for Taiwan manufacturers.

TFDA Experiences of Actual Inspection (2)

- Taiwan FDA and its DAOs have, on several occasions, participated and observed U.S. FDA's quality system inspections of medical device manufacturers in Taiwan.
- Taiwan FDA and its DAOs have observed Japan PMDA's quality system inspections of medical device manufacturer in Taiwan.

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Proposals for further activities

- QSD/QMS WG identified that the requirement and evaluation process of TAIWAN QSD regulation and Japanese QMS Regulation are almost equivalent.

- QSD/QMS WG will investigate the possibilities to eliminate the duplicate tasks for QSD/QMS submission and evaluation process with abbreviated submission method.

謝謝

Thank you very much
for your kind attention.