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Japan's Efforts to Promote Development of Orphan Medical Devices

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Regulatory Authorities in Japan

MHLW

(Ministry of Health, Labour and Welfare)

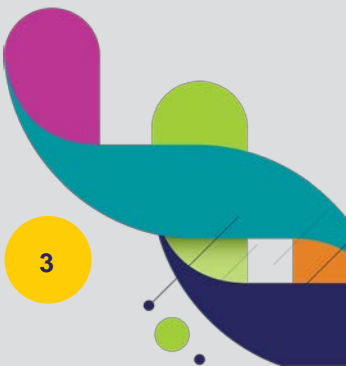
- Law Enforcement
- Final Authorization
- Publishing Guidelines
- Advisory Committee
- Supervising PMDA
- etc.



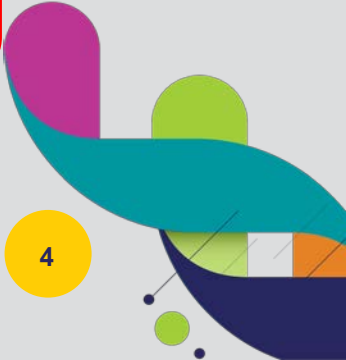
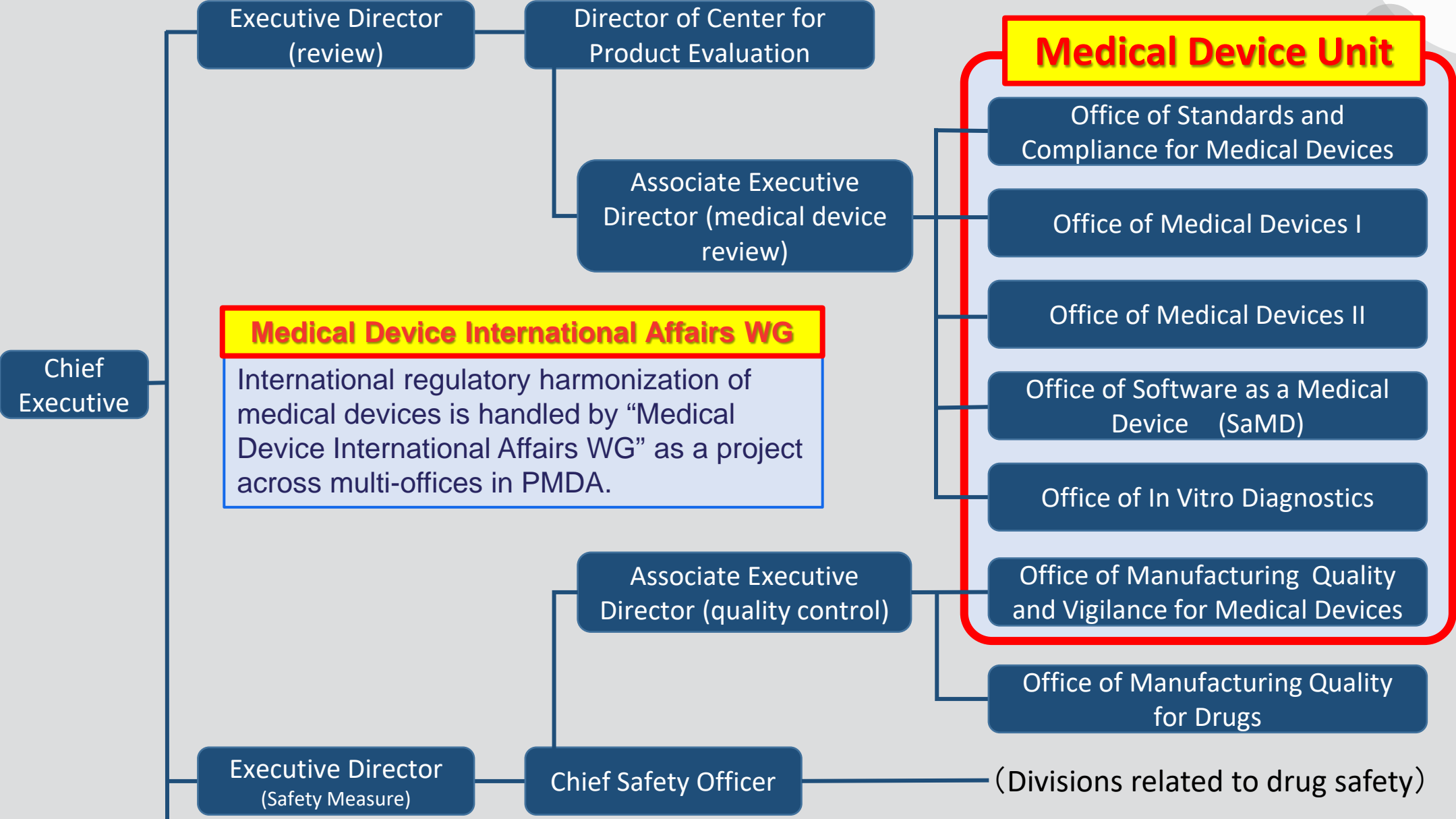
PMDA

(Pharmaceuticals and Medical Devices Agency)

- Scientific Review
- Post Market Safety
- GCP, QMS Inspection
- Consultation on Development Strategy
- etc.



PMDA Organizational Structure



Designation Criteria for Orphan MD

1. Small number of patients

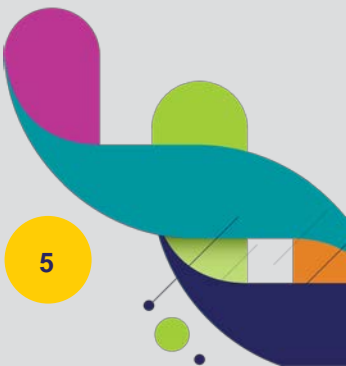
- < 50,000 in Japan (Prevalence Rate < 3.9 in 10,000 people)
- Or designated intractable disease

2. High medical needs

- Unmet needs (No alternative medical intervention is available)
- Significant benefit (Significantly improved efficacy and/or safety expected compared to existing products)

3. High probability of successful development

- Strong rationale to use the product, and an appropriate development plan



Incentives for R&D Promotion

1. Grant-in-Aid for R&D Expenses

- Up to ½ of direct expenditure up to 3 yrs. from NIBIOHN*

2. Administrative and Scientific Advices

- Pre-submission meeting/advices by MHLW on the application for orphan designation
- Administrative and scientific advices by PMDA (Priority Consultation) and NIBIOHN* on R&D after the designation

* NIBIOHN: National Institutes of Biomedical Innovation, Health and Nutrition

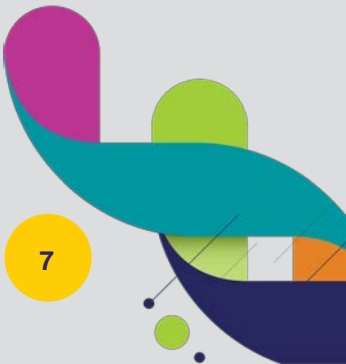
Incentives for R&D Promotion

3. R&D Tax Deduction

- 20% of R&D expenses excluding grant-revenue for orphan products during granted period (up to 3yrs.) is deductible in corporate taxation

4. Priority Review

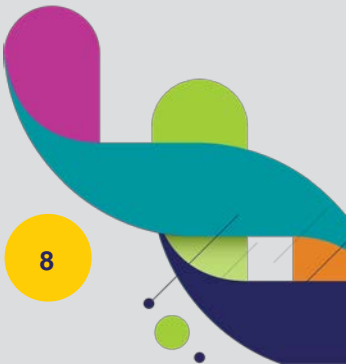
- Priority review (Fast-track review) by MHLW/PMDA
 - SAKIGAKE Designation System, Conditional Early Approval System for Innovative Medical Device Products, etc.
 - 9 months (cf. 12 month for standard new MDs)



Incentives for R&D Promotion

5. Premium for Medical Device Pricing

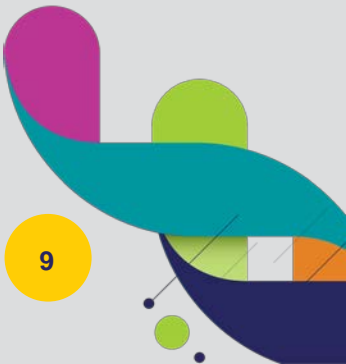
- Orphan medical devices are given the 10% premium.
- The premium is up to 1.5 times of average price in foreign countries. (cf. up to 1.25 times for standard new MDs)
- Unaffected by the market price of other similar medical devices for a period of time.



Designated and Approved Orphan MDs

(Nov. 1993 – Jan. 2023)

Orphan MDs	Products
Designated	32
(Approved)	(22)





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THANK YOU / QUESTIONS

[Contact Us | Pharmaceuticals and Medical Devices Agency \(pmda.go.jp\)](https://pmda.go.jp)

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