Notiziario 21
Prot. 568 / 7 settembre 2017
<www.fimmgtv.org>

Ai Medici della FIMMG di Treviso
Loro Sedi

1. SCIOPERO

Come è emerso nell'ultima Assemblea del 30 agosto, i medici della FIMMG di Treviso erano convinti di non aderire allo sciopero regionale, ma **la lettera inviata** (sulla mail aziendale mai autorizzata, in spregio a ripetute comunicazioni sindacali) **dal Direttore Generale con toni arroganti e intimidatori, ricca di inesattezze finalizzate a seminare il panico nella Categoria, ha sortito l'approvazione all'unanimità della proposta regionale di SCIOPERO.**
Infatti la comunicazione dell'Azienda ULSS 2 Marca Trevigiana (prot. 144598 del 10.8.2017) in risposta alla mobilitazione sindacale da parte di tutte le Organizzazioni Sindacali della Medicina Generale, non solo ha toni e contenuti che testimoniano un'assenza di volontà di dialogo e di confronto, e suona come un vero atto intimidatorio e di pressione nei confronti dei medici, ma trasuda di sentimento antisindacale, inaccettabile per la Categoria.
Per maggiori chiarimenti siete invitati a partecipare alla

2. Assemblea Provinciale venerdì 15 settembre 2017

alle ore 21 in sede, via Montebelluna 2, Treviso, 0422.405095
Odg:
1) **Situazione sindacale**

- **nazionale** (ACN: ricusazione della proposta SISAC)
- **regionale** (Sciopero, Assemblea regionale 16 settembre presso l'Hotel Crowne Plaza, Via Po n. 197 Limena, Catagolo Veneto del Prescrivibile)
- **provinciale** (Patti scaduti, mail aziendale, Oltre CUP, Ecofarmacie e Fascicolo Sanitario, POS, consegna manifesto per MODULI DI RMN/TAC, Rinnovo Consiglio Ordine Medici)

2) **Sciopero regionale della MG**: modalità e ritiro del manifesto

Mese	Giorni	Modalità dello sciopero
Settembre	19 e 20	Cessazione dell'invio telematico di tutte la ricette da parte dei MMG
Settembre	26 e 27	Cessazione dell'invio telematico di tutte la ricette da parte dei MMG
Ottobre	10, 11 e 12	Cessazione dell'invio telematico di tutte la ricette da parte dei MMG
Novembre	8 e 9	Chiusura degli studi medici dei MMG
Dicembre	13 e 14	Chiusura degli studi medici dei MMG
Gennaio	16,17 e 18	Chiusura degli studi medici dei MMG
Febbraio	13, 14 e 15	Chiusura degli studi medici dei MMG
Marzo	13,14, 15 e16	Chiusura degli studi medici dei MMG
Aprile	10, 11, 12 e 13	Chiusura degli studi medici dei MMG
Maggio	15, 16,17 e 18	Chiusura degli studi medici dei MMG

3) Varie ed eventuali.

3. CONVEGNI MEDICI

- Venerdi 22 Settembre 2017 ore 20.30 AIDM organizza "D**onne oggi nei territori di guerra**" Treviso Palazzo dei Trecento
- venerdì 20 e sabato 21 ottobre **Geriatrics in Primary Care, Campo S,stefano 2945** a Venezia; iscrizione gratuita rispondendo a questa mail.

4. FDA Calls for Opana ER's Removal Due to Abuse Concerns

FDA asked EndoPharmaceuticals to pull its opioid pain medication, reformulated Opana ER (oxymorphone hydrochloride) from the market because of concerns that the drug's benefits may no longer outweigh its risks.

This is the first time the agency has taken steps to stop the sale of a currently marketed opioid pain medication based on the public health consequences of possible abuse.

"We are facing an opioid epidemic -- a public health crisis, and we must take all necessary steps to reduce the scope of opioid misuse and abuse," said FDA Commissioner Scott Gottlieb, M.D., in a news release announcing the agency's action. "We will continue to take regulatory steps when we see situations where an opioid product's risks outweigh its benefits, not only for its intended patient population but also in regard to its potential for misuse and abuse."

The FDA said its decision was based on a review of all available postmarketing data, which showed a substantial shift in the route of abuse of the drug -- from nasal to injection -- even after it was reforulated in 2012. That reformulation was intended to thwart physical and/or chemical manipulation that would allow the drug to be snorted or injected.

The agency noted that injection abuse of the reformulated Opana ER has been associated with a serious outbreak of HIV and hepatitis C infections, as well as cases of thrombotic microangiopathy.

"The abuse and manipulation of reformulated Opana ER by injection has resulted in a serious disease outbreak. When we determined that the product had dangerous unintended consequences, we made a decision to request its withdrawal from the market," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research, in the release. "This action will protect the public from further potential for misuse and abuse of this product."
The FDA said if Endo Pharmaceuticals doesn't voluntarily remove reformulated Opana ER from the market, the agency plans to formally require its removal by withdrawing approval of the drug.
This decision comes on the heels of a joint FDA advisory committee meeting(www.fda.gov) in March during which a group of independent experts decided in an 18-8 vote that the benefits of reformulated Opana ER no longer outweigh its risks.
The FDA first approved the drug in 2006 for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.
At that time, despite meeting the regulatory standards for approval, the FDA determined that data on Opana ER didn't show that the reformulation could be expected to meaningfully reduce abuse and declined Endo Pharmaceuticals' request to include labeling that would have described the potentially abuse-deterrent properties of the drug.
Regarding the current development, Endo Pharmaceuticals issued a statement (www.endo.com) the same day as the FDA announcement saying it was aware of the agency's action and was reviewing the request and evaluating "the full range of potential options" as it determines its next steps.
In the meantime, the FDA is focusing its efforts on educating health care professionals about this request to remove Opana ER from the market.
"The FDA will continue to examine the risk-benefit profile of all approved opioid analgesic products and take further actions as appropriate as a part of our response to this public health crisis," the news release said.

5. **FDA: H**erbal Remedy Linked to High Lead Levels, Developmental Delay in Child

Balguti Kesaria Ayurvedic Medicine is an herbal remedy marketed for use in infants and children for various conditions
The Food and Drug Administration (FDA) is alerting parents and caregivers not use Balguti Kesaria Ayurvedic Medicine due to the risk of lead poisoning.
Balguti Kesaria (or Kesaria Balguti) Ayurvedic Medicine is an herbal remedy marketed for use in infants and children for various conditions such as rickets, cough and cold, worms, and teething. According to the product packaging, the product claims to help with digestion and bowel movement and improve the immune system.
The risk of lead poisoning was initially communicated by the North Carolina Division of Public Health who tested the product and found high levels of lead. In addition, the Michigan Department of Health and Human Services notified the FDA that two children were found to have high levels of lead associated with the use of this product. The families of the children affected stated that they had the product mailed to them from India. At this time, the FDA has received one report of developmental delays in a child who was administered this product.
The Agency urges parents and caregivers to stop giving the product to children and to consult a healthcare professional. Balguti Kesaria is sold online and made by different companies, including Kesari Ayurvedic Pharmacy in India. The product has also been mailed or brought into the United States. Healthcare professionals are asked to report any adverse events related to this product to the FDA's MedWatch Adverse Event Reporting Program.

Cordiali saluti

IL SEGRETARIO PROVINCIALE
Dott. Brunello Gorini