THE HOSPITALS' DRUGS & MEDICAL DEVICES COMMITTEES IN FRANCE

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By regulation, a Drugs and Medical Devices Committee has been created in all public and private hospitals established in France.

This committee is defining the hospital internal policy applied to medicinal products and medical devices. In practical terms, several missions should be conducted under the responsibility of this committee:

- The choice of medicinal products and medical devices available inside the hospital (internal formulary)
- Promotion of rational use of these medicinal products and medical devices
- Prevention of iatrogenic risks related to the use of these products
- Quantitative and qualitative evaluation of the use of these health products (including the level of compliance to valid recommendations for use of these drugs and devices)

Various competences defined by national regulation contribute to the work of this committee:

- Physicians and pharmacists (20 maximum in total, with a number of pharmacists not superior to but at least one third of the total number of physicians)
- One representative of nurses
- One representative of pharmacist assistants
- The qualified person in charge of risk management and control of nosocomial infections in the hospital
- The qualified person in charge of pharmacovigilance in the hospital
- The qualified person in charge of risk surveillance of medical devices in the hospital

Members of the committee should not only participate in their speciality but on all subjects as they should prepare subjects and discussions in advance and are nominated for their experience and ability for multidisciplinarity. However, if needed, other professionals from the hospital not member of the committee can be involved on specific issues when additional expertise is needed on an ad hoc basis.

Each meeting should be organised and run according to internal rules defined at the hospital level in order to insure a fair and transparent process: agenda and related documentation timely available, quorum, voting procedure, minutes with rules of adoption, evaluation procedure before providing opinions, etc. Chair and co-chair(s) should be elected by peers and for a limited number of mandates (two).

Agenda and minutes (once formally adopted) encompassing opinions of the committee on each specific subject should be internally published (e.g. on the hospital intranet portal).

Choice of drugs and medical devices to be bought and used by each hospital represent a major subject assessed by these committees. Procedures vary depending on local organisations but basic principles should be applied. Templates can be used to facilitate evaluation of each product (see example in annex). Management of conflicts of interests of staff members participating to this scientific evaluation and selection of products is essential for credibility of the committee and of its opinions established on evidence based medicine principles. Written and updated (at least yearly) assessment of interests of professionals involved in these procedures should be systematically collected.

For selecting specific medicinal products for their internal formulary, they can use scientific opinions delivered by a specific national committee responsible in France to evaluate the possible (or absence of) clinical-added value of medicinal products on the market: the Transparency Commission of the National Health Authority. Scores from one to five are delivered for medicinal products and each of their clinical indications. A score of five refers to absence of significant clinical benefit over other methods (drugs, surgical procedure or other) already available and usually reimbursed by the National Health Fund (see example: http://www.has-sante.fr/portail/upload/docs/application/pdf/2010-03/tarceva_ct_5077.pdf).

These committees are also responsible to optimize quality of use of medicinal products and medical devices in their respective hospitals. Actions can be of various nature, including audits to identify field of activities requiring corrective actions, development of internal training or information of specific health professionals. Internal audits should be run on subjects identified by the committee as priorities to improve the use (better efficiency and/or safety) of medicinal products and medical devices.

Reporting of errors and adverse events should be encouraged. In France, such events are subject of mandatory reporting using specific circuits of information with ultimately data transmission to the competent authorities. Hospitals Drugs and Medical Devices Committees should be kept informed on any new information relevant to the safety of the use of medicinal products and medical devices. This role is of the particular competencies of members of the committee in charge of pharmacovigilance and safety of medical devices. Each hospital should establish a system to encourage and easily collect errors (with or without clinical consequences for patients) in order to prevent their re-occurrence and possibly more serious consequences for patients.

These committees are working under the responsibility of upper management of their hospitals but are providing independent scientific opinions. These opinions should not supersede or contradict national guidelines validated by national or European authorities, e.g. well-established cancer chemotherapy protocols (unless exceptional circumstances which can be scientifically justified).

These committees should meet at least three times a year and report on their activities to both medical committees of their respective hospitals (a medical committee called '*Commission Médicale d'Etablissement*' is established in all French hospitals) and their management (Directors as well as Management Boards of their hospitals). This communication is usually insured through written annual reports.

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CoMéDiMS Medicine Evaluation Grid

Version 8 July 2010

Report date: ____ / ____ / _____

Reporters:

- physician: _____
- pharmacist: _____
- other(s), surname(s) and position(s):

Medicine (commercial name and international non-proprietary name)[1]:

Indication(s) according to the le SmPC (summary of product characteristics)[1]:

Clinical Data

❶ Results of the Phase III clinical trials (specify the following information for each trial):
- Methodology (notably the design: superiority, non-inferiority…)
- Inclusion and exclusion criteria
- Selected comparator medication(s) (or not) for the control group(s), their pertinence in relation to the usual therapeutic use
- Primary end point, its clinical pertinence
- Observed results in terms of efficacy and tolerance (and their limits)

❷ What was the principal objective of the Phase III pivotal trial (if applicable)?

❸ Has a risk management plan[2] been prepared? If yes, specify briefly.

❹ SMR (*Service Médical Rendu,* Actual Benefit) and ASMR (*Amélioration du Service Médical Rendu, Actual Benefit Improvement)* attributed by the Transparency Commission of the *Haute Autorité de Santé*[3]

❺ What place does this medication occupy in the therapeutic strategy?

❻ Can we expect off-label prescribing? Specify (e.g. clinical trial results published not yet integrated to the market authorisation (*Autorisation de Mise sur le Marché*), PTT (*Protocoles Thérapeutiques Temporaires*)[4]…)

❼ Would we expose patients any harm in the absence of the availability of this drug in our institution? If so, define precisely which patient population would be concerned as well as the potential opportunity loss for these patients.

Pharmacological and pharmaceutical data

❶ Origin of the product (chemical synthesis, biotechnological synthesis...)

❷ What are the principal pharmacokinetic characteristics?

❸ What is its mechanism of action?

❹ Pharmaceutical form, qualitative and quantitative composition

❺ Practical modalities of administration. Specify in particular:
- the material required for the preparation of the administration of the drug
- potentially necessary precautions (e.g. long upper limit-rated administration, incompatibles fluids, titration difficulties…)
- monitoring (e.g. risk of anaphylactic reaction requiring a specific environment and the presence of nurse…)

❻ Stocking conditions

Regulatory and economical data

❶ Date of AMM (first AMM? Extension of indication?)

❷ Will this medicine take the place of a therapeutic agent already prescribed at hospital (*CHU de Bordeaux*) (AMM, ATU [*Autorisations Temporaires d'Utilisation*, Temporary Utilisation Autorisations][5], other)?

❸ Does this medicine have particular prescription requirements (narcotic, orphan drug[6], "restricted" prescription[7]...)

❹ Does the use of this medication need training for the professionals or education for patients (or their relatives)?

❺ Is this about a medication retroceded[8]?

❻ Expected annual consumption (specify the sources and calculation method, even if approximate)

❼ Economic impact evaluation (for more information on unit prices, approach the Hospital Medicine Procurement Unit[9])

Conclusion

❶ Is this medication innovated? If yes, briefly summarize the progress made.

❷ Does this medication present ***advantages*** in comparison to therapeutic agents currently available at University Hospital Centre of Bordeaux (*CHU de Bordeaux*)? If yes, which ones?

❸ Does this medication present ***disadvantages*** in comparison to therapeutic agents currently available at University Hospital Centre of Bordeaux (*CHU de Bordeaux*)? If yes, which ones?

❹ Description of the target patient population (quantitative and qualitative)

Comments of the physician reporter:

Comments of the pharmacist reporter:

Comments of the other reporters (if applicable):

Date:

Signatures of the reporters:

Comments of the CoMéDiMS and final decision:

Inscription on medication booklet of CHU de Bordeaux: ☐ yes ☐ no

References

[1] Pour les AMM (Autorisation de Mise sur le Marché, y compris l'annexe RCP) :
http://afssaps-prd.afssaps.fr/php/ecodex/index.php
http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/community-register/html/alfregister.htm

[2] Pour les PGR (Plan de Gestion des Risques) :
http://www.ema.europa.eu/htms/human/epar/a.htm

[3] Pour les avis de la Commission de Transparence :
http://www.has-sante.fr/portail/jcms/c_5268/medicaments?cid=c_5268
Sur les définitions du SMR (Service Médical Rendu) et de l'ASMR (Amélioration du Service Médical Rendu):
http://www.has-sante.fr/portail/upload/docs/application/pdf/ri_ct_2005_v.04-10-06.pdf (voir annexe 1, page 13 de ce document)

[4] Protocoles Thérapeutiques Temporaires
Souce INCa : http://www.e-cancer.fr/soins/referentiels-de-bon-usage
Voir aussi :
- AFSSAPS : http://www.afssaps.fr/Dossiers-thematiques/Tarification-a-l-activite-T2A-medicaments/Accueil-T2A/(offset)/0
- Fiches de bon usage de la HAS : http://www.has-sante.fr/portail/jcms/c_412202/bon-usage-du-medicament

[5] Autorisations Temporaires d'Utilisation :
http://www.afssaps.fr/Activites/Autorisations-temporaires-d-utilisation/Autorisations-temporaires-d-utilisation/(offset)/0

[6] Pour le statut de médicament orphelin :
http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/community-register/html/alforphreg.htm

[7] Prescription "*restreinte*"
Source AFSSAPS :
http://www.afssaps.fr/Dossiers-thematiques/Retrocession-hospitaliere/Retrocession-hospitaliere/(offset)/0
Source Assurance Maladie :
http://www.ameli.fr/professionnels-de-sante/medecins/exercer-au-quotidien/prescriptions/la-prescription-de-medicaments/regles-particulieres-de-prescription.php

[8] La rétrocession hospitalière
Source AFSSAPS :
http://www.afssaps.fr/Dossiers-thematiques/Retrocession-hospitaliere/Retrocession-hospitaliere/(offset)/0
Source Assurance Maladie :
http://www.ameli.fr/fileadmin/user_upload/documents/ref-jur-produits-sante-2009.pdf (voir page 137)

[9] Coordonnées de l'Unité d'Achats *Médicaments* :
http://www.chu-bordeaux.fr/chub/fournisseur/les-acheteurs-du-chu-de-bordeaux/les-unites-d-achat/pharmacie-des-medicaments/medicaments-et-fluides-medicaux/

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Grille d'évaluation des médicaments par le CoMéDiMS

Version du 8 juillet 2010

Date du rapport : ____ / ____ / _____

Rapporteurs :

- médecin : _____
- pharmacien : _____
- autre(s), nom(s) et qualité(s) :

Médicament (nom de spécialité et dénomination commune internationale)[1]:

Indication(s) selon le RCP (résumé des caractéristiques du produit)[1]:

Données cliniques

❶ Résultats des essais cliniques de phase III (préciser les informations suivantes pour chaque essai) :
- Méthodologie choisie (notamment le type de test choisi : supériorité, non infériorité…)
- Critères cliniques d'inclusion et d'exclusion des patients
- Comparateur(s) médicamenteux (ou non) choisis pour le(s) groupe(s) de contrôle, leur pertinence par rapport à l'usage thérapeutique habituel
- Critère principal d'évaluation, sa pertinence clinique
- Résultats observés en terme d'efficacité et de tolérance (et leurs limites)

❷ Quel a été l'objectif principal de l'essai pivot de phase III (si applicable) ?

❸ Un Plan de Gestion des Risques[2] a-t-il été prévu ? Si oui, préciser brièvement.

❹ SMR et ASMR délivrée par la Commission de la Transparence de la Haute Autorité de Santé[3]

❺ Quelle place ce médicament occupe-t-il dans la stratégie thérapeutique ?

❻ Peut-on s'attendre à une prescription hors AMM ? Préciser (ex. résultats d'essais cliniques publiés non encore intégrés à l'AMM, PTT[4]…)

❼ Exposerait-on des patients à un quelconque préjudice en l'absence de mise à disposition de ce médicament dans notre établissement? Dans l'affirmative, définir précisément sur quel type de population de patients ce préjudice s'exercerait ainsi que la perte de chance potentielle pour ces patients.

Données pharmacologiques et pharmaceutiques

❶ Origine du produit (synthèse chimique, biotechnologique...)

❷ Quelles sont ses principales caractéristiques pharmacocinétiques ?

❸ Quel est son mécanisme d'action ?

❹ Forme pharmaceutique, composition qualitative et quantitative

❺ Modalités pratiques d'administration. Préciser en particulier :
- le matériel nécessaire à la préparation et l'administration du médicament
- les précautions possiblement nécessaires (ex. administration longue à débit plafonné, solutés incompatibles, difficulté de titration…)
- les modalités de surveillance (ex. risque de réaction anaphylactique nécessitant un environnement spécifique et une présence infirmière importante…)

❻ Conditions de conservation

Données règlementaires et économiques

❶ Date d'AMM (Première AMM ? Extension d'indication ?)

❷ Ce médicament va-t-il se substituer à une thérapeutique déjà prescrite au CHU (AMM, ATU[5], autre)?

❸ S'agit-il d'un médicament à modalités de prescription particulière (stupéfiant, médicament orphelin[6], médicament à prescription dite ″restreinte″[7]...)

❹ L'usage de ce médicament rend-elle nécessaire une action de formation auprès des professionnels ou d'éducation thérapeutique auprès des patients (ou leur entourage) ?

❺ S'agit-il d'un médicament rétrocédable[8] ?

❻ Consommation annuelle prévisible (préciser les sources et la modalité de calcul même approximatif)

❼ Evaluation indicative de l'impact économique (pour tout renseignement sur les prix unitaires, se rapprocher de l'Unité d'Achats Médicaments du CHU[9])

Conclusion

❶ Ce médicament est-il innovant ? Si oui, résumer brièvement le progrès apporté

❷ Ce médicament présente-t-il des ***avantages*** par rapport aux thérapeutiques actuellement disponibles au CHU de Bordeaux ? Si oui, lesquels ?

❸ Ce médicament présente-t-il des ***inconvénients*** par rapport aux thérapeutiques actuellement disponibles au CHU de Bordeaux ? Si oui, lesquels ?

❹ Description de la population cible de patients (quantitative et qualitative)

Commentaires du rapporteur médecin :

Commentaires du rapporteur pharmacien :

Commentaires d'autres rapporteurs (si applicable) :

Date :

Signatures des rapporteurs :

Commentaires du CoMéDiMS et décision finale :

Inscription au livret des médicaments du CHU de Bordeaux : ☐ oui ☐ non

Références

[1] Pour les AMM (Autorisation de Mise sur le Marché, y compris l'annexe RCP) :
http://afssaps-prd.afssaps.fr/php/ecodex/index.php
http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/community-register/html/alfregister.htm

[2] Pour les PGR (Plan de Gestion des Risques) :
http://www.ema.europa.eu/htms/human/epar/a.htm

[3] Pour les avis de la Commission de Transparence :
http://www.has-sante.fr/portail/jcms/c_5268/medicaments?cid=c_5268
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http://www.has-sante.fr/portail/upload/docs/application/pdf/ri_ct_2005_v.04-10-06.pdf (voir annexe 1, page 13 de ce document)

[4] Protocoles Thérapeutiques Temporaires
Souce INCa : http://www.e-cancer.fr/soins/referentiels-de-bon-usage
Voir aussi :
- AFSSAPS : http://www.afssaps.fr/Dossiers-thematiques/Tarification-a-l-activite-T2A-medicaments/Accueil-T2A/(offset)/0
- Fiches de bon usage de la HAS : http://www.has-sante.fr/portail/jcms/c_412202/bon-usage-du-medicament

[5] Autorisations Temporaires d'Utilisation :
http://www.afssaps.fr/Activites/Autorisations-temporaires-d-utilisation/Autorisations-temporaires-d-utilisation/(offset)/0

[6] Pour le statut de médicament orphelin :
http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/community-register/html/alforphreg.htm

[7] Prescription "*restreinte*"
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Source Assurance Maladie :
http://www.ameli.fr/professionnels-de-sante/medecins/exercer-au-quotidien/prescriptions/la-prescription-de-medicaments/regles-particulieres-de-prescription.php

[8] La rétrocession hospitalière
Source AFSSAPS :
http://www.afssaps.fr/Dossiers-thematiques/Retrocession-hospitaliere/Retrocession-hospitaliere/(offset)/0
Source Assurance Maladie :
http://www.ameli.fr/fileadmin/user_upload/documents/ref-jur-produits-sante-2009.pdf (voir page 137)

[9] Coordonnées de l'Unité d'Achats *Médicaments* :
http://www.chu-bordeaux.fr/chub/fournisseur/les-acheteurs-du-chu-de-bordeaux/les-unites-d-achat/pharmacie-des-medicaments/medicaments-et-fluides-medicaux/